UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark one)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 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 **001-15771**

ABEONA THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Delaware	**83-0221517**
(State or Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)

6555 Carnegie Avenue, 4th Floor
Cleveland, OH 44103
(Address of principal executive offices, zip code)

(646) 813-4701
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	ABEO	Nasdaq Capital 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 ☒
Emerging growth company ☐

Accelerated filer ☐
Smaller reporting 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 ☒

The number of shares outstanding of the registrant's common stock as of November 7, 2025 was 54,191,361 shares.

ABEONA THERAPEUTICS INC.
Form 10-Q
For the Quarter Ended September 30, 2025

INDEX

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (including information incorporated by reference) contains statements that express management's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Words such as "expects," "anticipates," "intends," "plans," "believes," "could," "would," "seeks," "estimates," and variations of such words and similar expressions, and the negatives thereof, are intended to identify such forward-looking statements. Such "forward-looking statements" speak only as of the date made and are not guarantees of future performance and involve certain risks, uncertainties, estimates, and assumptions by management that are difficult to predict. Various factors, some of which are beyond the Company's control, could cause actual results to differ materially from those expressed in, or implied by, such forward-looking statements. In addition, we disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of this report, except as may otherwise be required by the federal securities laws.

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in forward-looking statements due to a number of factors. These statements include statements about: our ability to successfully generate commercial sales of ZEVASKYN® and generate future revenue; our plans to continue development of AAV-based gene therapies designed to treat ophthalmic diseases; the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals; our pipeline of product candidates; our dependence upon our third-party customers and vendors and their compliance with regulatory bodies; our estimates regarding expenses, future revenues, capital requirements, and needs for additional financing; our intellectual property position and our ability to obtain, maintain and enforce intellectual property protection and exclusivity for our proprietary assets; our estimates regarding the size of the potential markets for ZEVASKYN® and our product candidates, the strength of our commercialization strategies and our ability to serve and supply those markets; and future economic conditions or performance.

Important factors that could affect performance and cause results to differ materially from management's expectations are 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 fiscal year ended December 31, 2024, as updated from time to time in the Company's SEC filings, including this Quarterly Report on Form 10-Q. These factors include: our ability to maintain existing and obtain additional regulatory approvals of ZEVASKYN® and any future product candidates; our ability to successfully commercialize and market ZEVASKYN® and any future product candidates, if approved, and the timing of any commercialization and marketing efforts; our ability to manufacture sufficient batches of ZEVASKYN® to meet demand; our ability to access our existing at-the-market sale agreement; our ability to access additional financial resources and/or our financial flexibility to reduce operating expenses if required; our ability to obtain additional equity funding from current or new stockholders; the potential impacts of global healthcare emergencies, such as pandemics, on our business, operations, and financial condition; the potential impact of unpredicted changes in the structure and/or administration of the United States government or its agencies; our ability to out-license technology and/or other assets, deferring and/or eliminating planned expenditures, restructuring operations and/or reducing headcount, and sales of assets; the dilutive effect that raising additional funds by selling additional equity securities would have on the relative equity ownership of our existing investors, including under our existing at-the-market sale agreement; the outcome of any interactions with the FDA or other regulatory agencies relating to any of our products or product candidates; our ability to continue to secure and maintain regulatory designations for our product candidates; our ability to develop manufacturing capabilities compliant with current good manufacturing practices for our product candidates; our ability to manufacture cell and gene therapy products and produce an adequate product supply to support clinical trials and potentially future commercialization; the rate and degree of market acceptance of our product candidates for any indication once approved; our ability to meet our obligations contained in license agreements to which we are party; and macroeconomic uncertainty resulting from changes to U.S. trade policy, including current or future tariffs or other trade restrictions.

