

**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 June 30, 2025

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

(State or other jurisdiction of incorporation or organization)

56-2590442

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

465 State Route 17, Ramsey, New Jersey

(Address of principal executive offices)

07446

(Zip Code)

(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

Non-accelerated filer

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 August 1, 2025, there were 238,630,719 shares of the issuer's common stock outstanding.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

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PART I FINANCIAL INFORMATION

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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

This Quarterly Report on Form 10-Q contains certain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, (the “Exchange Act”), and such forward-looking statements involve risks and uncertainties. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions that are not historical facts and typically are identified by use of terms such as “may,” “should,” “could,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “project,” “continue,” or the negative thereof, or other variations or comparable terminology, although some forward-looking statements are expressed differently. The forward-looking statements included herein represent management’s current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. These statements include, among others, statements about:

- our ability to further commercialize ASCENIV and BIVIGAM;
- our plans to develop, manufacture, market, launch and expand our commercial infrastructure and commercialize our current and future products and the success of such efforts;
- the safety, efficacy and expected timing of and our ability to obtain and maintain regulatory approvals for our current products and product candidates, the labeling or nature of any such approvals, and whether any of our current products may be subject to post-marketing restrictions or withdrawal from the market;
- the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals for our product candidates;
- our dependence upon our third-party customers, suppliers and vendors and their compliance with applicable regulatory requirements;
- our belief that we have addressed the delays experienced with final drug product current Good Manufacturing Practices (“cGMP”) release testing by our third-party vendors by adding additional release testing laboratories to our U.S. Food and Drug Administration (“FDA”)-approved consortium listed in our drug approval documents;
- our ability to obtain adequate quantities of FDA-approved plasma with proper specifications;
- our plans to increase our supplies of source plasma (including source plasma containing certain levels of antibodies to Respiratory Syncytial Virus), our ability to obtain and maintain regulatory compliance and reliance on third-party supply agreements as well as any extensions to such agreements;
- the potential indications for our products and product candidates;
- potential investigational new product applications;
- the acceptability of any of our products, including ASCENIV, BIVIGAM and Nabi-HB, for any purpose, including FDA-approved indications, by physicians, patients or payers;
- our plans to evaluate the clinical and regulatory paths to grow the ASCENIV franchise through expanded FDA-approved uses;
- Federal, state and local regulatory and business review processes and timing by such governmental and regulatory agencies of our business and regulatory submissions;
- concurrence by the FDA with our conclusions concerning our products and product candidates;
- the comparability of results of our hyperimmune and immune globulin (“IG”) products to other comparably run hyperimmune and immune globulin clinical trials;

- the potential for ASCENIV and BIVIGAM to provide meaningful clinical improvement for patients living with Primary Humoral Immunodeficiency (“PI”), also known as Primary Immunodeficiency Disease (“PIDD”) or Inborn Errors of Immunity, or other immune deficiencies or any other condition for which the products may be prescribed or evaluated;
- our ability to market and promote Nabi-HB in a highly competitive environment with increasing competition from other antiviral therapies and to generate meaningful revenues from this product;
- our intellectual property position and the defense thereof, including our expectations regarding the scope of patent protection with respect to ASCENIV, SG-001 or other future pipeline product candidates;
- our ability to develop, manufacture, receive regulatory approval and commercialize our potential pipeline of any new hyperimmune globulins, including SG-001;
- our manufacturing capabilities, third-party contractor capabilities and vertical integration strategy;
- our plans related to the expansion and efficiencies of our manufacturing capacity, yield improvements, supply-chain robustness, in-house fill-finish capabilities, distribution and other collaborative agreements and the success of such endeavors;
- our estimates regarding revenues, earnings, expenses, capital requirements, capital expenditures, ASCENIV’s growth, ability to maintain profitability and positive cash flows and the potential need for and availability of additional financing;
- production yield and revenue and earnings benefits following FDA approval of our innovative yield enhancement production process, and the timing associated with realizing such benefits;
- 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, which could have a material impact on our financial condition or financial results;
- our estimates of future effective tax rates and corresponding tax obligations and expenses, including our expectations for the One Big Beautiful Bill Act’s 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;
- intended uses and benefits of the recently acquired real estate in Boca Raton, FL;
- the recent refinancing of our senior credit facility;
- the potential for pandemics, or a resurgence of a pandemic, to adversely affect our business, financial condition, liquidity or results of operations; and
- future domestic and global economic conditions including, but not limited to, supply chain constraints, inflationary pressures or performance or geopolitical conditions, including the continuing conflicts in Europe and in the Middle East and surrounding areas, and any anticipated effects of such factors on the pricing and availability of imported raw materials used in the production of our products.

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 for the quarter ended June 30, 2025 (this “Form 10-Q”). 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, 2024 (the “2024 10-K”) and in this Form 10-Q. Any forward-looking statement included or incorporated by reference in this 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 release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

PART I
FINANCIAL INFORMATION

Item 1. Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2025	December 31, 2024
	(Unaudited)	
	<i>(In thousands, except share data)</i>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 90,285	\$ 103,147
Accounts receivable, net	109,726	49,999
Inventories, net	191,464	170,235
Prepaid expenses and other current assets	8,088	8,029
Total current assets	399,563	331,410
Property and equipment, net	57,501	54,707
Intangible assets, net	527	460
Goodwill	3,530	3,530
Deferred tax assets, net	79,235	84,280
Right-to-use assets	8,961	8,634
Deposits and other assets	9,063	5,657
TOTAL ASSETS	\$ 558,380	\$ 488,678
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 29,769	\$ 20,219
Accrued expenses and other current liabilities	43,902	33,962
Current portion of deferred revenue	143	143
Current portion of lease obligations	1,127	1,218
Total current liabilities	74,941	55,542
Senior notes payable, net of discount	73,397	72,337
Deferred revenue, net of current portion	1,476	1,547
End of term fee	938	1,313
Lease obligations, net of current portion	9,301	8,561
Other non-current liabilities	2	360
TOTAL LIABILITIES	160,055	139,660
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, June 30, 2025: 239,383,545 issued and 238,567,308 outstanding; December 31, 2024: 236,620,545 issued and outstanding	24	24
Treasury stock, at cost, 816,237 and 0 shares as of June 30, 2025 and December 31, 2024, respectively	(15,148)	-
Additional paid-in capital	660,909	657,577
Accumulated deficit	(247,460)	(308,583)
TOTAL STOCKHOLDERS' EQUITY	398,325	349,018
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 558,380	\$ 488,678

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

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

	<u>Three Months ended June 30,</u>		<u>Six Months ended June 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
	<i>(In thousands, except share and per share data)</i>			
REVENUES	\$ 121,984	\$ 107,191	\$ 236,786	\$ 189,066
Cost of product revenue	54,757	49,738	108,463	92,505
Gross profit	<u>67,227</u>	<u>57,453</u>	<u>128,323</u>	<u>96,561</u>
OPERATING EXPENSES:				
Research and development	1,031	560	1,858	1,010
Plasma center operating expenses	1,152	942	2,438	1,947
Amortization of intangible assets	32	142	57	335
Selling, general and administrative	22,214	16,608	46,292	32,247
Total operating expenses	<u>24,429</u>	<u>18,252</u>	<u>50,645</u>	<u>35,539</u>
INCOME FROM OPERATIONS	<u>42,798</u>	<u>39,201</u>	<u>77,678</u>	<u>61,022</u>
OTHER INCOME (EXPENSE):				
Interest income	400	449	1,008	833
Interest expense	(1,834)	(3,783)	(3,809)	(7,552)
Loss on extinguishment of debt	(1,159)	-	(1,159)	-
Other expense	(108)	(16)	(172)	(51)
Other expense, net	<u>(2,701)</u>	<u>(3,350)</u>	<u>(4,132)</u>	<u>(6,770)</u>
INCOME BEFORE INCOME TAXES	<u>40,097</u>	<u>35,851</u>	<u>73,546</u>	<u>54,252</u>
Provision for income taxes	5,878	3,789	12,424	4,384
NET INCOME	<u>\$ 34,219</u>	<u>\$ 32,062</u>	<u>\$ 61,122</u>	<u>\$ 49,868</u>
BASIC EARNINGS PER COMMON SHARE	<u>\$ 0.14</u>	<u>\$ 0.14</u>	<u>\$ 0.26</u>	<u>\$ 0.22</u>
DILUTED EARNINGS PER COMMON SHARE	<u>\$ 0.14</u>	<u>\$ 0.13</u>	<u>\$ 0.25</u>	<u>\$ 0.21</u>
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic	<u>241,490,715</u>	<u>232,417,645</u>	<u>238,309,156</u>	<u>230,646,246</u>
Diluted	<u>248,608,460</u>	<u>242,167,072</u>	<u>245,750,155</u>	<u>239,645,940</u>

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 Six Months Ended June 30, 2025

	Common Stock		Additional	Accumulated	Treasury	Total
	Shares	Amount	Paid-in Capital	Deficit	Stock	Stockholders' Equity
Balance at December 31, 2024	236,620,545	\$ 24	\$ 657,577	\$ (308,583)	\$ -	\$ 349,018
Stock-based compensation	-	-	4,624	-	-	4,624
Cashless exercise of warrants	866,302	-	-	-	-	-
Vesting of Restricted Stock Units, net of shares withheld for taxes	1,016,005	-	(7,228)	-	-	(7,228)
Exercise of stock options	29,400	-	101	-	-	101
Net income	-	-	-	26,904	-	26,904
Balance at March 31, 2025	238,532,252	24	655,074	(281,679)	-	373,419
Stock-based compensation	-	-	4,963	-	-	4,963
Cashless exercise of warrants	-	-	-	-	-	-
Vesting of Restricted Stock Units, net of shares withheld for taxes	105,543	-	(1,192)	-	-	(1,192)
Exercise of stock options	745,750	-	2,064	-	-	2,064
Acquisition of treasury stock	-	-	-	-	(15,148)	(15,148)
Net income	-	-	-	34,219	-	34,219
Balance at June 30, 2025	239,383,545	24	660,909	(247,460)	(15,148)	398,325

For the Three and Six Months Ended June 30, 2024

	Common Stock		Additional	Accumulated	Treasury	Total
	Shares	Amount	Paid-in Capital	Deficit	Stock	Stockholders' Equity
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

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)

	Six Months Ended June 30,	
	2025	2024
	<i>(In thousands)</i>	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$ 61,122	\$ 49,868
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	4,027	4,161
Loss on disposal of fixed assets	-	24
Deferred income tax provision	5,045	-
Stock-based compensation	9,587	5,004
Amortization of debt discount	350	480
Loss on extinguishment of debt	1,159	-
Amortization of license revenue	(71)	(71)
Changes in operating assets and liabilities:		
Accounts receivable	(59,726)	(2,692)
Inventories	(21,229)	(6,904)
Prepaid expenses and other current assets	(2,095)	(190)
Deposits and other assets	(306)	(68)
Accounts payable	9,409	(1,410)
Accrued expenses	(5,206)	(5,193)
Other current and non-current liabilities	(602)	419
Net cash provided by operating activities	<u>1,464</u>	<u>43,428</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(7,123)	(4,413)
Acquisition of intangible assets	(124)	(314)
Net cash used in investing activities	<u>(7,247)</u>	<u>(4,727)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on term loan	(30,000)	-
Proceeds from issuance on revolver	30,000	-
Prepayment penalties on repayment of debt	(450)	-
Taxes paid on vested restricted stock units	(8,419)	(3,169)
Net proceeds from the exercise of stock options	2,165	1,360
Payment of end of term fee	(375)	-
Net cash used in financing activities	<u>(7,079)</u>	<u>(1,809)</u>
Net (decrease) increase in cash and cash equivalents	(12,862)	36,892
Cash and cash equivalents - beginning of period	103,147	51,352
Cash and cash equivalents - end of period	<u>\$ 90,285</u>	<u>\$ 88,244</u>

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 a U.S. based, 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 – sIra 10% Liquid), an intravenous immune globulin (“IVIG”) product indicated for the treatment of Primary Humoral Immunodeficiency (“PI”), also known as Primary Immunodeficiency Disease (“PIDD”) or Inborn Errors of Immunity, for which the Company received FDA approval in April 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 in May 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 intermediates that result from the immunoglobulin production process and from time to time provides contract manufacturing and laboratory services for certain clients. The Company seeks to develop a pipeline of plasma-derived therapeutics, and its products and product candidates are intended to be used by physician specialists focused on caring for immune-compromised patients with or at risk for certain infectious diseases.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of consolidation and 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”).

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, 2024 included in the 2024 10-K. All intercompany balances and transactions have been eliminated in consolidation. The preparation of our interim consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported and disclosed. We have made reasonable estimates and judgments of such items within our financial statements and there may be changes to those estimates in future periods.

During the three and six months ended June 30, 2025 and 2024, comprehensive income was equal to the net income amounts presented for the respective periods in the accompanying condensed consolidated statements of operations. Results for interim periods are not necessarily indicative of the results that may be expected for the full fiscal year.

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

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 deducted from gross revenues and estimates related to the Company's effective tax rate.

Accounts Receivable

Accounts receivable is reported at realizable value, net of allowances for customer credits and credit losses in the amount of \$0.2 million at June 30, 2025 and December 31, 2024. 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 June 30, 2025 and December 31, 2024, three customers accounted for an aggregate of approximately 95% and 91%, respectively, 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 June 30, 2025 and December 31, 2024 was \$3.5 million. All of the Company's goodwill is attributable to its ADMA BioManufacturing business segment.

The Company did not record any impairment charges related to goodwill for the three and six months ended June 30, 2025 and 2024.

Revenue Recognition

Revenues 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 intermediates; 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 21 years.

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

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.

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 three and six months ended June 30, 2025, three customers represented an aggregate of approximately 88% and 81%, respectively, of the Company's consolidated revenues. For the three and six months ended June 30, 2024, 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 manufacturing of the Company's FDA-approved products, intermediates and the collection of human source plasma, depreciation of the production equipment, 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

For the three and six months ended June 30, 2025 and 2024, basic and diluted earnings per share are calculated as follows:

	Three Months ended June 30,		Six Months ended June 30,	
	2025	2024	2025	2024
Net income available to common stockholders (\$000's) (numerator)	\$ 34,219	\$ 32,062	\$ 61,122	\$ 49,868
Weighted-average number of common shares (denominator)	241,490,715	232,417,645	238,309,156	230,646,246
Basic earnings per common share	\$ 0.14	\$ 0.14	\$ 0.26	\$ 0.22
Weighted-average number of common shares	241,490,715	232,417,645	238,309,156	230,646,246
Potential shares of common stock arising from outstanding stock options	3,760,947	3,716,289	4,036,608	3,158,952
Potential shares of common stock arising from outstanding warrants	-	2,803,564	28,671	3,975,656
Potential shares of common stock arising from outstanding RSUs	3,356,798	3,229,574	3,375,720	1,865,086
Total shares - diluted (denominator)	248,608,460	242,167,072	245,750,155	239,645,940
Diluted earnings per common share	\$ 0.14	\$ 0.13	\$ 0.25	\$ 0.21

For the three and six months ended June 30, 2025 and 2024, there were no shares with an anti-dilutive effect that needed to be excluded from the earnings per share computation.

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Recent Accounting Pronouncements

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

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

3. INVENTORIES

The following table provides the components of inventories:

	June 30, 2025	December 31, 2024
	<i>(In thousands)</i>	
Raw materials	\$ 100,373	\$ 60,473
Work-in-process	43,173	61,641
Finished goods	47,918	48,121
Total inventories, net	\$ 191,464	\$ 170,235

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. PROPERTY AND EQUIPMENT

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

	June 30, 2025	December 31, 2024
	<i>(In thousands)</i>	
Manufacturing and laboratory equipment	\$ 27,348	\$ 21,305
Office equipment and computer software	6,414	5,772
Furniture and fixtures	6,205	5,840
Construction in process	4,096	8,149
Leasehold improvements	21,138	21,066
Land	4,339	4,339
Buildings and building improvements	25,483	21,788
	95,023	88,259
Less: Accumulated depreciation	(37,522)	(33,552)
Total property and equipment, net	\$ 57,501	\$ 54,707

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The Company recorded depreciation expense on property and equipment for the three and six months ended June 30, 2025 of \$2.0 million and \$4.0 million, respectively, and \$1.9 million and \$3.8 million for the three and six months ended June 30, 2024, respectively.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities at June 30, 2025 and December 31, 2024 are as follows:

	<u>June 30, 2025</u>	<u>December 31, 2024</u>
	<i>(In thousands)</i>	
Accrued rebates	\$ 4,173	\$ 4,155
Accrued distribution fees	11,389	11,565
Accrued incentives	3,065	5,892
Accrued interest	1,269	2,857
Accrued testing	389	827
Accrued payroll and other compensation	3,426	3,332
Income taxes payable	2,700	3,481
Other	17,491	1,853
Total accrued expenses and other current liabilities	\$ 43,902	\$ 33,962

As of June 30, 2025, Other accrued expenses include liability of \$15.1 million related to share repurchases (none as of December 31, 2024), further discussed in Note 7.

6. DEBT

A summary of outstanding senior notes payable is as follows:

	<u>June 30, 2025</u>	<u>December 31, 2024</u>
	<i>(In thousands)</i>	
Term loan	\$ 2,500	\$ 32,500
Revolving credit facility	72,500	42,500
Less:		
Debt discount	(1,603)	(2,663)
Senior notes payable	\$ 73,397	\$ 72,337

On December 18, 2023 (the “Ares Closing Date”), the Company and all of its subsidiaries entered into a new senior secured credit facility (the “Ares Credit Agreement”) with Ares Capital Corporation and certain credit funds affiliated with Ares Capital Corporation (collectively, “Ares”). The Ares Credit Agreement provided for a total of \$135.0 million in senior secured credit facilities (the “Ares Credit Facility”) consisting of (i) a term loan in the aggregate principal amount of \$62.5 million and (ii) a revolving credit facility in the aggregate principal amount of \$72.5 million (collectively, the “Ares Loans”), both of which were fully drawn on the Ares Closing Date. The Ares Credit Facility has a maturity date of December 20, 2027 (the “Ares Maturity Date”).

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 June 30, 2025 and December 31, 2024, the interest rate on the term loan was approximately 10.81% and 10.85%, respectively, and the interest rate on the revolving facility was approximately 8.05% and 8.34%, respectively.

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On the Ares Maturity Date, the Company is required to pay Ares the entire outstanding principal amount underlying the Ares term loan and revolving loan (together, 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 Loans. After giving effect to the principal payments made during the year ended December 31, 2024 and six months ended June 30, 2025, the Company is required to make quarterly interest payments to Ares of approximately \$1.6 million. The Company may prepay the outstanding principal under the revolving facility, together with any accrued but unpaid interest on the prepaid principal amount, at any time and from time to time upon three business days’ prior written notice with no prepayment premium. However, in the event the Company pays down an aggregate amount under the revolving facility that is greater than 50% of the \$72.5 million commitment amount, or \$36,250,000, the Company will still be required to pay an amount of interest on the revolving facility that would have been payable had \$36,250,000 been outstanding, through the Ares Maturity Date. 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) 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 (ii) 1.0% of the prepaid principal amount, if prepaid on or prior to the third anniversary of the Ares Closing Date. In May 2025, the Company repaid \$30.0 million against the term loan using a draw of \$30.0 million against the revolving credit facility made in May 2025, as a result of which, the Company recorded debt extinguishment losses of \$1.2 million during the three and six months ended June 30, 2025.

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 June 30, 2025, 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.

7. STOCKHOLDERS’ EQUITY

Treasury Stock

In May 2025, the Company’s board of directors (the “Board”) authorized a share repurchase program of up to \$500.0 million of the Company’s outstanding shares of common stock (the “Repurchase Program”). The Repurchase Program does not obligate the Company to acquire any particular amount of its common stock, and may be modified, suspended, or terminated at any time at the Company’s discretion. The Repurchase Program has no expiration date.

A summary of common stock repurchase activity under the Repurchase Program is as follows:

<i>(in thousands)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Shares repurchased	816	n/a	816	n/a
Total cost of shares repurchased	\$ 15,148	n/a	\$ 15,148	n/a

The repurchased shares are included in treasury stock in our condensed consolidated balance sheet.

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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 June 30, 2025 and December 31, 2024.

Common Stock

As of June 30, 2025 and December 31, 2024, the Company was authorized to issue 300,000,000 shares of its common stock, \$0.0001 par value per share, and 238,567,308 and 236,620,545 shares of common stock were outstanding as of June 30, 2025 and December 31, 2024, respectively. After giving effect to shares reserved for the issuance of warrants and for awards issued under the Company's equity incentive plans, 37.5 million shares of common stock were available for issuance as of June 30, 2025.

Warrants

On January 7, 2025, affiliates of a former noteholder of the Company exercised warrants to purchase an aggregate of 966,554 shares of common stock on a cashless basis, and the Company issued 866,302 shares of common stock to these entities. 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, affiliates of a former noteholder 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 such noteholders. 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 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 June 30, 2024 and December 31, 2023, the Company had outstanding warrants to purchase an aggregate of 3,122,350 and 12,502,906 shares, respectively, of common stock, with weighted-average exercise prices of \$2.08 and \$2.32 per share, respectively, with expiration dates ranging between October 2024 and May 2030.

There were no outstanding warrants as of June 30, 2025 and outstanding warrants to purchase 966,554 shares of common stock as of December 31, 2024.

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 six months ended June 30, 2025 and 2024:

	Six Months Ended June 30,	
	2025	2024
Expected term	5.5 - 6.3 years	5.5 - 6.3 years
Volatility	66%	66%
Dividend yield	0.0	0.0
Risk-free interest rate	4.40%	4.29-4.34%

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

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	Shares	Weighted-Average Exercise Price
Options outstanding, vested and expected to vest at December 31, 2024	5,141,516	\$ 3.90
Forfeited	(203,985)	\$ 3.20
Expired	(2,164)	\$ 2.34
Granted	683,720	\$ 16.10
Exercised	(802,544)	\$ 3.60
Options outstanding, vested and expected to vest at June 30, 2025	<u>4,816,543</u>	\$ 5.80
Options exercisable	<u>2,627,230</u>	\$ 3.50

As of June 30, 2025, the Company had \$11.1 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.

The Company's RSUs generally vest annually over a period of four years for employees and semi-annually over a period of one year for directors. 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, 2024	5,745,990	\$ 5.50
Granted	1,775,774	\$ 16.30
Vested	(1,620,430)	\$ 4.25
Forfeited	(403,492)	\$ 7.53
Balance at June 30, 2025	<u>5,497,842</u>	\$ 9.20

As of June 30, 2025, the Company had \$44.4 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 six months ended June 30, 2025 and 2024 was as follows:

<i>(in thousands)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development	\$ 51	\$ 24	\$ 90	\$ 41
Plasma center operating expenses	101	48	178	87
Selling, general and administrative	3,955	2,405	7,828	4,246
Cost of product revenue	856	386	1,491	630
Total stock-based compensation expense	<u>\$ 4,963</u>	<u>\$ 2,863</u>	<u>\$ 9,587</u>	<u>\$ 5,004</u>

8. RELATED PARTY TRANSACTIONS

The Company leases an office building and equipment from Areth, LLC ("Areth") pursuant to an agreement for services effective as of January 1, 2016, as amended from time to time, and pays monthly rent on this facility in the amount of \$10,000. Either party may terminate the agreement by providing the other party with one year's prior written notice. Rent expense for the three and six months ended June 30, 2025 and 2024 amounted to \$30,000 and \$60,000, respectively. Areth is a company controlled by Dr. Jerrold B. Grossman, the Vice Chairman of the Board, and Adam S. Grossman, the Company's President and Chief Executive Officer. The Company also reimburses Areth for office, warehousing and building related (common area) expenses, equipment and certain other operational expenses, which were not material to the consolidated financial statements for the three and six months ended June 30, 2025 and 2024.

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During the six months ended June 30, 2025 and 2024, the Company purchased certain specialized equipment and repair services used for the collection and processing of source plasma from GenesisBPS in the amount of \$0.1 million. Genesis is owned by Dr. Grossman and Adam Grossman.

9. 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. On December 10, 2018, the Company's former contract manufacturer assigned its rights and obligations under the 2011 Plasma Purchase Agreement to Grifols Worldwide Operations Limited ("Grifols") as its successor-in-interest, effective January 1, 2019. Effective October 1, 2024, the Company entered into an Amended and Restated Plasma Purchase Agreement with Grifols (the "A&R Grifols Agreement") with a term expiring in September 2039, after which it may be renewed for two additional multi-year periods if agreed to by the parties. Pursuant to the A&R Grifols Agreement, Grifols supplies, on a non-exclusive basis, to ADMA BioManufacturing a minimum of 35,000 liters of RSV plasma annually to be used in the manufacture of ASCENIV, with an escalating price per liter depending on the volume supplied in a given 12-month period, with a minimum annual price increase every 12 months. Additionally, Grifols will be entitled to receive a fixed bonus payment if a specified liter amount of high-titer plasma is supplied to the Company in any 12-month period during the term of the A&R Grifols Agreement.

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

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

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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 three and six months ended June 30, 2025, the Company incurred expenses related to this study in the amount of \$0.3 million and \$0.9 million, respectively. For the three and six months ended June 30, 2024, the Company incurred expenses related to this study in the amount of \$0.4 million and \$0.7 million, respectively. The study has been completed, and the Company submitted the ASCENIV pediatric indication for approval to the FDA during the second quarter of 2025.

Other Commitments

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its employees, licensors, suppliers and service providers. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company's request in such capacities. The Company's maximum exposure under these arrangements is unknown as of June 30, 2025. The Company does not anticipate recognizing any significant losses relating to these arrangements.

10. 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 6). 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:

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Three Months Ended June 30, 2025

<i>(in thousands)</i>	ADMA BioManufacturing	Plasma Collection Centers	Total
Revenues	\$ 121,948	\$ -	\$ 121,948
Cost of product revenue	54,757	-	54,757
Research and development	1,031	-	1,031
Plasma center operating expenses	-	1,152	1,152
Selling, marketing and distribution	5,868	-	5,868
Amortization of intangible assets	32	-	32
General and administrative expense	14,941	-	14,941
Other expense, net	(108)	-	(108)
Income (loss) before taxes	45,211	(1,152)	44,059
Expenditures for additions to long-lived assets	2,034	(7)	2,027
Total assets	368,229	29,161	397,390
<i>Reconciliation of revenues:</i>			
Segment revenue			\$ 121,948
License revenue			36
Consolidated revenues			<u>\$ 121,984</u>
<i>Reconciliation of selling, general and administrative expense:</i>			
Segment selling, marketing and distribution expense			\$ 5,868
Segment general and administrative expense			14,941
Corporate general and administrative expense (a)			1,405
Consolidated selling, general and administrative expense			<u>\$ 22,214</u>
<i>Reconciliation of income before taxes:</i>			
Segment income before taxes			\$ 44,059
License revenue			36
Unallocated interest expense, primarily related to interest on senior debt (see Note 6)			(1,834)
Unallocated interest income			400
Loss on extinguishment of debt			(1,159)
Corporate general and administrative expense (a)			(1,405)
Consolidated income before taxes			<u>\$ 40,097</u>
<i>Reconciliation of total assets:</i>			
Total segment assets			\$ 397,390
Corporate (b)			160,990
Consolidated total assets			<u>\$ 558,380</u>

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

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

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Six Months Ended June 30, 2025

<i>(in thousands)</i>	ADMA BioManufacturing	Plasma Collection Centers	Total
Revenues	\$ 235,665	\$ 1,050	\$ 236,715
Cost of product revenue	107,814	649	108,463
Research and development	1,858	-	1,858
Plasma center operating expenses	-	2,438	2,438
Selling, marketing and distribution	11,911	-	11,911
Amortization of intangible assets	57	-	57
General and administrative expense	30,024	-	30,024
Other expense, net	(172)	-	(172)
Income (loss) before taxes	83,829	(2,037)	81,792
Expenditures for additions to long-lived assets	6,733	14	6,747
Total assets	368,229	29,161	397,390
<i>Reconciliation of revenues:</i>			
Segment revenue			\$ 236,715
License revenue			71
Consolidated revenues			<u>\$ 236,786</u>
<i>Reconciliation of selling, general and administrative expense:</i>			
Segment selling, marketing and distribution expense			\$ 11,911
Segment general and administrative expense			30,024
Corporate general and administrative expense (a)			4,357
Consolidated selling, general and administrative expense			<u>\$ 46,292</u>
<i>Reconciliation of income (loss) before taxes:</i>			
Segment income before taxes			\$ 81,792
License revenue			71
Unallocated interest expense, primarily related to interest on senior debt (see Note 6)			(3,809)
Unallocated interest income			1,008
Loss on extinguishment of debt			(1,159)
Corporate general and administrative expense (a)			(4,357)
Consolidated income before taxes			<u>\$ 73,546</u>
<i>Reconciliation of total assets:</i>			
Total segment assets			\$ 397,390
Corporate (b)			160,990
Consolidated total assets			<u>\$ 558,380</u>

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

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

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

Three Months Ended June 30, 2024

<i>(in thousands)</i>	ADMA BioManufacturing	Plasma Collection Centers	Total
Revenues	\$ 106,183	\$ 972	\$ 107,155
Cost of product revenue	48,471	1,267	49,738
Research and development	560	-	560
Plasma center operating expenses	-	942	942
Selling, marketing and distribution	4,504	-	4,504
Amortization of intangible assets	142	-	142
General and administrative expense	5,791	-	5,791
Other expense, net	(13)	(3)	(16)
Income (loss) before taxes	46,702	(1,240)	45,462
Expenditures for additions to long-lived assets	1,210	58	1,268
Total assets	258,094	33,607	291,701
<i>Reconciliation of revenues:</i>			
Segment revenue			\$ 107,155
License revenue			36
Consolidated revenues			<u>\$ 107,191</u>
<i>Reconciliation of selling, general and administrative expense:</i>			
Segment selling, marketing and distribution expense			\$ 4,504
Segment general and administrative expense			5,791
Corporate general and administrative expense (a)			6,313
Consolidated selling, general and administrative expense			<u>\$ 16,608</u>
<i>Reconciliation of income (loss) before taxes:</i>			
Segment income before taxes			\$ 45,462
License revenue			36
Unallocated interest expense, primarily related to interest on senior debt (see Note 6)			(3,783)
Unallocated interest income			449
Corporate general and administrative expense (a)			(6,313)
Consolidated income before taxes			<u>\$ 35,851</u>
<i>Reconciliation of total assets:</i>			
Total segment assets			\$ 291,701
Corporate (b)			84,698
Consolidated total assets			<u>\$ 376,399</u>

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

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

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

Six Months Ended June 30, 2024

<i>(in thousands)</i>	ADMA BioManufacturing	Plasma Collection Centers	Total
Revenues	\$ 186,297	\$ 2,698	\$ 188,995
Cost of product revenue	89,462	3,043	92,505
Research and development	1,010	-	1,010
Plasma center operating expenses	-	1,947	1,947
Selling, marketing and distribution	8,935	-	8,935
Amortization of intangible assets	335	-	335
General and administrative expense	11,140	-	11,140
Other expense, net	(47)	(4)	(51)
Income (loss) before taxes	75,368	(2,296)	73,072
Expenditures for additions to long-lived assets	4,338	75	4,413
Total assets	258,094	33,607	291,701
<i>Reconciliation of revenues:</i>			
Segment revenue			\$ 188,995
License revenue			71
Consolidated revenues			<u>\$ 189,066</u>
<i>Reconciliation of selling, general and administrative expense:</i>			
Segment selling, marketing and distribution expense			\$ 8,935
Segment general and administrative expense			11,140
Corporate general and administrative expense (a)			12,172
Consolidated selling, general and administrative expense			<u>\$ 32,247</u>
<i>Reconciliation of income (loss) before taxes:</i>			
Segment income before taxes			\$ 73,072
License revenue			71
Unallocated interest expense, primarily related to interest on senior debt (see Note 6)			(7,552)
Unallocated interest income			833
Corporate general and administrative expense (a)			(12,172)
Consolidated income before taxes			<u>\$ 54,252</u>
<i>Reconciliation of total assets:</i>			
Total segment assets			\$ 291,701
Corporate (b)			84,698
Consolidated total assets			<u>\$ 376,399</u>

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

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

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

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

<i>(in thousands)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
United States	\$ 121,984	\$ 102,726	\$ 232,714	\$ 180,717
International	-	4,465	4,072	8,349
Total revenues	<u>\$ 121,984</u>	<u>\$ 107,191</u>	<u>\$ 236,786</u>	<u>\$ 189,066</u>

11. 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 June 30, 2025 and 2024 was approximately \$0.6 million, and aggregate lease expense for the six months ended June 30, 2025 and 2024 was \$1.2 million. Cash paid for the Company's leases for the three months ended June 30, 2025 and 2024 was also approximately \$0.6 million, and cash paid for the six months ended June 30, 2025 and 2024 was approximately \$1.2 million.