This Quarterly Report on Form 10-Q includes our trademarks, trade names and service marks, such as "ZEVASKYN®" and "AIM™," which are protected under applicable intellectual property laws and are the property of Abeona Therapeutics Inc. or its subsidiaries. Solely for convenience, trademarks, trade names and service marks referred to in this report appear without the ® and ™ 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.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Abeona Therapeutics Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
($ in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 82,884	$ 23,357
Short-term investments	124,233	74,363
Restricted cash	338	338
Inventory	4,850	—
Other receivables	1,616	1,652
Prepaid expenses and other current assets	2,209	1,143
Total current assets	216,130	100,853
Property and equipment, net	10,338	4,430
Operating lease right-of-use assets	4,086	3,552
Other assets	541	96
Total assets	$ 231,095	$ 108,931
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,927	$ 3,441
Accrued expenses	6,888	6,333
Current portion of long-term debt	8,889	5,926
Current portion of operating lease liability	102	823
Accrued taxes	339	—
Other current liabilities	35	64
Total current liabilities	22,180	16,587
Long-term operating lease liabilities	4,254	3,262
Long-term debt	10,862	13,037
Warrant liabilities	22,566	32,014
Total liabilities	59,862	64,900
Commitments and contingencies		
Stockholders' equity:		
Preferred stock - $0.01 par value; authorized 2,000,000 shares; No shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	—	—
Common stock - $0.01 par value; authorized 200,000,000 shares; 52,400,415 and 45,644,091 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	524	457
Additional paid-in capital	892,314	856,824
Accumulated deficit	(721,615)	(813,258)
Accumulated other comprehensive income	10	8
Total stockholders' equity	171,233	44,031
Total liabilities and stockholders' equity	$ 231,095	$ 108,931

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

Abeona Therapeutics Inc. and Subsidiaries
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
($ in thousands, except share and per share amounts)
(Unaudited)

	For the three months ended September 30,		For the nine months ended September 30,	
	2025	2024	2025	2024
Revenues:				
License and other revenues	$ —	$ —	$ 400	$ —
Costs and expenses:				
Cost of sales	$ 488	$ —	$ 488	$ —
Royalties	—	—	100	—
Research and development	4,216	8,941	20,100	25,366
Selling, general and administrative	19,314	6,404	46,249	22,173
Total costs and expenses	24,018	15,345	66,937	47,539
Loss from operations	(24,018)	(15,345)	(66,537)	(47,539)
Interest income	1,672	1,189	4,009	3,223
Interest expense	(901)	(1,102)	(2,856)	(3,126)
Change in fair value of warrant and derivative liabilities	2,760	(15,156)	4,617	(7,530)
Gain from sale of priority review voucher, net	—	—	152,366	—
Other income	129	145	359	531
Income (loss) before income taxes	(20,358)	(30,269)	91,958	(54,441)
Income tax (benefit) expense	(15,197)	—	315	—
Net (loss) income	$ (5,161)	$ (30,269)	$ 91,643	$ (54,441)
Basic (loss) income per common share	$ (0.10)	$ (0.63)	$ 1.76	$ (1.41)
Dilutive (loss) income per common share	$ (0.10)	$ (0.63)	$ 1.35	$ (1.41)
Weighted average number of common shares outstanding:				
Basic	54,242,507	48,081,758	52,198,290	38,504,273
Dilutive	54,242,507	48,081,758	65,780,650	38,504,273
Other comprehensive income (loss):				
Change in unrealized gains related to available-for-sale debt securities	55	50	2	(18)
Comprehensive (loss) income	$ (5,106)	$ (30,219)	$ 91,645	$ (54,459)

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

Abeona Therapeutics Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Equity
($ in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at June 30, 2024	41,661,993	$ 417	$ 846,654	$ (773,696)	$ (134)	$ 73,241
Stock-based compensation expense	—	—	1,804	—	—	1,804
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement	1,742,713	17	(205)	—	—	(188)
Reclassification of derivative liability	—	—	1,135	—	—	1,135
Net loss	—	—	—	(30,269)	—	(30,269)
Other comprehensive income	—	—	—	—	50	50
Balance at September 30, 2024	43,404,706	$ 434	$ 849,388	$ (803,965)	$ (84)	$ 45,773