The Company has aggregate lease liabilities of \$10.4 million and \$9.8 million as of June 30, 2025 and December 31, 2024, 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. As of June 30, 2025, the Company's operating leases have a weighted-average remaining term of 6.4 years. Scheduled payments under the Company's lease obligations are as follows *(in thousands)*:

Remainder of 2025	\$ 1,228
Year ended December 31, 2026	2,403
2027	2,376
2028	2,433
2029	2,463
2030	2,201
Thereafter	2,296
Total payments	15,400
Less: imputed interest	(4,972)
Current portion	(1,127)
Balance at June 30, 2025	<u>\$ 9,301</u>

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

12. INCOME TAXES

The Company uses the estimated annual effective tax rate approach as prescribed by ASC 740-270, Interim Reporting, to calculate its interim provision for income taxes.

<i>(in thousands, except percentages)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Provision for income taxes	\$ 5,878	\$ 3,789	\$ 12,424	\$ 4,384
Effective tax rate	14.7%	10.6%	16.9%	8.1%

The effective tax rate for the three and six months ended June 30, 2025, differed from the federal statutory rate primarily due to the excess tax benefits on stock-based compensation. The effective tax rate for the three and six months ended June 30, 2024 differed from the federal statutory tax rate primarily due to the valuation allowance maintained on the Company's federal and state net deferred tax assets until December 31, 2024.

13. SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Supplemental cash flow information for the six months ended June 30, 2025 and 2024 is as follows:

<i>(In thousands)</i>	2025	2024
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	\$ 4,957	\$ 3,843
Cash paid for income taxes	\$ 6,890	\$ 1,550
Noncash Financing and Investing Activities:		
Equipment acquired reflected in accounts payable and accrued liabilities	\$ 1,025	\$ 207
Purchases of treasury shares reflected in accrued liabilities	\$ 15,148	\$ -
Operating lease right-of-use assets obtained in exchange for operating lease obligations	\$ 1,236	\$ -

14. SUBSEQUENT EVENTS

Infrastructure Expansion

In July 2025, the Company acquired real estate in Boca Raton, FL consisting of 5 acres of land and a building for a total purchase price of \$12.6 million, which is inclusive of deposits aggregating \$0.5 million made in May 2025. This real estate purchase is intended to allow the Company to expand its production operations and related activities as well as provide for certain redundancies for ambient and cold-chain storage of raw materials, work in process and finished goods inventory.

Debt Refinancing

On August 5, 2025 (the "JPM Closing Date"), the Company and all of the Company's subsidiaries entered into a Credit Agreement (the "JPM Credit Agreement") with the lenders party thereto and JPMorgan Chase Bank, N.A., as administrative agent. The JPM Credit Agreement provides for \$300 million of senior secured credit facilities, consisting of (a) a term loan in the aggregate principal amount of \$75 million (the "JPM Term Loan Facility") and (b) a revolving credit facility in the aggregate principal amount of \$225 million (the "JPM Revolving Facility"). The Company may also request, subject to customary conditions, additional incremental revolving commitments or term loans in an aggregate principal amount not to exceed \$100 million (together with the JPM Term Loan Facility and the JPM Revolving Facility, the "JPM Credit Facilities"). The JPM Term Loan Facility has a maturity date of August 5, 2028 (the "JPM Term Maturity Date") and the JPM Revolving Facility has a maturity date of August 5, 2028 or any earlier date on which the commitments under the JPM Revolving Facility are reduced to zero or otherwise terminated pursuant to the terms of the JPM Credit Agreement (the "JPM Revolving Maturity Date").

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

On the JPM Closing Date, the Company used the proceeds of the JPM Credit Facilities to terminate and pay in full all of the outstanding obligations under the Ares Credit Facility, including the outstanding principal of all loans, all accrued and unpaid interest thereon, and any unpaid fees, charges, premiums (including prepayment premiums) and costs, and expenses related thereto. The Company expects to recognize debt extinguishment losses of approximately \$2.0 million as a result of this repayment. The Company may also use the proceeds of the JPM Credit Facilities to finance share repurchases and for working capital and general corporate purposes.

Interest on borrowings under the JPM Credit Facilities will accrue at an applicable rate equal to (i) an alternate base rate plus an applicable spread (each such borrowing, an “ABR Borrowing”) or (ii) Term SOFR plus an applicable spread (each such borrowing, a “Term Benchmark Borrowing”), in each case based on the lower of the applicable rates set forth in the JPM Credit Agreement, which are based on the Company’s total leverage ratio. These applicable spreads range from 150 basis points to 200 basis points over the alternate base rate and 250 basis points to 300 basis points over Term SOFR, in each case, as determined in accordance with the provisions of the JPM Credit Agreement. The Company has agreed to pay a commitment fee at specified rates set forth in the JPM Credit Agreement, which, based on the Company’s total leverage ratio, ranges from 30 basis points to 35 basis points on the daily amount of the undrawn portion of the aggregate commitments of the lenders under the JPM Revolving Facility. At the Company’s request, each borrowing initially shall be either an ABR Borrowing or a Term Benchmark Borrowing, and the Company may thereafter elect to convert any such borrowing to a different type. During the occurrence and continuance of an Event of Default (as defined in the JPM Credit Agreement), all borrowings shall accrue interest at a rate per annum equal to 2% plus the applicable rate.

On the JPM Revolving Maturity Date, the Company will repay the unpaid principal amount outstanding under the JPM Revolving Facility. Under the JPM Term Loan Facility, the Company will make principal payments in accordance with and on the dates specified in the amortization schedule set forth in the JPM Credit Agreement, with the remaining unpaid principal amount to be paid in full on the JPM Term Maturity Date. The Company may prepay at any time and from time to time any borrowing in whole or in part, without premium or penalty (other than, if applicable, any break funding expenses), subject to customary notice requirements.

All of the Company’s obligations under the JPM Credit Agreement are secured by a first-priority lien and security interest in substantially all of the tangible and intangible assets, including intellectual property and equity interests, of the Company and all of its subsidiaries.

The JPM 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 a maximum total leverage ratio of 2.50 to 1.00 and a minimum fixed charge coverage ratio of 1.20 to 1.00. The negative covenants 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 JPM Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes; make certain investments; dispose of certain assets; engage in sale and leaseback transactions or swap agreements; make certain Restricted Payments (as defined in the JPM Credit Agreement); engage in certain affiliate transactions; enter into any other agreements that have the impact of restricting the Company’s ability to make loan repayments under the JPM Credit Agreement; or amend certain material documents.

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 (this “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, 2024, filed on March 18, 2025 (the “2024 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 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 a U.S. based, 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 (“PID”) or Inborn Errors of immunity in adults and adolescents, for which we received FDA approval in April 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 in May 2019 and commenced commercial sales in August 2019; and (iii) Nabi-HB (Hepatitis B Immune Globulin, Human), which is indicated for the treatment of acute exposure to blood containing HBsAg and other listed exposures to Hepatitis B. We seek to develop a pipeline of plasma-derived therapeutics, including a product based on our most recently approved patent application under U.S. Patent Nos. 10,259,865 and 11,084,870 related to methods of treatment and prevention of *S. pneumoniae* infection for an immunoglobulin manufactured to contain standardized antibodies to numerous serotypes of *S. pneumoniae*. We have successfully completed production of a pilot-scale batch and are conducting animal studies for our *S. pneumoniae* hyperimmune globulin program, SG-001. Our products and product candidates are intended to be used by physician specialists focused on caring for immune-compromised patients with or at risk for certain infectious diseases.

We manufacture these products at our FDA-licensed, plasma fractionation and purification facility located in Boca Raton, FL 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.

Through our ADMA BioCenters subsidiary, we currently operate ten source plasma collection facilities in the U.S., all of which hold FDA licenses. This business unit, which we refer to as our Plasma Collection Centers business segment, provides us with the blood plasma required for the manufacture of our products, and also allows us to sell certain quantities of source and hyperimmune plasma to third-party customers for further manufacturing. In addition, three of our FDA-approved plasma collection centers also have approvals from the Korean Ministry of Food and Drug Safety (“MFDS”), as well as FDA approval to operate a Hepatitis B immunization program. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase and market conditions at the time of sale. Plasma collected from ADMA BioCenters’ facilities that is not used to manufacture our products is sold to third-party customers in the U.S. and in other locations outside the U.S. where we are approved under supply agreements or in the open “spot” market.

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

Trends and Developments

For the year ended December 31, 2024, we achieved net income of \$197.7 million, the first time in our history that we achieved net income on a GAAP basis, and we generated positive cash flow from operations of \$118.7 million, the full details of which can be found in the 2024 10-K. Our improved operating results are primarily the result of the substantial revenue growth driven by the continued physician, patient and payer acceptance of ASCENIV.

In April 2025, the FDA approved our Prior Approval Supplement (the “PAS”) for our innovative yield enhancement production process (the “Yield Enhancement”) benefiting both ASCENIV and BIVIGAM. This PAS approval amends the Biologic License Application (BLA) approvals for ASCENIV and BIVIGAM and is intended to be the process the Company will manufacture these products on a go-forward basis. The production methods approved in this PAS are expected to result in additional bulk drug yield from the same starting raw material source plasma volumes and the Company believes it should experience meaningful revenue and earnings accretion beginning as early as the second half of 2025 and accelerating further into 2026 and beyond. This innovative process has demonstrated an ability to increase ASCENIV and BIVIGAM production yields by approximately 20% from the same starting source plasma volume.

In July 2025, the One Big Beautiful Bill Act (“OBBBA”) was enacted, which includes numerous changes to existing tax law including extending or making permanent certain business provisions initially established under the 2017 Tax Cuts and Jobs Act, which were set to expire. The OBBBA permanently eliminates the requirement to capitalize and amortize U.S.-based research and experimental expenditures, making these expenditures fully deductible in the period incurred. The OBBBA also permanently extends recognition of the accelerated bonus depreciation on qualifying assets in the period acquired. We expect these provisions to result in a reduction of current income tax liabilities and a corresponding reduction to income tax expense. While we are still evaluating these and other changes contained in the law, we do not expect these changes to have a material effect on our financial statements, including our effective tax rate.

As discussed above in Note 14 – Subsequent Events, to our condensed consolidated financial statements included in this Form 10-Q, in July 2025, we acquired real estate in Boca Raton, FL for a total purchase price of \$12.6 million, which included deposits aggregating \$0.5 million made in May 2025. This real estate purchase is intended to allow the Company to expand its production operations and related activities as well as provide for certain redundancies for ambient and cold-chain storage of raw materials, work in process and finished goods inventory.

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

In June 2025, we filed our supplemental Biologics License Application (“sBLA”) for the expansion of ASCENIV’s label to include the pediatric setting for patients who are two years and older and we anticipate potential FDA approval in the first half of 2026.

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.

In May 2019, the FDA approved 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 2019.

In April 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.

In December 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 in March 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 Policies and 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. Significant estimates include rebates and chargebacks deducted from gross revenues and estimates related to the Company's effective tax rate.

Some of the estimates and assumptions we are required to make under U.S. GAAP require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summary of accounting estimates and their application are considered to be critical to understanding our business operations, financial condition and results of operations. For a description of our significant accounting policies, see Note 2 to the Consolidated Financial Statements included in our 2024 10-K. Estimates and assumptions used in projecting future liquidity and capital requirements are described in Note 1 to the condensed consolidated financial statements appearing elsewhere in this Form 10-Q.

Revenue Deductions for Rebates and Chargebacks

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

Effective Tax Rate

Our provision for income taxes and the determination of our effective tax rate are subject to significant judgment and complexity. We estimate our income tax expense based on enacted tax laws and statutory tax rates in the jurisdictions in which we operate, as well as our interpretation of relevant tax regulations. The effective tax rate includes the impact of various estimates and judgments. Changes in these estimates or in tax laws could significantly affect our effective tax rate and results of operations. Due to the complexity of tax regulations and the potential for differing interpretations, it is reasonably possible that the ultimate resolution of these matters could result in material adjustments to our effective tax rate in future periods.

Three Months Ended June 30, 2025 Compared to Three Months Ended June 30, 2024

The following table presents a summary of the changes in our results of operations for the three months ended June 30, 2025, compared to the three months ended June 30, 2024:

	Three Months Ended June 30,		
	2025	2024	Increase (Decrease)
<i>(in thousands)</i>			
Revenues	\$ 121,984	\$ 107,191	\$ 14,793
Cost of product revenue	54,757	49,738	5,019
Gross profit	67,227	57,453	9,774
Research and development expenses	1,031	560	471
Plasma center operating expenses	1,152	942	210
Amortization of intangibles	32	142	(110)
Selling, general and administrative expenses	22,214	16,608	5,606
Income from operations	42,798	39,201	3,597
Interest expense	(1,834)	(3,783)	1,949
Loss on extinguishment of debt	(1,159)	-	(1,159)
Other income, net	292	433	(141)
Income before taxes	40,097	35,851	4,246
Provision for income taxes	5,878	3,789	2,089
Net income	<u>\$ 34,219</u>	<u>\$ 32,062</u>	<u>\$ 2,157</u>
Adjusted EBITDA *	<u>\$ 50,769</u>	<u>\$ 44,545</u>	<u>\$ 6,224</u>

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

Revenues

We recorded total revenues of \$122.0 million for the three months ended June 30, 2025, as compared to \$107.2 million for the three months ended June 30, 2024, an increase of \$14.8 million, or approximately 14%. The increase is primarily related to increased sales volume of ASCENIV, as we experienced increased physician, payer and patient acceptance and utilization of this product. During the three months ended June 30, 2025, and as previously disclosed in our Form 10-Q for the three months ended March 31, 2025 that was filed with the Securities and Exchange Commission (the "SEC") on May 7, 2025 (the "2025 1Q 10-Q"), we voluntarily withdrew three lots of BIVIGAM (such a withdrawal, hereinafter referred to as the "Voluntary Withdrawal") as a precautionary measure. This resulted in a reduction in revenue of \$0.2 million for credits issued to customers that were impacted by this Voluntary Withdrawal during the current period. This action was proactively initiated, and we believe this matter to be resolved. 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 2024 revenues by \$12.6 million), our second quarter 2025 revenue increased \$27.4 million, or 29%, as compared to the second quarter of 2024.

Cost of Product Revenue and Gross Profit

Cost of product revenue was \$54.8 million for the three months ended June 30, 2025, as compared to \$49.7 million for the three months ended June 30, 2024. This increase is primarily attributable to volume-driven increases in product revenue costs related to the increased sales of our IG products of \$10.9 million, partially offset by \$5.9 million of lower product revenue costs related to the reduction in plasma and intermediates sales.

For the three months ended June 30, 2025, we had gross profit of \$67.2 million, as compared to \$57.5 million for the same period of a year ago, which represents a gross margin in the second quarter of 2025 of 55.1%, as compared to 53.6%, or 47.4% excluding the \$12.6 million adjustment recorded in the second quarter of 2024 to decrease our accrual for U.S. Medicaid rebates (which had the effect of increasing 2024 revenue by \$12.6 million) in the second quarter of 2024. This improvement in gross margin is primarily driven by a significantly more favorable mix of higher margin IG sales in 2025 as compared to 2024.

Research and Development Expenses

Research and development ("R&D") expenses totaled \$1.0 million for the second quarter of 2025, as compared to \$0.6 million for the second quarter of 2024. The increase is primarily due to expenses incurred during the second quarter related to our *S. pneumoniae* hyperimmune globulin program, SG-001.

Plasma Center Operating Expenses

Plasma Center Operating Expenses increased from \$0.9 million for the three months ended June 30, 2024 to \$1.2 million for the three months ended June 30, 2025. The increase is primarily due to higher employee-related costs.