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at December 31, 2023	26,523,878	$ 265	$ 764,151	$ (749,524)	$ (66)	$ 14,826
Stock-based compensation expense	—	—	4,673	—	—	4,673
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement	1,693,417	17	(534)	—	—	(517)
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	1,902,376	19	9,943	—	—	9,962
Issuance of common stock in connection with underwritten offering, net of offering costs	12,285,056	123	70,030	—	—	70,153
Issuance of common stock upon exercise of pre-funded warrants, net of shares settled	999,979	10	(10)	—	—	—
Reclassification of derivative liability	—	—	1,135	—	—	1,135
Net loss	—	—	—	(54,441)	—	(54,441)
Other comprehensive loss	—	—	—	—	(18)	(18)
Balance at September 30, 2024	43,404,706	$ 434	$ 849,388	$ (803,965)	$ (84)	$ 45,773

Abeona Therapeutics Inc. and Subsidiaries
Condensed Consolidated Statements of Stockholders' Equity, Continued
($ in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance at June 30, 2025	51,248,032	$ 512	$ 879,563	$ (716,454)	$ (45)	$ 163,576
Stock-based compensation expense	—	—	2,689	—	—	2,689
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement	65,427	1	(1)	—	—	—
Issuance of common stock upon exercise of warrants	1,086,956	11	5,152	—	—	5,163
Reclassification of warrant liability	—	—	4,911	—	—	4,911
Net loss	—	—	—	(5,161)	—	(5,161)
Other comprehensive income	—	—	—	—	55	55
Balance at September 30, 2025	52,400,415	$ 524	$ 892,314	$ (721,615)	$ 10	$ 171,233

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance at December 31, 2024	45,644,091	$ 457	$ 856,824	$ (813,258)	$ 8	$ 44,031
Stock-based compensation expense	—	—	8,220	—	—	8,220
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement	2,158,479	21	(58)	—	—	(37)
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	3,510,889	35	17,265	—	—	17,300
Issuance of common stock upon exercise of warrants	1,086,956	11	5,152	—	—	5,163
Reclassification of warrant liability	—	—	4,911	—	—	4,911
Net income	—	—	—	91,643	—	91,643
Other comprehensive income	—	—	—	—	2	2
Balance at September 30, 2025	52,400,415	$ 524	$ 892,314	$ (721,615)	$ 10	$ 171,233

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

Abeona Therapeutics Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
($ in thousands)
(Unaudited)

	For the nine months ended September 30,	
	2025	**2024**
Cash flows from operating activities:		
Net income (loss)	$ 91,643	$ (54,441)
Adjustments to reconcile net income (loss) to cash used in operating activities:		
Depreciation and amortization	1,686	1,465
Stock-based compensation expense	8,220	4,673
Change in fair value of warrant and derivative liabilities	(4,617)	7,530
Accretion and interest on short-term investments	202	54
Amortization of right-of-use lease assets	785	666
Non-cash interest	868	1,146
Gain on disposal of property and equipment	—	(2)
Gain from sale of priority review voucher	(152,366)	—
Change in operating assets and liabilities:		
Inventory	(4,850)	—
Other receivables	36	831
Prepaid expenses and other current assets	(1,066)	(426)
Other assets	(445)	189
Accounts payable and accrued expenses	2,302	(200)
Accrued taxes	339	—
Lease liabilities	(1,048)	(941)
Other current liabilities	(62)	—
Net cash used in operating activities	(58,373)	(39,456)
Cash flows from investing activities:		
Proceeds from sale of priority review voucher, net of transaction costs of $2.6 million	152,366	—
Capital expenditures	(6,822)	(1,840)
Proceeds from disposal of property and equipment	—	18
Purchases of short-term investments	(168,850)	(146,527)
Proceeds from maturities of short-term investments	118,780	90,233
Net cash provided by (used in) investing activities	95,474	(58,116)
Cash flows from financing activities:		
Proceeds from ATM sales of common stock, net of issuance costs	17,300	9,962
Payments related to net settlement of restricted share awards	(37)	(327)
Proceeds from underwritten sales of common stock, net of issuance costs	—	70,153
Proceeds from exercise of warrants	5,163	—
Proceeds from issuance of long-term debt	—	20,000
Payment of debt issuance costs	—	(963)
Net cash provided by financing activities	22,426	98,825
Net increase in cash, cash equivalents and restricted cash	59,527	1,253
Cash, cash equivalents and restricted cash at beginning of period	23,695	14,811
Cash, cash equivalents and restricted cash at end of period	$ 83,222	$ 16,064
Supplemental cash flow information:		
Cash and cash equivalents	$ 82,884	$ 15,726
Restricted cash	338	338
Total cash, cash equivalents and restricted cash	$ 83,222	$ 16,064
Supplemental non-cash flow information:		
Right-of-use asset obtained in exchange for new operating lease liabilities	$ 1,319	$ —
Derivative and warrant additions associated with loan and security agreement	$ 80	$ 1,042
Reclassification of derivative and warrant liability to equity	$ 4,911	$ 1,135
Changes in accrued property and equipment	$ 301	$ 166
Cash paid for interest	$ 1,988	$ 1,980
Cash paid for taxes	$ —	$ 7