Amortization of Intangibles

Amortization expense mainly pertains to the amortization of internally developed software and was less than \$0.1 million and \$0.1 million for the three months ended June 30, 2025 and 2024 respectively.

Selling, General and Administrative Expenses

Selling, general and administrative (“SG&A”) expenses increased \$5.6 million to \$22.2 million for the three months ended June 30, 2025, as compared to \$16.6 million, for the three months ended June 30, 2024. The increase is primarily driven by higher compensation-related costs due to increased headcount to support the growth of our business and manufacturing operations. In addition, higher stock-based compensation costs, insurance premium costs and higher professional fees contributed to this increase.

Interest Expense

Interest expense for the three months ended June 30, 2025 was \$1.8 million, as compared to \$3.8 million for the three months ended June 30, 2024, primarily driven by the decrease in debt balances due to principal repayments made in 2024 and 2025.

Loss on Extinguishment of Debt

As a result of the prepayment we made on our term loan in May 2025, we incurred a prepayment penalty in the amount of \$0.5 million and recorded a partial write-down of unamortized debt discount of approximately \$0.7 million, for a loss on this partial extinguishment of debt in the amount of \$1.2 million.

Other Income, Net

Other income, net, for the three months ended June 30, 2025 was \$0.3 million, as compared to \$0.4 million for the three months ended June 30, 2024.

Provision for Income Taxes

The provision for income taxes of \$5.9 million for the three months ended June 30, 2025 represented an effective tax rate of 14.7%, as compared to the provision of \$3.8 million for the three months ended June 30, 2024, with an effective tax rate of 10.6%. As of June 30, 2024, the Company had a full valuation allowance for its net deferred tax assets, and the effective tax rate for the three months ended June 30, 2024 differed from the federal statutory tax rate of 21% primarily due to the recognition of deferred tax assets for the net operating losses. The Company released its valuation allowance in December 2024, and the effective tax rate for the three months ended June 30, 2025 differed from the federal statutory rate primarily due to the excess tax benefits on stock-based compensation.

Six Months Ended June 30, 2025 Compared to Six Months Ended June 30, 2024

The following table presents a summary of the changes in our results of operations for the six months ended June 30, 2025, compared to the six months ended June 30, 2024:

<i>(in thousands)</i>	Six Months Ended June 30,		
	2025	2024	Increase (Decrease)
Revenues	\$ 236,786	\$ 189,066	\$ 47,720
Cost of product revenue	108,463	92,505	15,958
Gross profit	128,323	96,561	31,762
Research and development expenses	1,858	1,010	848
Plasma center operating expenses	2,438	1,947	491
Amortization of intangibles	57	335	(278)
Selling, general and administrative expenses	46,292	32,247	14,045
Income from operations	77,678	61,022	16,656
Interest expense	(3,809)	(7,552)	3,743
Loss on extinguishment of debt	(1,159)	-	(1,159)
Other income, net	836	782	54
Income before taxes	73,546	54,252	19,294
Provision for income taxes	12,424	4,384	8,040
Net income	<u>\$ 61,122</u>	<u>\$ 49,868</u>	<u>\$ 11,254</u>
Adjusted EBITDA *	<u>\$ 98,706</u>	<u>\$ 70,969</u>	<u>\$ 27,737</u>

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

Revenues

We recorded total revenues of \$236.8 million for the six months ended June 30, 2025, as compared to \$189.1 million for the six months ended June 30, 2024, an increase of \$47.7 million, or approximately 25%. The increase is primarily related to increased sales volume of ASCENIV, as we experienced increased physician, payer and patient acceptance and utilization of this product. During the six months ended June 30, 2025, and as previously disclosed in the 2025 1Q 10-Q, we effected the Voluntary Withdrawal as a precautionary measure. This resulted in a reduction in revenue of \$4.0 million for credits issued to customers that were impacted by this Voluntary Withdrawal during the current period. This action was proactively initiated, and we believe this matter to be resolved. 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 2024 revenues by \$12.6 million), our revenues for the six months ended June 30, 2025 increased \$60.3 million, or 34%, as compared to the six months ended June 30, 2024.

Cost of Product Revenue and Gross Profit

Cost of product revenue was \$108.5 million for the six months ended June 30, 2025, as compared to \$92.5 million for the six months ended June 30, 2024. This increase is primarily attributable to volume-driven increases in product revenue costs related to the increased sales of our IG products of \$23.9 million, partially offset by \$8.0 million of lower product revenue costs related to the reduction in plasma and intermediates sales.

For the six months ended June 30, 2025, we had gross profit of \$128.3 million, as compared to \$96.6 million for the same period of a year ago, which represents a gross margin in 2025 of 54.2%, as compared to 51.1%, or 47.6% when excluding the \$12.6 million adjustment recorded in the second quarter of 2024 to decrease our accrual for U.S. Medicaid rebates (which had the effect of increasing 2024 revenue by \$12.6 million) in the same period of 2024. This improvement in gross margin is primarily driven by a significantly more favorable mix of higher margin IG sales in 2025 as compared to 2024, along with the operational efficiencies achieved resulting in a reduction in other manufacturing costs.

Research and Development Expenses

Research and development (“R&D”) expenses totaled \$1.9 million for the six months ended June 30, 2025, as compared to \$1.0 million for the six months ended June 30, 2024. The increase is primarily due to expenses incurred in 2025 related to the ASCENIV pediatric study and our *S. pneumoniae* hyperimmune globulin program, SG-001.

Plasma Center Operating Expenses

Plasma Center Operating Expenses increased from \$1.9 million for the six months ended June 30, 2024 to \$2.4 million for the six months ended June 30, 2025. The increase is primarily due to an increase in employee-related costs of \$0.5 million.

Amortization of Intangibles

Amortization expense mainly pertains to the amortization of internally developed software and was \$0.1 million and \$0.3 million for the six months ended June 30, 2025 and 2024, respectively.

Selling, General and Administrative Expenses

Selling, general and administrative (“SG&A”) expenses increased \$14.0 million to \$46.3 million for the six months ended June 30, 2025, as compared to \$32.2 million, for the six months ended June 30, 2024. The increase is primarily driven by higher compensation-related costs due to increased headcount to support the growth of our business and manufacturing operations. In addition, higher stock-based compensation costs, insurance premium costs and higher professional fees contributed to this increase.

Interest Expense

Interest expense for the six months ended June 30, 2025 was \$3.8 million, as compared to \$7.6 million for the six months ended June 30, 2024, primarily driven by the decrease in debt balances due to principal repayments made in 2024 and 2025.

Loss on Extinguishment of Debt

As a result of the prepayment we made on our term loan in May 2025, we incurred a prepayment penalty in the amount of \$0.5 million and recorded a partial write-down of unamortized debt discount of approximately \$0.7 million, for a loss on this partial extinguishment of debt in the amount of \$1.2 million.

Other Income, Net

Other income, net, was \$0.8 million during the six months ended June 30, 2025 and 2024.

Provision for Income Taxes

The provision for income taxes of \$12.4 million for the six months ended June 30, 2025, represented an effective tax rate of 16.9%, as compared to \$4.4 million for the six months ended June 30, 2024, with an effective tax rate of 8.1%. As of June 30, 2024, the Company had a full valuation allowance for its net deferred tax assets, and the effective tax rate for the six months ended June 30, 2024 differed from the federal statutory tax rate of 21% primarily due to the recognition of deferred tax assets for the net operating losses. The Company released its valuation allowance in December 2024, and the effective tax rate for the six months ended June 30, 2025 differed from the federal statutory rate primarily due to the excess tax benefits on stock-based compensation.

Non-GAAP Financial Measures

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

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

Because EBITDA, Adjusted EBITDA and Adjusted net income are measures not deemed to be in accordance with U.S. GAAP and are susceptible to varying calculations, our EBITDA, Adjusted EBITDA and Adjusted net income may not be comparable to similarly titled measures of other companies, including companies in our industry, because other companies may calculate EBITDA, Adjusted EBITDA and Adjusted net income in a different manner than we calculate these measurements. Although the Company uses Adjusted EBITDA as one of several financial measures to assess its operating performance, its use is limited as it excludes certain significant operating expenses. EBITDA, Adjusted EBITDA and Adjusted net income are not intended to represent cash flows for the periods presented, nor have they been presented as an alternative to operating income, net income 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 to EBITDA and Adjusted EBITDA for the three and six months ended June 30, 2025 and 2024:

	Three Months ended June 30,		Six Months ended June 30,	
	2025	2024	2025	2024
	<i>(In thousands, except share and per share data)</i>			
Net income	\$ 34,219	\$ 32,062	\$ 61,122	\$ 49,868
Depreciation	2,027	1,906	3,970	3,826
Amortization	32	142	57	335
Income taxes	5,878	3,789	12,424	4,384
Interest expense	1,834	3,783	3,809	7,552
EBITDA	43,990	41,682	81,382	65,965
Stock-based compensation	4,963	2,863	9,587	5,004
Customer credits related to the Voluntary Withdrawal	164	-	4,001	-
Yield enhancement	493	-	1,395	-
Loss on extinguishment of debt	1,159	-	1,159	-
Non-recurring professional fees (pre-tax) (a)	-	-	1,182	-
Adjusted EBITDA	<u>\$ 50,769</u>	<u>\$ 44,545</u>	<u>\$ 98,706</u>	<u>\$ 70,969</u>

(a) Non-recurring professional fees represent incremental costs associated with a vendor change that we do not expect to incur in future periods.

Adjusted EBITDA increased for the three and six months ended June 30, 2025, as compared to the same periods of a year ago, by \$6.2 million and \$27.7 million, respectively. The improvement is primarily due to the increased sales and gross profit in 2025.

The following table presents the reconciliation of Net income to Adjusted net income for the three and six months ended June 30, 2025 and 2024:

	Three months ended	Six months ended
	June 30, 2025	June 30, 2025
	<i>(In thousands)</i>	
Net income	\$ 34,219	\$ 61,122
Stock-based compensation modifications (pre-tax)	-	474
Customer credits related to the Voluntary Withdrawal (pre-tax)	164	4,001
Loss on extinguishment of debt (pre-tax)	1,159	1,159
Yield Enhancement (pre-tax)	493	1,395
Non-recurring professional fees (pre-tax) (a)	-	1,182
Adjusted net income (b)	<u>\$ 36,035</u>	<u>\$ 69,333</u>

(a) Non-recurring professional fees represent incremental costs associated with a vendor change that we do not expect to incur in future periods.

(b) Excludes estimated tax effect of the add-backs of \$0.3 and \$1.4 million for the three and six months ended June 30, 2025, respectively.

LIQUIDITY AND CAPITAL RESOURCES

At June 30, 2025, we had working capital of \$324.6 million, primarily consisting of \$191.5 million of inventory, cash and cash equivalents of \$90.3 million and \$109.7 million of accounts receivable, partially offset by current liabilities of \$74.9 million, as compared to working capital at December 31, 2024 of \$275.9 million, primarily consisting of \$170.2 million of inventory, cash and cash equivalents of \$103.1 million and accounts receivable of \$50.0 million, partially offset by current liabilities of \$55.5 million. 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;
- The Boca Facility maintenance, improvements, repairs and supplies;
- Research and development activities; and
- Continuous improvements and updates to our IT infrastructure, laboratory equipment and assays, and facilities and engineering equipment.

As discussed above in Note 14 – Subsequent Events, to our condensed consolidated financial statements included in this Form 10-Q, in July 2025, we acquired real estate in Boca Raton, FL for a total purchase price of \$12.6 million, which included deposits aggregating \$0.5 million made in May 2025. This property was purchased to add redundancies, expand operations and prepare for future growth opportunities. In addition, our end-to-end production cycle time from procurement of raw materials to commercial release of finished product can take between seven and 12 months or potentially longer, requiring substantial inventories of raw material plasma and other manufacturing and laboratory testing materials and single use disposables.

We currently anticipate, based upon our projected revenue and expenditures, that our current cash, cash equivalents and accounts receivable, along with our projected future operating cash flow, will be sufficient to fund our operations, as currently conducted, through the first half of 2026 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, economic or inflationary 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 senior secured credit facility (the “Ares Credit Agreement”) with Ares Capital Corporation and certain credit funds affiliated with Ares Capital Corporation (collectively, “Ares”). The Ares Credit Agreement provided for a total of \$135.0 million in senior secured credit facilities (the “Ares Credit Facility”) consisting of (i) a term loan in the aggregate principal amount of \$62.5 million and (ii) a revolving credit facility in the aggregate principal amount of \$72.5 million (collectively, the “Ares Loans”), both of which were fully drawn on the Ares Closing Date. The Ares Credit Facility had a maturity date of December 20, 2027 (the “Ares Maturity Date”).

On August 14, 2024, we repaid \$30.0 million against the revolving credit facility and the outstanding balance on the revolving credit facility as of March 31, 2025 was \$42.5 million. On December 19, 2024, we repaid \$30.0 million against the term loan facility and the outstanding balance on the term loan facility as of March 31, 2025 was \$32.5 million. On May 5, 2025, we borrowed \$30.0 million under our revolving credit facility, which we used to concurrently repay an additional \$30.0 million against the term loan facility on May 6, 2025, as a result of which, the Company recorded debt extinguishment losses of \$1.2 million during the three and six months ended June 30, 2025. Following such transactions, and as of June 30, 2025, we had \$72.5 million outstanding under our revolving credit facility and \$2.5 million outstanding under our term loan facility.

Borrowings under the term loan bore 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 bore 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 June 30, 2025 and December 31, 2024, the interest rate on the term loan was approximately 10.81% and 10.85%, respectively, and the interest rate on the revolving facility was approximately 8.05% and 8.34%, respectively.

On the Ares Maturity Date, we would have been 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 were no scheduled principal payments on the Ares Credit Facility, and we were required to make quarterly interest payments during the term of Ares Credit Facility. We were permitted to 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 prepaid an amount under the revolving facility that was greater than 50% of the current \$72.5 million outstanding balance, or \$36,250,000, we would have still been required to pay an amount of interest on the revolving facility that would have been payable had \$36,250,000 been outstanding, through the term of Ares Credit Facility. We were permitted to 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) 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 (ii) 1.0% of the prepaid principal amount, if prepaid on or prior to the third anniversary of the Ares Closing Date.

All of our obligations under the Ares Credit Agreement were secured by a first-priority lien and security interest in substantially all of our tangible and intangible assets, including intellectual property and all of the equity interests in our subsidiaries. The Ares Credit Agreement contained certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings. The negative covenants included certain financial covenants, including maximum total leverage ratios and a \$15.0 million liquidity covenant, and also restricted or limited 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 June 30, 2025, we were in compliance with all of the covenants contained in the Ares Credit Agreement.

Events of default on the Ares Loans included, 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 was an event of default, we would have incurred an increase in the rate of interest on the Ares Loans of 2% per annum.

On August 5, 2025 (the "JPM Closing Date"), we and all of our subsidiaries entered into a Credit Agreement (the "JPM Credit Agreement") with the lenders party thereto and JPMorgan Chase Bank, N.A., as administrative agent ("JPMorgan"). The JPM Credit Agreement provides for \$300 million of senior secured credit facilities, consisting of (a) a term loan in the aggregate principal amount of \$75 million (the "JPM Term Loan Facility") and (b) a revolving credit facility in the aggregate principal amount of \$225 million (the "JPM Revolving Facility"). We may also request, subject to customary conditions, additional incremental revolving commitments or term loans in an aggregate principal amount not to exceed \$100 million (together with the JPM Term Loan Facility and the JPM Revolving Facility, the "JPM Credit Facilities"). The JPM Term Loan Facility has a maturity date of August 5, 2028 (the "JPM Term Maturity Date") and the JPM Revolving Facility has a maturity date of August 5, 2028 or any earlier date on which the commitments under the JPM Revolving Facility are reduced to zero or otherwise terminated pursuant to the terms of the JPM Credit Agreement (the "JPM Revolving Maturity Date").

On the JPM Closing Date, we used the proceeds of the JPM Credit Facilities to terminate and pay in full all of the outstanding obligations under the Ares Credit Facility, including the outstanding principal of all loans, all accrued and unpaid interest thereon, and any unpaid fees, charges, premiums (including prepayment premiums) and costs, and expenses related thereto. We may also use the proceeds of the JPM Credit Facilities to finance share repurchases and for working capital and general corporate purposes.

Interest on borrowings under the JPM Credit Facilities will accrue at an applicable rate equal to (i) an alternate base rate plus an applicable spread (each such borrowing, an “ABR Borrowing”) or (ii) Term SOFR plus an applicable spread (each such borrowing, a “Term Benchmark Borrowing”), in each case based on the lower of the applicable rates set forth in the JPM Credit Agreement, which are based on our total leverage ratio. These applicable spreads range from 150 basis points to 200 basis points over the alternate base rate and 250 basis points to 300 basis points over Term SOFR, in each case, as determined in accordance with the provisions of the JPM Credit Agreement. We have agreed to pay a commitment fee at specified rates set forth in the JPM Credit Agreement, which, based on our total leverage ratio, ranges from 30 basis points to 35 basis points on the daily amount of the undrawn portion of the aggregate commitments of the lenders under the JPM Revolving Facility. At our request, each borrowing initially shall be either an ABR Borrowing or a Term Benchmark Borrowing, and we may thereafter elect to convert any such borrowing to a different type. During the occurrence and continuance of an Event of Default (as defined in the JPM Credit Agreement), all borrowings shall accrue interest at a rate per annum equal to 2% plus the applicable rate.

On the JPM Revolving Maturity Date, we will repay the unpaid principal amount outstanding under the JPM Revolving Facility. Under the JPM Term Loan Facility, we will make principal payments in accordance with and on the dates specified in the amortization schedule set forth in the JPM Credit Agreement, with the remaining unpaid principal amount to be paid in full on the JPM Term Maturity Date. We may prepay at any time and from time to time any borrowing in whole or in part, without premium or penalty (other than, if applicable, any break funding expenses), subject to customary notice requirements.

All of our obligations under the JPM Credit Agreement are secured by a first-priority lien and security interest in substantially all of the tangible and intangible assets, including intellectual property and equity interests, of us and all of our subsidiaries.

The JPM 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 a maximum total leverage ratio of 2.50 to 1.00 and a minimum fixed charge coverage ratio of 1.20 to 1.00. The negative covenants also restrict or limit our ability and the ability of our subsidiaries to, among other things and subject to certain exceptions contained in the JPM Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes; make certain investments; dispose of certain assets; engage in sale and leaseback transactions or swap agreements; make certain Restricted Payments (as defined in the JPM Credit Agreement); engage in certain affiliate transactions; enter into any other agreements that have the impact of restricting our ability to make loan repayments under the JPM Credit Agreement; or amend certain material documents.

Cash Flows

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

	Six Months Ended June 30,	
	2025	2024
<i>(in thousands)</i>		
Net cash provided by operating activities	\$ 1,464	\$ 43,428
Net cash used in investing activities	(7,247)	(4,727)
Net cash used in financing activities	(7,079)	(1,809)
Net change in cash and cash equivalents	(12,862)	36,892
Cash and cash equivalents - beginning of period	103,147	51,352
Cash and cash equivalents - end of period	<u>\$ 90,285</u>	<u>\$ 88,244</u>

Net Cash Provided by Operating Activities

Cash provided by operating activities for the six months ended June 30, 2025 was \$1.5 million, a decrease of \$42.0 million from the same period of a year ago, primarily due to the unfavorable impact of the timing of sales and due to inventory investments made in 2025 to support the Company’s manufacturing and distribution objectives, partially offset by higher net income and favorable impact of timing of payments. The following table illustrates the primary components of our cash flows from operations:

	Six Months Ended June 30,	
	2025	2024
<i>(in thousands)</i>		
Net income	\$ 61,122	\$ 49,868
Non-cash expenses, gains and losses	20,097	9,598
Changes in accounts receivable	(59,726)	(2,692)
Changes in inventories	(21,229)	(6,904)
Changes in accounts payable and accrued expenses	4,203	(6,603)
Other	(3,003)	161
Cash provided by operations	<u>\$ 1,464</u>	<u>\$ 43,428</u>

Net Cash Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2025 and 2024 was \$7.2 million and \$4.7 million, respectively. The increase is primarily related to the roof replacement at the Boca Facility in the amount of \$1.3 million, due to capital expenditures associated with the Yield Enhancement project. While as of June 30, 2025 we had no firm commitments for capital expenditures with the exception of the July 2025 purchase of the real estate in Boca Raton, FL, we expect our total capital expenditures will be between \$18.0 million and \$21.6 million for the remainder of fiscal 2025, mainly for additional upgrades to the Boca Facility manufacturing operations, related operational systems, and the purchase of the real estate in Boca Raton, FL, which was completed in July 2025. Of the total remaining 2025 capital expenditures, \$13.0 million represents the acquisition cost and improvements of the new Boca Raton real estate.

Net Cash Used in Financing Activities

Net cash used in financing activities was \$7.1 million and \$1.8 million for the six months ended June 30, 2025 and 2024, respectively. The increase is primarily due to higher taxes paid in connection with shares that were withheld from RSUs that vested during the period, as a result of an increase in the value of our common stock as compared to 2024.

Effect of Inflation

Inflation impacted a number of facets of our business during the six months ended June 30, 2025 and 2024 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 2025 and potentially longer, which could have a significant impact on our future results of operations. In addition, some of our third-party inventory purchase agreements provide for scheduled price increases that are tied to various consumer price indexes, which have resulted in higher than historical percentage price increases and could result in higher source plasma and other raw material and supplies costs in 2025 and beyond. Also, in a higher inflationary environment, we may not be able to raise the prices of our products to maintain the rate of inflation, and this may affect our product margins. 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 a result of changes in interest rates. Our senior credit facility with Ares required quarterly payments of interest based on the adjusted Term SOFR plus the applicable margin. Our new senior credit facility with JPMorgan requires quarterly payments of interest, in the case of an alternate base rate borrowing, and one-month or three-month payments of interest, in the case of a Term SOFR borrowing, in each case, plus the applicable rate. We currently do not utilize any derivative financial instruments, such as interest rate swaps or caps, to mitigate this risk. As of June 30, 2025, we had \$75.0 million outstanding under our senior credit facility with Ares that was subject to a variable interest rate. As a result, the effect of a hypothetical, instantaneous and unfavorable change of 100 basis points in the interest rate would have an approximate \$0.8 million annualized negative impact on our earnings and cash flows.

Item 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 U.S. Securities and Exchange Commission (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 June 30, 2025. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of June 30, 2025, 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 June 30, 2025, 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 Form 10-Q, the 2024 10-K and our other filings with the U.S. Securities and Exchange Commission, or the SEC, before making an investment decision regarding our common stock.

- Although we achieved net income on a GAAP basis for the year ended December 31, 2024 for the first time, we may not be able to maintain profitability and continue to generate positive cashflows in the future.
- We contract with third parties for the filling, packaging, testing and labeling of the drug substance we manufacture, and we also obtain source plasma from certain third parties. This reliance on third parties carries the risk that the services and raw materials upon which we rely may not be performed in a timely manner, in sufficient quantities or according to our specifications, which could delay the availability of our finished drug product and could adversely affect our commercialization efforts and our revenues.
- The estimates of market opportunity and forecasts of market and revenue growth included in our filings may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business could fail to grow at similar rates, if at all.
- Both of our business segments and our facilities, as well as our suppliers and contractors, are subject to periodic inspections by the FDA and other regulatory authorities, which, depending on the outcome of such inspections, could result in certain regulatory actions, including the issuance of observations, notices, citations, warning letters or other enforcement actions.
- Business interruptions could adversely affect our business.
- Although we have received approval from the FDA to market ASCENIV as a treatment for PIDD, our ability to market or seek approval for ASCENIV for alternative indications could be limited unless additional clinical trials are conducted successfully and the FDA approves a Biologics License Application ("BLA") or other required submission for review.
- With the approval of ASCENIV, there can be no assurance that we will be successful in further developing and expanding commercial operations, collecting and procuring an adequate supply of high-titer antibody RSV plasma or balancing our research and development activities with our commercialization activities.
- We depend on third-party researchers, developers and vendors to develop, manufacture, supply materials for or test our products and product candidates, as well as for other pre-and post-approval services, and such parties' performance is, to some extent, outside of our control.
- We may be unable to successfully expand our manufacturing processes to fulfill demand for our products or increase our production capabilities through the addition of new equipment, including if we do not obtain requisite approval from the FDA.
- Our products, and any additional products for which we may obtain marketing approval in the future, could be subject to post-marketing restrictions or withdrawal from the market and we could be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products following approval.

- Historically, a few customers have accounted for a significant amount of our total revenue and accounts receivable and the loss of any of these customers could have a material adverse effect on our business, results of operations and financial condition.
- Issues with product quality and compliance could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.
- If physicians, payers and patients do not accept and use our current products or our future product candidates, our ability to generate revenue from these products will be materially impaired.
- Our accruals for U.S. Medicaid rebates and other liabilities related to the sale of our immunoglobulin products are estimates based on historical experience and other assumptions. These estimates are subject to change based on actual results and other factors. Any such change could have a material effect on our business, financial position and operating results.
- Our long-term success may depend on our ability to supplement our existing product portfolio through new product development or the in-license or acquisition of other new products, product candidates and label expansion of existing products, and if our business development efforts are not successful, our ability to maintain profitability may be adversely impacted.
- Our ADMA BioCenters operations collect information from donors in the United States that subjects us to consumer and health privacy laws, which could create enforcement and litigation exposure if we fail to meet their requirements.
- Our senior secured credit facility with JPMorgan Chase Bank, N.A. and certain other lenders party thereto (collectively “JPMorgan”) is subject to acceleration in specified circumstances, which may result in JPMorgan taking possession and disposing of any collateral.
- If we are unable to protect our patents, trade secrets or other proprietary rights, if our patents are challenged or if our provisional patent applications do not get approved, our competitiveness and business prospects may be materially damaged.
- Cyberattacks and other security breaches could compromise our proprietary and confidential information or otherwise penetrate our network, which could harm our business and reputation.
- Our ability to continue to produce safe and effective products depends on the safety of our plasma supply, testing by third parties and the timing of receiving the testing results, and the manufacturing processes we have in place to counter transmittable diseases.
- We could become supply-constrained and our financial performance would suffer if we cannot obtain adequate quantities of FDA-approved source and high-titer plasma with proper specifications or other necessary raw materials.
- Our ability to use our net operating loss carryforwards (“NOLs”) may be limited.
- Fluctuations in our tax obligations and effective tax rate and realization of our net deferred tax assets may result in volatility of our operating results and materially impact our financial condition or financial results.
- The market price of our common stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

Risk Factors

Described below are various risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other companies in our industry or business in general, may also affect our business. If any of the risks described below actually occur, our business, financial condition or results of operations could be materially and adversely affected. You should carefully consider the following risk factors and the section entitled “Special Note Regarding Forward-Looking Statements” before you decide to invest in our securities.

Risks Relating to our Business

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

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

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

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

Our business may be adversely affected by a pandemic, epidemic, or outbreak of an unknown or emerging infectious disease.

Our business could be adversely affected by health epidemics in regions where we have concentrations of business activities and such epidemics could cause significant disruption in the operations of third-party service providers upon whom we rely. A resurgence of a global pandemic or health epidemic could adversely affect our business, financial condition, liquidity or results of operations. These adverse effects include, but are not limited to, the potential adverse effects on the global economy, our manufacturing processes, including our supply chain, our submissions or applications to the FDA and our employees. The ultimate impact will depend on the severity and duration of the pandemic and actions taken by governmental authorities and other third parties in response, each of which is unforeseeable and difficult to predict.

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

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

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

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

- we may be unable to identify contractors on acceptable terms or at all because the number of potential service providers is limited and the FDA must inspect and qualify any contract manufacturers for current cGMP compliance as part of our marketing application;
- a new fill/finisher would have to be educated in, or develop substantially equivalent processes for, the production of our products and product candidates;
- a pandemic, or the resurgence of a pandemic such as the COVID-19 pandemic, or a cyberattack or data breach, could adversely affect our contractors' operations, supply chain or workforce;
- our contracted fill/finishers' resources and level of expertise with plasma-derived biologics may be limited, therefore they may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to deliver our finished drug product;
- our third-party contractors might be unable to timely provide finished drug product or raw material plasma in sufficient quantity or in accordance with our specifications to meet our commercial needs;
- contractors may not be able to execute our inspection procedures and required tests appropriately;
- contractors are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations, and we do not have control over third-party providers' compliance with these regulations;
- contractors may fail to comply with applicable regulatory requirements, placing them and us at risk of regulatory enforcement actions, recalls and other adverse consequences, and which place our patients at risk, which may negatively impact our business and their ability to supply products to meet our development, clinical and commercial needs;
- our third parties could breach or terminate their agreements with us; and
- our contract fill/finishers may have unacceptable or inconsistent drug product quality success rates and yields, and we have no direct control over our contract fill/finishers' ability to maintain adequate quality control, quality assurance and qualified personnel.

Each of these risks could delay or prevent production, the completion of our finished drug product and the release of finished drug product by us or the FDA, which could result in higher costs or adversely impact our revenues. These risks could also result in the delay in obtaining clinical supplies, which would delay our development programs. In addition, our contract fill/finishers and our other third-party vendors may source their materials and supplies globally and are therefore subject to supply disruptions in the event of fire, weather related events such as hurricanes, wind and rain, international conflicts, strikes, embargoes, trade and sanction requirements and limits, other acts of God or force majeure events or global health occurrences and emergencies.

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

Market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. In particular, the size and growth of the overall U.S. IVIG and source plasma markets and the potential market opportunity for an *S. pneumoniae* hyperimmune globulin are subject to significant variables that can be difficult to measure, estimate or quantify.

Our business depends on, among other things, successful manufacturing and 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, including but not limited to our current expectations with respect to our yield enhancement production process, which received FDA approval in April 2025. As a result, we may not be able to accurately forecast or predict revenue. For these reasons, the estimates and forecasts in our filings relating to revenue generation and growth may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and forecasted growth, our business could fail to grow at similar rates, if at all.

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

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

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

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

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

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

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

Business interruptions could adversely affect our business.

Our operations, including our headquarters located in Ramsey, NJ, the Boca Facility, our new real estate in Boca Raton, FL and our plasma collection facilities, are vulnerable to interruption by fire, weather related events such as hurricanes, wind and rain, other acts of God or force majeure events, electric power loss, telecommunications failure, equipment failure and breakdown, cyberattacks on our operations and information technology systems as well as the systems of our customers, suppliers and related entities, human error, employee issues, global health occurrences such as a pandemic, global and economic uncertainty, war, terrorism, geopolitical conditions and emergencies, product liability claims and events beyond our control. While we maintain several insurance policies with reputable carriers that provide partial coverage for a variety of these risks, including replacing or rebuilding a part of our facilities, these policies are subject to the insurance carriers' final determination of compensation to us and we may not have adequate coverage if we need to rebuild or replace our inventory, infrastructure, business income or our entire facility. In addition, our disaster recovery plans for our facilities may not be adequate and we do not have an alternative manufacturing facility or contractual arrangements with other manufacturers in the event of a casualty to or destruction of any of our facilities. If we are required to rebuild or relocate any of our facilities, a substantial investment in improvements and equipment would be necessary. We carry only a limited amount of business interruption insurance, which may not sufficiently compensate us for losses that may occur. As a result, any significant business interruption could adversely affect our business and results of operations.

If we are unsuccessful in obtaining regulatory approval for any of our product candidates or if any of our product candidates do not provide positive results, we may be required to delay or abandon development of such product, which would have a material adverse impact on our business.

Product candidates require extensive clinical data analysis and regulatory review and may require additional testing. Clinical trials and data analysis can be very expensive, time-consuming and difficult to design and implement. The conduct of preclinical studies and clinical trials is subject to numerous risks and results of the studies and trials are highly uncertain. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. Furthermore, delays or setbacks can occur at any stage of the process, and we could encounter problems that cause us to abandon our product development programs and related IND applications or BLAs, or to repeat clinical trials. The commencement and completion of clinical trials or ultimate product approval for any current or future development product candidate may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of safety or effectiveness, or other adverse study results during clinical trials;
- slower than expected rates of patient recruitment or noncompliance with clinical trial requirements;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

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

In addition, the FDA or an IRB may not permit us to commence a clinical trial, may require amendments to our clinical trial protocols, or may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA or IRB finds deficiencies in our IND submissions or the conduct of these trials. Regulatory authorities may also not accept data from clinical trials if the trials are not conducted in accordance with the applicable regulatory requirements. Failure to comply with the applicable regulatory requirements may also result in enforcement actions. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. In the event we do not ultimately receive regulatory approval for our product candidates, we may be required to terminate development of such product candidates. If we fail to obtain regulatory approval to market and sell our product candidates, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished and the capital necessary to fund our operations will increase.