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

NOTE 1 – NATURE OF OPERATIONS

Background

Abeona Therapeutics Inc. (together with the Company's subsidiaries, "Abeona" or the "Company"), a Delaware corporation, is a commercial-stage biopharmaceutical company developing cell and gene therapies for life-threatening diseases. On April 28, 2025, the U.S. Food and Drug Administration ("FDA") approved ZEVASKYN® (prademagene zamikeracel) gene-modified cellular sheets, also known as pz-cel, as the first and only autologous cell-based gene therapy for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa ("RDEB"), a serious and debilitating genetic skin disease. The Company's development portfolio also features adeno-associated virus ("AAV")-based gene therapies designed to treat ophthalmic diseases with high unmet need using novel AIM™ capsids.

Liquidity

As a biopharmaceutical organization, the Company has devoted substantially all of its resources since inception to research and development activities for ZEVASKYN® and other product candidates, business planning, raising capital, establishing its intellectual property portfolio, acquiring or discovering product candidates, and providing general and administrative support for these operations.

As a result, the Company has incurred significant operating losses and negative cash flows from operations since its inception, other than the nine months ended September 30, 2025 with the gain on sale of its Priority Review Voucher ("PRV"). The Company anticipates such losses and negative cash flows will continue until ZEVASKYN® can provide sufficient revenue for the Company to be profitable and generate positive cash flows. Through September 30, 2025, the Company has relied primarily on its sale of equity securities, its proceeds from the sale of its PRV, and strategic collaboration arrangements to finance its operations. The Company expects that its capital resources will be sufficient to fund its on-going operations for the next 12 months from the issuance date of these unaudited condensed consolidated financial statements. The Company may need to raise additional capital to fully implement its business plans through the issuance of equity, borrowings, or strategic alliances with partner companies. However, if such financing is not available at adequate levels, the Company would need to reevaluate its operating plans.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

There have been no new or material changes to the significant accounting policies discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 other than those identified below.

Basis of Presentation

The Company's unaudited interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). All intercompany balances and transactions have been eliminated in consolidation. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, except as otherwise disclosed, necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made. These unaudited interim condensed consolidated financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period. Certain information that is normally required by U.S. GAAP has been condensed or omitted in accordance with rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). The December 31, 2024 condensed consolidated balance sheet was derived from the audited statements but does not include all disclosures required by U.S. GAAP.

Therefore, these unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the SEC on March 20, 2025.

Use of Estimates

The preparation of unaudited interim condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amount of assets and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reported period. The Company's significant estimates include, but are not limited to, fair value of warrant and derivative liabilities, the incremental borrowing rate related to the Company's operating leases and stock-based compensation. Due to the uncertainty inherent in such estimates, actual results could differ from these estimates and assumptions.