If the results of our clinical trials do not support our product candidate claims, completing the development of such product candidate may be significantly delayed or we may be forced to abandon development of such product candidate altogether.

We cannot be certain that the clinical trial results of our product candidates will support our product candidates' claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing.

The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay the development of other product candidates. Any delay in, or termination of, our clinical trials will delay our ability to commercialize our product candidates and generate product revenues.

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

- Delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our contract research organizations ("CROs");
- Regulators requiring us to perform additional or unanticipated clinical trials to obtain approval or becoming subject to additional post-marketing testing, surveillance, or Risk Evaluation and Mitigation Strategies requirements to maintain regulatory approval;
- Failure by our third-party contractors to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or our being required to engage in additional clinical trial site monitoring;
- The cost of clinical trials of our product candidates being greater than we anticipate;
- Insufficient supply or inadequate quality of our product candidates or other materials necessary to conduct clinical trials;
- Inability to achieve sufficient study enrollment, subjects dropping out or withdrawing from our studies, delays in adding new investigators or clinical trial sites or a withdrawal of clinical trial sites;
- Flaws in our clinical trial design that are not discoverable until the clinical trial has progressed;
- Disagreement by the FDA or comparable foreign regulatory authorities with our intended indications or study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials, finding that a product candidate's benefits do not outweigh its safety risks or requiring that we conduct additional development or study work;
- The need to make changes to our product candidates that require additional testing or that cause our product candidates to perform differently than expected;
- Global trade policies that may impact our ability to obtain raw materials and/or finished product for commercialization;
- FDA or comparable regulatory authorities taking longer than we anticipate to make decisions on our products or product candidates; and
- Potential inability to demonstrate that a product or product candidate provides an advantage over current standards of care or current or future competitive therapies in development.

In addition, our clinical trials involve a relatively small patient population. Because of the small sample size, the results of these clinical trials may not be indicative of future results. In addition, certain portions of our clinical trials and product testing for our product candidates may be performed outside of the United States, and therefore, may not be performed in accordance with standards normally required by the FDA and other regulatory agencies.

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

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

- delay commercialization of, and our ability to derive revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject our product candidate's BLA. In addition, the FDA could determine that we must test additional subjects and/or require that we conduct further studies with more subjects. We may never obtain regulatory approval for any future potential product candidate or label expansion activity. Failure to obtain FDA approval for any of our product candidates will severely undermine our business by leaving us without the ability to generate additional accretive revenues. There is no guarantee that we will ever be able to develop or acquire other product candidates. In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any products or product candidates outside the U.S. Foreign regulatory approval processes generally include all of the risks and uncertainties associated with the FDA review, inspection and approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any product candidate for sale outside the United States.

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

The FDA and other governmental authorities strictly regulate and monitor marketing, labeling and the advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the Internet and off-label promotion. The FDA does not allow drugs to be promoted for "off-label" uses - that is, uses that are not described in the product's labeling and that differ from those that were approved by the FDA. The FDA limits approved uses to those studied by a company in its clinical trials. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. Although we have received approval from the FDA to market ASCENIV as a treatment for PIDD, we cannot be sure whether we will be able to obtain FDA approval for any desired future indications for ASCENIV.

While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling, and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote our products is narrowly limited to those indications that are specifically approved by the FDA. "Off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If the FDA determines that our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines related to promotion and advertising may cause the FDA to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from the market, require a recall, require payment of civil fines or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, among other consequences, any of which could harm our reputation and our business.

With the approval of ASCENIV, there can be no assurance that we will be successful in further developing and expanding commercial operations, collecting and procuring an adequate supply of high-titer antibody RSV plasma or balancing our research and development activities with our commercialization activities.

Since receiving FDA approval for ASCENIV, we have been commercializing this product while also continuing our research and development activities. There can be no assurance that we will be able to successfully manage the balance of our research and development operations with our commercialization activities. Potential investors and stockholders should be aware of the problems, delays, expenses and difficulties frequently encountered by companies balancing development of product candidates, which can include problems such as unanticipated issues related to clinical trials and receipt of approvals from the FDA and foreign regulatory bodies, with commercialization efforts, which can include problems related to managing manufacturing and supply, including supply chain constraints, reimbursement, marketing challenges, development of a comprehensive compliance program, and other related and additional costs. For example, the raw material plasma we collect and procure to manufacture ASCENIV using our patented proprietary microneutralization assay is comprised of plasma collected from donors which contains high-titer antibodies to RSV. This high-titer plasma which meets our internal specifications for the manufacture of ASCENIV that we are able to identify with our patented testing assay amounts to less than 10% of the total donor collection samples we test. As a result, we may experience an insufficient supply of this plasma.

Our product candidates will require significant additional research and clinical trials, and we will need to overcome significant regulatory burdens prior to commercialization in the United States and other countries. In addition, we may be required to spend significant funds on building out our commercial operations. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize any of our product candidates, generate any significant revenues or ever achieve and maintain a substantial level of sales of our products.

We depend on third-party researchers, developers and vendors to develop, manufacture, supply materials for or test our products and product candidates, as well as for other pre and post-approval services, and such parties' performance is, to some extent, outside of our control.

We depend on independent investigators and collaborators, such as universities and medical institutions, contract laboratories, CROs, contract manufacturers, contract fill/finishers, third-party plasma centers and consultants to conduct our preclinical activities, clinical trials, CMC testing and other activities under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These third parties may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our products and/or development programs, or if their performance is substandard or does not comply with the applicable regulatory standards, our trials may be repeated, extended, delayed, or terminated, the approval of our FDA application(s), if any, and our introduction of new products, if any, will be delayed, and we may not be able to maintain existing approvals or meet our regulatory requirements 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. We also depend on third-party suppliers for materials used in our operations. Certain of our third-party suppliers may be single-sourced, or may not be able to supply sufficient materials for our operations at a reasonable price, and it may be time-consuming, expensive or otherwise not feasible to locate an alternative supplier. In the event a single-source supplier is unable to provide us with a sufficient amount of materials, such shortage could have a material adverse effect on our business, results of operations and financial condition. 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 potential future expansion of our manufacturing capacity and product output capability of the Boca Facility. Following the expansion of any of our manufacturing processes or the addition of new equipment, we will be required to validate the expanded facility, process changes if any 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 and approval process, we may experience a supply shortage of our products or our production capabilities may be limited until completion of and validation of our facility expansion and new manufacturing equipment.

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

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

- restrictions on such products or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- clinical holds or termination of clinical trials;
- requirements to conduct further post-marketing studies or clinical trials, implement risk mitigation strategies, or to issue corrective information;
- warning letters or untitled letters;

- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payers;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of products;
- FDA debarment, suspension and debarment from government programs, refusal of orders under existing government contracts, exclusion from participation in federal healthcare programs, consent decrees, deferred or non-prosecution agreements or corporate integrity agreements;
- product seizure or detention; or
- injunctions or the imposition of civil penalties or criminal fines.

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

For the six months ended June 30, 2025 and 2024, two customers, BioCARE, Inc. (“BioCare”) and Priority Healthcare Distribution, Inc. d/b/a CuraScript SD Specialty Distribution (“Curascript”), represented an aggregate of approximately 72%, respectively, of our consolidated revenues.

As of June 30, 2025, and December 31, 2024, three customers, BioCare, Healix Infusion Therapy, LLC (“Healix”) and Cencora, Inc. (f/k/a AmerisourceBergen Corporation), represented an aggregate of approximately 90% and 91%, respectively, of our consolidated accounts receivable.

The loss of any key customers or a material change in the revenue generated by any of these customers, could have a material adverse effect on our business, results of operations and financial condition. 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, withdrawals, 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. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products. We may elect, in the interest of public safety, to voluntarily withdraw our products from the market for labeled adverse events or for other reasons. For example, during the three and six months ended June 30, 2025, as a precautionary measure, we voluntarily withdrew three lots of BIVIGAM and recorded a reduction to revenue of \$0.2 million and \$4.0 million, respectively, for credits issued to customers for related product returns. Recalls or withdrawals of any of our products could divert managerial and financial resources which could have an adverse effect on our financial condition and results of operations. 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 prior or future sales and difficulty in successfully commercializing our current products and launching new products.

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

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

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

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

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

Our accruals for U.S. Medicaid rebates and other liabilities related to the sale of our immunoglobulin products are estimates based on historical experience and other assumptions. These estimates are subject to change based on actual results and other factors. Any such change could have a material effect on our business, financial position, and operating results.

Our gross product revenues are subject to a variety of deductions which are estimated and recorded in the same period that the revenues are recognized. These deductions primarily consist of rebates, distribution fees, chargebacks and sales allowances. These deductions represent estimates of the related obligations, some of which are contractual in nature and do not require extensive judgment to be exercised by management, while other estimates require complex or subjective matters of knowledge and judgment when estimating the impact of these revenue deductions on net revenues for a reporting period. Significant estimates include, among other things, accruals for U.S. Medicaid rebates related to the sale of our immunoglobulin products. We accrue these rebates at the time of sale based on our estimates of the sales mix of our products and the portion of the products we sell that will be prescribed to Medicaid beneficiaries. These estimates are based on historical experience and certain other assumptions, and while we believe that such estimates are reasonable, they are subject to change based on future experience, Medicaid utilization trends and other factors. If any of our ratios, factors, assessments, experiences or judgments are not indicative or accurate estimates of our future experience, our results could be materially affected. Estimates that are most at risk for material adjustment include those associated with U.S. Medicaid rebates because of the extensive time delay between the recording of the accrual and its ultimate settlement, an interval that can generally take up to several years or more. These estimates may change from time to time based on changes in utilization, payer and channel mixes or the ultimate settlement or resolution of payor claims. For example, during 2024 we engaged a third-party specialist to assist in the evaluation of our accrual for U.S. Medicaid rebates related to the sale of our immunoglobulin products. As a result of this evaluation, we recognized a reduction in this accrual and a corresponding increase to net revenues of \$12.6 million for the year ended December 31, 2024. We considered several qualitative factors when evaluating our rebate accrual, such as the absence of a statutory limitation on the rebate amounts drug manufacturers pay to state Medicaid programs and general uncertainty that pharmaceutical manufacturers have historically seen with government payors often submitting lagged claims many periods after the initial dispensing of a product to an end patient. There was additional new information that arose during June 2024 that suggested our liabilities for certain payor claims were successfully resolved, which resulted in the \$12.6 million adjustment to the accrual for U.S. Medicaid rebates in June 2024.

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

Our long-term success may depend on our ability to supplement our existing product portfolio through new product development or the in-license or acquisition of other new products, product candidates and label expansion of existing products, and if our business development efforts are not successful, our ability to maintain profitability may be adversely impacted.

Our current product development portfolio consists primarily of label expansion activities for ASCENIV, as well as expanding our IP estate with patents issued for *S. pneumoniae* hyperimmune IG. We have initiated small-scale preclinical activities to potentially expand our current portfolio through new product development efforts. If we are not successful in developing or acquiring additional products and product candidates, we will have to depend on our ability to continue to generate revenues from ASCENIV, BIVIGAM, Nabi-HB, intermediates, contract manufacturing and plasma attributable to the operations of ADMA BioCenters to support our operations.

Our ADMA BioCenters operations collect information from donors in the United States that subjects us to consumer and health privacy laws, which could create enforcement and litigation exposure if we fail to meet their requirements.

Consumer privacy is highly protected by federal and state law. The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), and their respective implementing regulations, impose requirements with respect to safeguarding the privacy, security and transmission of protected health information (“PHI”) held by covered entities and business associates. HIPAA “covered entities” include health plans/insurers, healthcare providers engaging in HIPAA standard electronic transactions and healthcare clearinghouses. A “business associate” provides services to covered entities (directly or as subcontractors to other business associates) involving arranging, creating, receiving, maintaining, or transmitting PHI on a covered entity’s behalf. In order to legally provide access to PHI to service providers, covered entities and business associates must enter into a “business associate agreement” with the service provider that receives PHI on behalf of the entity.

While we are not a covered entity or business associate subject to HIPAA, personal information that we obtain pursuant to a clinical trial may be subject to U.S. Federal Trade Commission (the “FTC”) privacy regulation. Failing to take appropriate steps to keep consumers’ personal information secure may constitute an unfair act or practice violating Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC’s guidance for appropriately securing consumers’ personal information is similar to, but less prescriptive than, what is required by the HIPAA Security Rule. In addition, states impose a variety of laws protecting consumer information, with certain sensitive information such as HIV/Sexually Transmitted Disease status subject to heightened standards. In addition, federal and state privacy, data security, and breach notification laws, rules and regulations, and other laws apply to the collection, use and security of personal information, including social security numbers, driver’s license numbers, government identifiers, credit card and financial account numbers. For example, the CCPA was amended by the CPRA, effective January 1, 2023. The CCPA, among other things, imposes data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with 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 JPMorgan Credit Facilities are subject to acceleration in specified circumstances, which may result in JPMorgan taking possession and disposing of any collateral.

On August 5, 2025 (the “JPM Closing Date”), we entered into a credit agreement with JPMorgan and certain other lenders party thereto (the “JPM Credit Agreement”) (see “Liquidity and Capital Resources”). The JPM Credit Agreement provides for a total of \$300 million in senior secured credit facilities (the “JPM Credit Facilities”) consisting of (i) a term loan in the aggregate principal amount of \$75 million, which was drawn in full on the JPM Closing Date, and (ii) a revolving credit facility in the aggregate principal amount of up to \$225 million (collectively, the “JPM Loans”), none of which was drawn on the JPM Closing Date. The JPM Credit Facility has a maturity date of August 5, 2028.

The JPM 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 JPM Loans of 2% per annum. The occurrence of an event of default could result in, among other things, the termination of commitments under the JPM Credit Facilities, the declaration that all outstanding loans are immediately due and payable in whole or in part, and JPMorgan taking immediate possession of, and selling, any collateral securing the JPM Loans.

Developments by competitors may render our products or technologies obsolete or non-competitive.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our current products and any future product we may develop will have to compete with other marketed therapies. In addition, other companies may pursue the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the United States and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater financial resources, larger research and development staffs and facilities, longer product development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations.

If we are unable to protect our patents, trade secrets or other proprietary rights, if our patents are challenged or if our provisional patent applications do not get approved, our competitiveness and business prospects may be materially damaged.

As we move forward in clinical development, we continue to discover novel technologies related to our products and we may draft patent applications directed to these technologies. We rely on a combination of patent rights, trade secrets, intellectual property assignment agreements and nondisclosure and non-competition agreements to protect our proprietary intellectual property, and we will continue to do so. There can be no assurance that our patents, trade secret policies and practices or other agreements will adequately protect our intellectual property. Our issued patents may be challenged, found to be over-broad or otherwise invalidated in subsequent proceedings before courts, the U.S. Patent and Trademark Office or foreign patent offices. Even if enforceable, we cannot provide any assurances that they will provide significant protection from competition. The processes, systems, and/or security measures we use to preserve the integrity and confidentiality of our data and trade secrets may be breached, and we may not have adequate remedies as a result of any such breaches. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. There can be no assurance that the confidentiality, invention assignment, nondisclosure and non-competition agreements with employees, consultants and other parties with access to our proprietary information to protect our trade secrets, proprietary technology, processes and other proprietary rights, or any other security measures relating to such trade secrets, proprietary technology, processes and proprietary rights, will be adequate, will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We could lose market exclusivity of a product earlier than expected.

In the pharmaceutical and biotechnology industries, the majority of an innovative product's commercial value is realized during its market exclusivity period. In the United States and in some other countries, when market exclusivity expires and generic or biosimilar versions are approved and marketed or when biosimilars are introduced (even if only for a competing product), there are usually very substantial and rapid declines in a product's revenues.

Market exclusivity for our products is based upon patent rights and certain regulatory forms of exclusivity. The scope of our patent rights may vary from country to country and may also be dependent on the availability of meaningful legal remedies in a country. The failure to obtain patent and other intellectual property rights, limitations on the use or loss of such rights could be material to us. In some countries, basic patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents and/or we (or our licensors) did not file in those markets. In addition, the patent environment can be unpredictable and the validity and enforceability of patents cannot be predicted with certainty. Absent relevant patent protection for a product, once the data exclusivity period expires, generic versions can be approved and marketed.

Patent rights covering our products may become subject to patent litigation. In some cases, manufacturers may seek regulatory approval by submitting their own clinical trial data to obtain marketing approval or choose to launch a generic product "at risk" before the expiration of our patent rights/or before the final resolution of related patent litigation. Enforcement of claims in patent litigation can be very costly, time-consuming and no assurance can be given that we will prevail. In addition, any such litigation may divert our management's attention from our core business and reduce the resources available for our clinical development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome.

There is no assurance that ASCENIV, or any other of our products for which we are issued a patent, will enjoy market exclusivity for the full time period of the respective patent.

Third parties could obtain patents that may require us to negotiate licenses to conduct our business, and there can be no assurance that the required licenses would be available on reasonable terms or at all.

We may not be able to operate our business without infringing third-party patents. Numerous U.S. and foreign patents and pending patent applications owned by third parties exist in fields that relate to the development and commercialization of IG. In addition, many companies have employed intellectual property litigation as a way to gain a competitive advantage. It is possible that infringement claims may occur as the number of products and competitors in our market increases. In addition, to the extent that we gain greater visibility and market exposure as a public company, we face a greater risk of being the subject of intellectual property infringement claims. We cannot be certain that the conduct of our business does not and will not infringe intellectual property or other proprietary rights of others in the United States and in foreign jurisdictions. If our products, methods, processes and other technologies are found to infringe third-party patent rights, we could be prohibited from manufacturing and commercializing the infringing technology, process or product unless we obtain a license under the applicable third-party patent and pay royalties or are able to design around such patent. We may be unable to obtain a license on terms acceptable to us, or at all, and we may not be able to redesign our products or processes to avoid infringement. Even if we are able to redesign our products or processes to avoid an infringement claim, our efforts to design around the patent could require significant time, effort and expense and ultimately may lead to an inferior or more costly product and/or process. Any claim of infringement by a third party, even those without merit, could cause us to incur substantial costs defending against the claim and could distract our management from our business. Furthermore, if any such claim is successful, a court could order us to pay substantial damages, including compensatory damages for any infringement, plus prejudgment interest and could, in certain circumstances, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently prohibit us, our licensees, if any, or our customers from making, using, selling, offering to sell or importing one or more of our products or practicing our proprietary technologies or processes, or could enter an order mandating that we undertake certain remedial activities. Any of these events could seriously harm our business, operating results and financial condition.

If we are unable to successfully manage our growth, our business may be harmed.

Our success will depend on the expansion of our commercial and manufacturing activities, supply of raw material plasma and overall operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we must expand our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business could be harmed.

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

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

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

In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information. The secure storage, maintenance, and transmission of and access to this information is important to our operations and reputation. Computer hackers may attempt to penetrate our computer systems and, if successful, misappropriate our proprietary and confidential information including e-mails and other electronic communications. Cybersecurity vulnerabilities can also arise from human error, fraud or malice on the part of our employees, other insiders or third parties, or from technology or product enhancements or the migration of information and data to new technology platforms, systems or applications. Hackers may impersonate our vendors, suppliers or other third parties with whom we do business, which may result in financial harm to our business. Further, while many of our employees and certain suppliers with whom we do business operate in a remote working environment, the risk of cybersecurity attacks and data breaches, particularly through phishing attempts, may be increased as we and third parties with whom we interact leverage our IT infrastructure in unanticipated ways. In addition, an employee, contractor, or other third party with whom we do business may attempt to obtain such information and may purposefully or inadvertently cause a breach involving such information. While we have certain safeguards in place to reduce the risk of and detect cyberattacks, including a Company-wide cybersecurity policy, our information technology networks and infrastructure may be vulnerable to unpermitted access by hackers or other breaches, or employee error or malfeasance. Any such compromise of our data security and access to, or public disclosure or loss of, confidential business or proprietary information could disrupt our operations, damage our reputation, provide our competitors with valuable information and subject us to additional costs which could adversely affect our business.

If we are unable to hire and retain a substantial number of qualified personnel, our ability to sustain and grow our business may be harmed.

Our success depends in part on our ability to attract, motivate, and retain a sufficient number of qualified employees across various areas of our operations, such as research and development, manufacturing operations and sales, who understand and appreciate our strategy and culture and are able to contribute to our mission. We will need to hire additional qualified personnel with expertise in commercialization, sales, marketing, medical affairs, reimbursement, government regulation, formulation, quality control, manufacturing, finance, general and operational management and plasma collections. In particular, over the next 12-24 months, we expect to hire several new employees devoted to our plasma collection centers, commercialization, sales, marketing, medical and scientific affairs, regulatory affairs, quality control, information technology, finance and general and operational management. Qualified individuals of the requisite caliber and number needed to fill these positions may be in short supply in some areas. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot assure you that our search for such personnel will be successful. If we are unable to hire and retain personnel capable of consistently performing at a high level, our business and operations could be materially adversely affected. Additionally, any material increases in existing employee turnover rates or increases in labor costs could have a material adverse effect on our business, financial condition or operating results.

We currently collect human blood plasma at our ADMA BioCenters facilities, and if we cannot maintain FDA licensure for these facilities or obtain FDA licensure for additional facilities that we may construct or acquire rights to, we may be adversely affected and may not be able to sell or use this human blood plasma for future commercial purposes.

We intend to maintain FDA licensure of our current and future ADMA BioCenters collection facilities for the collection of human blood plasma and we may seek other governmental and regulatory approvals for these facilities. Collection facilities are subject to FDA and potentially other governmental and regulatory inspections and extensive regulation, including compliance with current cGMP and blood standards and FDA licensure and other governmental approvals, as applicable. Failure to comply with applicable governmental regulations or to receive applicable approvals for our current or future facilities may result in enforcement actions, such as adverse inspection reports, warning or untitled letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of regulatory authority approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses, any of which may significantly delay or suspend our operations for these locations, potentially having a material adverse effect on our ability to manufacture our products or offer for sale plasma collected at the affected sites. Failure to comply with applicable governmental regulations may also impact the ultimate quality and compliance of our finished biologic products, which may have a material adverse effect on our business.

We manufacture our current marketed products, pipeline products, and products for third parties in our manufacturing and testing facilities, and if we or our vendors cannot maintain appropriate FDA status for these facilities, we may be adversely affected, and may not be able to sell, manufacture or commercialize these products.

There are no assurances we will be able to maintain compliance with all FDA or other regulations. There is also no guarantee that we will be able to fulfill our contractual requirements to our customers. Moreover, to the extent that we use third-party vendors to fulfill our regulatory or contractual requirements, these third-party vendors may perform activities for themselves or other clients and we may not be privy to all regulatory findings or issues discovered by the FDA or other regulatory agencies. Such findings, which are out of our control, may adversely affect our ability to continue to work with these vendors, or our ability to release commercial drug product or perform necessary testing or other actions for us or our clients, which may be required in order to remain FDA compliant or to commercialize our products. If we are not able to maintain manufacturing compliance at our facilities or our vendors' facilities for our products and product candidates, we may not be able to successfully develop and commercialize our products and product candidates and we may face potential contractual or regulatory actions, which would have an adverse impact on our business.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Product liability claims may also result in recalls and/or regulatory enforcement actions. Even successful defense, however, could impair our results of operations. Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, either alone or with collaborators.

Many of our business practices are subject to scrutiny by federal and state regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us.

The laws governing our conduct in the United States are enforceable on the federal, state and local levels by criminal, civil and administrative sanctions. Violations of laws such as the FDCA, the Social Security Act (including the Anti-Kickback Statute), the Public Health Service Act, the civil and criminal federal False Claims Act, the civil monetary penalty statute, requirements regarding the reporting and repayment of overpayments, other fraud and abuse laws and any regulations promulgated under the authority of the preceding, may result in significant criminal and/or civil sanctions, including jail sentences, fines or exclusion from participation in or debarment from federal and state healthcare or government procurement programs, pursuant to enforcement actions by DOJ, Medicare, Medicaid, OIG and other regulatory authorities. Similarly, the violation of applicable laws, rules and regulations of states, including the State of Florida, with respect to the manufacture and marketing of our products and product candidates may result in significant criminal and/or civil sanctions, including jail sentences, fines or exclusion from participation in applicable state healthcare programs. There can be no assurance that our activities will not come under the scrutiny of federal and/or state regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws.

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

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

Failure to satisfy requirements under the FDCA can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct. In addition, while regulatory authorities generally do not regulate physicians' discretion in their choice of treatments for their patients, they do restrict communications by manufacturers on unapproved uses of approved products or on the potential safety and efficacy of unapproved products in development. Companies in the United States, Canada and the European Union cannot promote approved products for other indications that are not specifically approved by the competent regulatory authorities such as the FDA in the United States, nor can companies promote unapproved products. In limited circumstances, companies may disseminate to physicians information regarding unapproved uses of approved products or results of studies involving investigational products. If such activities fail to comply with applicable regulations and guidelines of the various regulatory authorities, we may be subject to warnings from, or enforcement action by, these authorities. Furthermore, if such activities are prohibited, it may harm demand for our products. Promotion of unapproved drugs or devices or unapproved indications for a drug or device is a violation of the FDCA and subjects us to civil and criminal sanctions. Furthermore, sanctions under the federal False Claims Act have been brought against companies accused of promoting off-label uses of drugs, because such promotion induces unapproved use and subsequent claims for reimbursement under Medicare and other federal programs. Similar actions for off-label promotion have been initiated by several states for Medicaid fraud. The Healthcare Reform Law significantly strengthened provisions of the federal False Claims Act, the federal Anti-Kickback Statute that applies to government healthcare programs, and other healthcare fraud provisions, leading to the possibility of greatly increased lawsuits by whistleblowers for perceived violations. Violations or allegations of violations of the foregoing restrictions could materially and adversely affect our business.

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

We have established systems for collecting and reporting this data accurately to CMS and have instituted a compliance program to assure that the information collected is complete in all respects. If we report pricing information that is not accurate to the federal government, we could be subject to fines and other sanctions that could adversely affect our business. If we choose to pursue clinical development and commercialization in the European Union or otherwise market and sell our products outside of the United States, we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, which would preclude us from commercializing products in those markets.

In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Such trials may be time-consuming and expensive and may not show an advantage in efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the U.S. or the European Union, we could be adversely affected.

Also, under the U.S. Foreign Corrupt Practices Act, the United States has increasingly focused on regulating the conduct by U.S. businesses occurring outside of the United States, generally prohibiting remuneration to foreign officials for the purpose of obtaining or retaining business. To enhance compliance with applicable healthcare laws, and mitigate potential liability in the event of noncompliance, regulatory authorities such as the HHS Office of Inspector General (the "OIG") have recommended the adoption and implementation of a comprehensive healthcare compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the U.S. Sentencing Commission Guidelines Manual. Most U.S.-based pharmaceutical companies have such programs. We will need to adopt healthcare compliance and ethics programs that would incorporate the OIG's recommendations and voluntary industry guidelines and train our employees. Such a program may be expensive and may not provide assurance that we will avoid compliance issues.

We are also required to comply with the applicable laws, rules, regulations and permit requirements of the various states and localities in which our business operates, including the State of Florida where our manufacturing facility is located. These regulations and permit requirements are not always in concert with applicable federal laws, rules and regulations regulating our business. Although compliant with applicable federal requirements, we may be required to comply with additional state and local laws, rules, regulations and permits. Failure to appropriately comply with such state and local requirements could result in temporary or long-term cessation of our manufacturing operations, as well as fines and other sanctions. Any such penalties may have a material adverse effect on our business and results of operations.

We are subject to extensive and rigorous governmental regulation, including the requirement of FDA and other federal, state and local business regulatory approvals before our products and product candidates may be lawfully marketed, and our ability to obtain regulatory approval of our products and product candidates from the FDA in a timely manner, access the public markets and obtain necessary capital in order to properly capitalize and continue our operations may be hindered by inadequate funding for the FDA, the SEC and other state and local government agencies.

Both before and after the approval of our products, our products, operations, facilities, suppliers and CROs are subject to extensive regulation by federal, state and local governmental authorities in the United States and other countries, with regulations differing from country to country. In the United States, the FDA regulates, among other things, the pre-clinical and nonclinical testing, clinical trials, manufacturing, safety, efficacy, potency, labeling, storage, record keeping, quality systems, advertising, promotion, sale and distribution of therapeutic products. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: notices of violation, untitled letters, warning letters, CRLs, fines and other monetary penalties, unanticipated expenditures, delays in approval or refusal to approve a product or product candidate, product recall or seizure, interruption of manufacturing or clinical trials, operating restrictions, injunctions and criminal prosecution. Our products and product candidates cannot be lawfully marketed in the United States without FDA and other federal, state and local business regulatory approvals. Any failure to receive the marketing approvals necessary to commercialize our products or product candidates could harm our business.

Additionally, the ability of the FDA and other federal, state and local business regulatory agencies to review and approve products and product candidates can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and to accept the payment of user fees, as well as statutory, regulatory, and policy changes. Average review times at the FDA and other federal, state and local business regulatory agencies have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for products and product candidate submissions to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including in December 2018 and January 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and 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. More recently, in April 2025, at least 15% of the FDA's staff was terminated as part of the new U.S. presidential administration's efforts to reduce the size of the federal government and cut costs. If a prolonged government shutdown or regulatory agency disruption reoccurs, or in the event the FDA has an insufficient amount of staff, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, conduct evaluations and inspections and other reporting requirements which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain capital that may be necessary in order to properly capitalize and continue our operations.

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

Plasma is a raw material that is susceptible to damage and contamination and may contain human pathogens, any of which would render the plasma unsuitable as raw material for further manufacturing. For instance, improper storage of plasma, by us or third-party suppliers, may require us to destroy some of our raw material. If unsuitable plasma is not identified and discarded prior to the release of the plasma to the manufacturing process, it may be necessary to discard intermediate or finished product made from that plasma or to recall any finished product released to the market, resulting in a charge to cost of product revenue. The manufacture of our plasma products is an extremely complex process of fractionation, purification, testing, filling and finishing. Our products can become non-releasable or otherwise fail to meet our stringent specifications or regulatory agencies' specifications through a failure in one or more of these process steps. We may detect instances in which an unreleased product was produced without adherence to our manufacturing procedures or plasma used in our production process was not collected or stored in a compliant manner consistent with cGMP or other regulations. Such an event of noncompliance would likely result in our determination that the implicated products should not be released or maybe replaced or withdrawn from the market and therefore should be destroyed. Once manufactured, our plasma-derived products must be handled carefully and kept at appropriate temperatures. Our failure, or the failure of third parties that supply, test, ship or distribute our products or product components to properly care for our products, may require that those products be destroyed. Even if handled properly, biologics may form or contain particulates or have other issues or problems after storage which may require products to be destroyed or recalled. While we expect to write off certain amounts of raw materials and work-in-process inventory in the ordinary course of business due to the complex nature of plasma, our processes and our products, unanticipated events may lead to write-offs and other costs materially in excess of our expectations and the reserves we have established for these purposes. Such write-offs or losses and other costs could cause material fluctuations in our results of operations. Product or component quality issues may also result in regulatory enforcement actions, liability, corrective actions and recalls, among other actions, as described elsewhere in our 2024 10-K.

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

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

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

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

In order for plasma to be used in the manufacturing of our products, the individual centers at which the plasma is collected must generally be licensed by the FDA and approved by the regulatory authorities of any country in which we may wish to commercialize our products. When we open a new plasma center, and on an ongoing basis after licensure, it must be inspected by the FDA for compliance with cGMP and other regulatory requirements. Therefore, even if we are able to construct new plasma collection centers to complement our current plasma collection facilities, an unsatisfactory inspection could prevent a new center from being licensed or risk the suspension or revocation of an existing license, among other enforcement actions. Additionally, although we achieved normal source plasma supply self-sufficiency with the approval of our tenth plasma collection center in November 2023, we remain reliant on the purchase of RSV plasma from third parties and the collection of RSV and normal source plasma from our FDA-licensed plasma collection centers to manufacture our products. We can give no assurances that appropriate plasma will be available to us through our own plasma collection facilities or on commercially reasonable terms, or at all, to manufacture our products, or that third parties will be able to supply plasma to us in accordance with plasma purchase agreements. Further, the COVID-19 pandemic resulted in significant constraints in raw material supply across various different industries, including the supply of plasma. It is possible that in the future, pandemics and government responses thereto will have an adverse effect on our ability to source plasma from donors in quantity and quality sufficient for our manufacturing processes. In order to maintain a plasma center’s license, its operations must continue to conform to cGMP and other regulatory requirements. In the event that we determine that plasma was not collected in compliance with cGMP and other applicable regulatory requirements, we may be unable to use and may ultimately destroy plasma collected from that center, which would be recorded as a charge to cost of product revenue. Additionally, if non-compliance in the plasma collection process is identified after the impacted plasma has been pooled with compliant plasma from other sources, entire plasma pools, in-process intermediate materials and final products could be impacted. Consequently, we could experience significant inventory impairment provisions and write-offs which could adversely affect our business and financial results. We plan to increase our supplies of plasma for use in the manufacturing processes through increased purchases of plasma from third-party suppliers as well as collections from our existing ADMA BioCenters plasma collection facilities. This strategy is dependent upon our ability to maintain a cGMP compliant environment at our plasma collection facilities and to expand production and attract donors to our facilities. There is no assurance that the FDA will inspect and license any of our current or future unlicensed plasma collection facilities in a timely manner consistent with our production plans. If we misjudge the readiness of a center for an FDA inspection, we may lose credibility with the FDA and cause the FDA to more closely examine all of our operations. Such additional scrutiny could materially hamper our operations and our ability to increase plasma collections. Our ability to expand production and increase our plasma collection facilities to more efficient production levels may be affected by changes in the economic environment and population in selected regions where ADMA BioCenters operates its current or future plasma facilities, by the entry of competitive plasma centers into regions where ADMA BioCenters operates such centers, by misjudging the demographic potential of individual regions where ADMA BioCenters expects to expand production and attract new donors, by unexpected facility related challenges, or by unexpected management challenges at selected plasma facilities held by us from time to time.

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

Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of insurance coverage. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, as well as to the timing, language, specifications and other details pertaining to the approval of such products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for products. Even if one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover such product. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our products, once approved, market acceptance of such product could be reduced. Prices in many countries, including many in Europe, are subject to local regulation and certain pharmaceutical products, such as plasma-derived products, are subject to price controls in several of the world's principal markets, including many countries within the European Union. In the United States, where pricing levels for our products are substantially established by third-party payers, including Medicare, if payers reduce the amount of reimbursement for a product, it may cause groups or individuals dispensing the product to discontinue administration of the product, to administer lower doses, to substitute lower cost products or to seek additional price-related concessions. These actions could have a negative effect on our financial results, particularly in cases where our products command a premium price in the marketplace, or where changes in reimbursement induce a shift in the site of treatment. The existence of direct and indirect price controls and pressures over our products could materially adversely affect our financial prospects and performance.

The biosimilar pathway established as part of healthcare reform may make it easier for competitors to market biosimilar products.

The ACA and the companion Healthcare and Education Reconciliation Act (which together are referred to as the "Healthcare Reform Law") introduced an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to an FDA-licensed biological product. A biological product may be demonstrated to be "biosimilar" if data shows that, among other things, the product is "highly similar" to an already-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. The law provides that a biosimilar application may be submitted as soon as four years after the reference product is first licensed, and that the FDA may not make approval of an application effective until 12 years after the reference product was first licensed. Since the enactment of the law, the FDA has issued several guidance documents to assist sponsors of biosimilar products in preparing their approval applications. Moreover, in an effort to increase competition in the biologic product marketplace, Congress, the executive branch, and the FDA have taken certain legislative and regulatory steps. For example, in 2020 the FDA finalized a guidance to facilitate biologic product importation. The 2020 Further Consolidated Appropriations Act included provisions requiring that sponsors of approved biologic products provide samples of the approved products to persons developing biosimilar products within specified timeframes, in sufficient quantities, and on commercially reasonable market-based terms. The FDA approved the first biosimilar product in 2015 and has since approved a number of biosimilars. As a result of the biosimilar pathway in the United States, we expect in the future to face greater competition from biosimilar products, including a possible increase in patent challenges.

The implementation of the Healthcare Reform Law in the United States may adversely affect our business.

Through the March 2010 adoption of the Healthcare Reform Law in the United States, substantial changes are being made to the current system for paying for healthcare in the United States, including programs to extend medical benefits to millions of individuals who currently lack insurance coverage. This reform establishes significant cost-saving measures with respect to several government healthcare programs, including Medicaid and Medicare Parts B and D, that may cover the cost of our future products, and these efforts could have a material adverse impact on our future financial prospects and performance. For example, in order for a manufacturer's products to be reimbursed by federal funding under Medicaid, the manufacturer must enter into a Medicaid rebate agreement with the Secretary of HHS and pay certain rebates to the states based on utilization data provided by each state to the manufacturer and to CMS and pricing data provided by the manufacturer to the federal government. The states share these savings with the federal government, and sometimes implement their own additional supplemental rebate programs. Under the Medicaid drug rebate program, the rebate amount for most branded drug products was previously equal to a minimum of 15.1% of the Average Manufacturer Price ("AMP") or the AMP less Best Price, whichever is greater, plus the inflation penalty if applicable. Effective January 1, 2010, the Healthcare Reform Law generally increased the size of the Medicaid rebates paid by manufacturers for single source and innovator multiple source (brand name) drug products from a minimum of 15.1% to a minimum of 23.1% of AMP, subject to certain exceptions, plus the inflation penalty if applicable. For non-innovator multiple source (generic) products, the rebate percentage was increased from a minimum of 11.0% to a minimum of 13.0% of AMP, and the Bipartisan Budget Act of 2015 established a new inflation penalty for these drugs. In 2010, the Healthcare Reform Law also newly extended the Medicaid drug rebate obligation to prescription drugs covered by Medicaid managed care organizations. These increases in required rebates may adversely affect our future financial prospects and performance. In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As the 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase, and recent regulations have established a civil monetary penalty for failure to refund these overcharges.

Effective in 2011, the Healthcare Reform Law imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs. These fees may adversely affect our future financial prospects and performance.

The Healthcare Reform Law also created new rebate obligations for our products under Medicare Part D, a partial, voluntary prescription drug benefit created by the U.S. federal government primarily for persons 65 years old and over. The Part D drug program is administered through private insurers that contract with CMS. Beginning in 2011, the Healthcare Reform Law generally requires that in order for a drug manufacturer's products to be reimbursed under Medicare Part D, the manufacturer must enter into a Medicare Coverage Gap Discount Program agreement with the Secretary of HHS, and reimburse each Medicare Part D plan sponsor an amount now equal to 70% savings for the manufacturer's brand name drugs and biologics which the Part D plan sponsor has provided to its Medicare Part D beneficiaries who are in the "donut hole" (or a gap in Medicare Part D coverage for beneficiaries who have expended certain amounts for drugs). The Part D plan sponsor is responsible for calculating and providing the discount directly to its beneficiaries and for reporting these amounts paid to CMS's contractor, which notifies drug manufacturers of the rebate amounts it must pay to each Part D plan sponsor. The rebate requirement could adversely affect our future financial performance, particularly if contracts with Part D plans cannot be favorably renegotiated or the Part D plan sponsors fail to accurately calculate payments due in a manner that overstates our rebate obligation. Regarding access to our products, the Healthcare Reform Law established and provided significant funding for a Patient-Centered Outcomes Research Institute to coordinate and fund Comparative Effectiveness Research ("CER"). While the stated intent of CER is to develop information to guide providers to the most efficacious therapies, outcomes of CER could influence the reimbursement or coverage for therapies that are determined to be less cost-effective than others. Should any of our products be determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our future financial prospects and results.

There have been repeated legal challenges and attempts by Congress to repeal or change the Healthcare Reform Law and the possibility of future challenges or legislative changes contribute to the uncertainty of the ongoing implementation and impact of the law and also underscores the potential for additional reform going forward. We cannot assure that the law, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business. Certain provisions of enacted or proposed legislative changes may negatively impact coverage and reimbursement of, or rebates paid by manufacturers for, healthcare items and services. We will continue to evaluate the effect that the Healthcare Reform Law and any potential changes may have on our business.

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

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

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

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

The JPM Credit Facilities provide for total senior secured loans in an aggregate principal amount of \$300.0 million, of which \$75.0 million is currently outstanding. The borrowing under the JPM Credit Facilities currently bears interest at a rate equal to approximately 6.9% per annum, which reflects the one-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 (i) payments of interest for our revolving facility, at quarterly, one-month or three-month intervals, depending upon the type of borrowing, during the remaining term of the JPM Credit Facilities, with all principal and unpaid interest due at maturity, and (ii) principal under our term loan facility, in accordance with and on the dates specified in the amortization schedule set forth in the JPM Credit Agreement, through the JPM Term Maturity Date. In addition, our monthly interest rate obligation under our revolving facility is subject to rising interest rates. The JPM Credit Facilities are subject to acceleration pursuant to the JPM Credit Agreement, including upon an event of default. All of our obligations under the JPM Credit Facilities are secured by a first-priority lien and security interest in substantially all of our and our subsidiaries’ tangible and intangible assets, including intellectual property, and all of the equity interests in our subsidiaries.

Our current and projected cash, cash equivalents and accounts receivable may not be sufficient to repay all of our current outstanding debt obligations as they mature. If we are unable to maintain sufficient positive cash flow to repay our outstanding debt obligations as they mature, we would need to obtain additional financing in the amounts necessary to repay our outstanding debt obligations when due. If we are unable to repay our outstanding debt obligations when they mature, our creditors would be able to accelerate all of the amounts due and, in the case of the JPM Credit Facilities, seek to enforce their security interests, which could lead to our creditors taking immediate possession of and selling substantially all of our assets with no return provided to our stockholders.

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

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

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and related rules (the “Sarbanes-Oxley Act”), we are required to maintain internal control over financial reporting and our management is required to report on the effectiveness of our internal control over financial reporting, including any material weaknesses in such internal controls. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we have been required to upgrade, and will need to implement further upgrades, to our financial, information and operating systems, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

Because we became a large accelerated filer effective December 31, 2023, the Sarbanes-Oxley Act requires our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting. Our transition to large accelerated filer status and becoming subject to additional requirements of the Sarbanes-Oxley Act has been and will continue to be time-consuming, and there is a risk of noncompliance. In addition, as a large accelerated filer, we have incurred and anticipate incurring additional fees due to the increased complexity of our financial statements and the additional efforts required by our status, including, but not limited to, higher accounting and auditor costs. Further, the costs associated with the compliance with and implementation of procedures under these and future laws and related rules could have a material impact on our results of operations.

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

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

We have incurred substantial losses during our history. As of December 31, 2024, we had federal and state NOLs of \$265.6 million and \$203.4 million, respectively. Federal and state NOLs of approximately \$33.4 million and \$62.0 million, respectively, will begin to expire at various dates beginning in 2028, if not limited by triggering events prior to such time. Under the provisions of the Internal Revenue Code of 1986, as amended (the “Code”), changes in our ownership, in certain circumstances, will limit the amount of federal NOLs that can be utilized annually in the future to offset taxable income. In particular, Section 382 of the Code (“Section 382”) imposes limitations on a company’s ability to use NOLs upon certain changes in such ownership. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs. The acquisition transaction that we completed on June 6, 2017, resulted in a change in ownership of ADMA under Section 382 and, as a result, we were required to write off \$57.6 million of federal NOLs. On October 25, 2021, we completed a public offering of our common stock whereby we issued 57,500,000 shares of our common stock resulting in another change of ownership for ADMA under section 382 of the Code, resulting in an additional write-off of \$3.0 million of federal NOLs, \$28.1 million of state NOLs and \$1.0 million of research and development credits. Although we did not experience any ownership changes for the years ended December 31, 2024 and 2023, we may experience ownership changes in the future as a result of subsequent changes in our stock ownership that we cannot predict or control that could result in further limitations being placed on our ability to utilize our federal NOLs.

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

We are subject to taxes by the U.S. federal, state, and local tax authorities. We record income tax expense based on our estimates of future payments, which may include the recording of, or adjustments to, liabilities for uncertain tax positions, and the determination of a need for a 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. For fiscal year 2025 and beyond there could be ongoing variability in our effective tax rate as events occur and exposures are evaluated. The volatility of our future effective tax rate could be materially impacted by a number of factors, including:

- changes in our assessment of the lack of a need for a valuation allowance on our deferred tax assets; or
- changes in U.S. federal, state and local tax rates, tax laws, regulations, or interpretations thereof.

In addition, our effective tax rate in a given financial statement period may be materially impacted by a variety of other factors including, but not limited to, changes in the mix and level of earnings, changes in the states and other jurisdictions in which we operate, and deductible expenses and limitations on the use of NOLs resulting from ownership changes. 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 August 1, 2025, most of our 238,630,719 outstanding shares of common stock, 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 June 30, 2025, BlackRock, Inc., The Vanguard Group, Inc., State Street Corporation, and our directors and executive officers and their affiliates collectively owned a significant amount 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 cash dividends 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 JPM 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 June 30, 2025, there were 37,520,883 shares remaining available for issuance, after giving effect to 10,314,385 shares of our common stock that were subject to outstanding stock options and RSUs as of June 30, 2025 that may be issued by us without stockholder approval, as well as an additional 13,597,424 shares reserved for the future issuance of awards under our equity compensation plans.

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

(a) Sales of Unregistered Securities and Use of Proceeds

None.

(c) Repurchases of Securities

The table below reflects shares of common stock we repurchased during the second quarter of 2025.

For the Month Ended	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs⁽¹⁾	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs⁽²⁾
April 30, 2025	-	\$ -	-	\$ -
May 31, 2025	-	\$ -	-	\$ -
June 30, 2025	816,237	\$ 18.35	816,237	\$ 485,002,210
Total	816,237	\$ 18.35	816,237	

(1) Shares were repurchased pursuant to our share repurchase program publicly announced on May 5, 2025.

(2) There is no expiration date for this share repurchase program. The authorization to repurchase shares will end when we have repurchased the maximum number of shares authorized, or if we have determined to terminate such program.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Insider Trading Arrangements

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 June 30, 2025, no such plans or other arrangements were adopted or terminated.

Item 6. Exhibits

See the Exhibit Index immediately preceding the signature page of this Form 10-Q.

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
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 June 30, 2025, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of June 30, 2025 (Unaudited) and December 31, 2024, (ii) Unaudited Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2025 and 2024, (iii) Unaudited Condensed Consolidated Statements of Changes in Stockholders' Equity for the three and six months ended June 30, 2025 and 2024, (iv) Unaudited Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2025 and 2024, 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, Exhibit 32.1 and Exhibit 32.2 are being furnished and not filed.

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: August 6, 2025

By: /s/ Adam S. Grossman

Name: Adam S. Grossman

Title: President and Chief Executive Officer

Date: August 6, 2025

By: /s/ Brad Tade

Name: Brad Tade

Title: Chief Financial Officer

CERTIFICATIONS

I, Adam S. Grossman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ADMA Biologics, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 6, 2025

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

CERTIFICATIONS

I, Brad Tade, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ADMA Biologics, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 6, 2025

By: /s/ Brad Tade
Name: Brad Tade
Title: Chief Financial Officer
(Principal Financial Officer)

CERTIFICATIONS

In connection with the Quarterly Report of ADMA Biologics, Inc., a Delaware corporation (the “Company”), on Form 10-Q for the quarter ended June 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Adam S. Grossman, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 6, 2025

By: /s/ Adam S. Grossman

Name: Adam S. Grossman

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

CERTIFICATIONS

In connection with the Quarterly Report of ADMA Biologics, Inc., a Delaware corporation (the "Company"), on Form 10-Q for the quarter ended June 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brad Tade, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

3. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
4. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 6, 2025

By: /s/ Brad Tade

Name: Brad Tade

Title: Chief Financial Officer
(Principal Financial Officer)