Inventory and Costs of Sales

The Company capitalizes inventory costs associated with products when future economic benefit is expected to be realized. These costs consist of raw materials, manufacturing-related costs, personnel costs, facility costs, and other indirect overhead costs. Prior to receiving FDA approval for ZEVASKYN® in April 2025, the Company expensed costs related to inventory for clinical and pre-commercial purposes directly to research and development expense. Following the FDA's approval of ZEVASKYN®, the Company began capitalizing inventory related to commercialized products held for sale, in-process of production for sale, and raw materials to be used in the manufacturing of inventory.

The Company values its inventory at the lower-of-cost and net realizable value, on a first-in, first-out basis. The Company adjusts the net realizable value of any excess, obsolete or unsalable inventory in the period in which they are identified. Such impairment charges, should they occur, are recorded within cost of product revenue. For the three and nine months ended September 30, 2025 there were no inventory write-downs. Inventory as of September 30, 2025 consisted of raw materials.

Cost of sales includes inventory and period costs related to overhead and manufacturing costs of ZEVASKYN® during the three and nine months ended September 30, 2025, including costs associated with the manufacturing of non-conforming products.

Other receivables

Other receivables include employee retention credits, sublease rent receivables and other miscellaneous receivables that are expected to be collected within the next twelve months. As of September 30, 2025 and December 31, 2024, the Company had employee retention credits receivables of $1.6 million.

Credit Losses

The Company reviews its available-for-sale investments for credit losses on a collective basis by major security type and in line with the Company's investment policy. As of September 30, 2025, the Company's available-for-sale investments were in securities that are issued by the U.S. treasury and U.S. federal agencies, are highly rated, and have a history of zero credit losses. The Company reviews the credit quality of its accounts receivables by monitoring the aging of its accounts receivable, the history of write-offs for uncollectible accounts, the credit quality of its significant customers, the current economic environment/macroeconomic trends, supportable forecasts, and other relevant factors. The Company's accounts receivables are with customers that do not have a history of uncollectibility or a history of significantly aged accounts receivables. As of September 30, 2025, the Company did not recognize a credit loss allowance for its investments or accounts receivable.

Segments

The Company determines and presents operating segments based on the information that is internally provided to the Company's chief operating decision maker ("CODM"), its Chief Executive Officer, in accordance with ASC 280, *Segment Reporting*. The Company has determined that it operates in a single business segment, which is a commercial-stage biopharmaceutical company developing cell and gene therapies for life-threatening diseases. Refer to Note 12 – Segment Information for further information related to the Company's segment.

Net Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing net income (loss) attributable to common shareholders by the weighted-average number of shares of common stock outstanding during the period. The weighted average number of shares of common stock includes the weighted average effect of outstanding pre-funded warrants for the purchase of shares of common stock for which the remaining unfunded exercise price is $0.0001 or less per share. Diluted net income (loss) per share is computed based on the weighted average number of shares of common stock plus the effect of dilutive potential common shares outstanding during the period using the treasury stock method and if-converted method. Dilutive potential securities result from outstanding restricted stock, stock options, stock purchase warrants and conversion features in the Company's Loan Agreement (as defined in Note 8 – Debt). When the Company has a net loss during the period, the Company does not include the potential impact of dilutive securities in diluted net loss per share, as the impact of these items is anti-dilutive.

A reconciliation of the numerators and the denominators of the basic and diluted net income (loss) per share computations are as follows (in thousands, except per share amounts):

	For the three months ended September 30,		For the nine months ended September 30,	
	2025	2024	2025	2024
Numerator:				
Net income (loss) used for basic net income (loss) per share	$ (5,161)	$ (30,269)	$ 91,643	$ (54,441)
Effect of dilutive securities:				
Fair value adjustments for warrant and derivative liabilities	—	—	(3,077)	—
Numerator for dilutive net income (loss) per share - net income available for common shareholders' after the effect of dilutive securities	$ (5,161)	$ (30,269)	$ 88,566	$ (54,441)
Denominator:				
Weighted average number of common shares outstanding - basic	54,242,507	48,081,758	52,198,290	38,504,273
Effect of dilutive shares:				
Shares of common stock issuable upon exercise of stock options	—	—	176,221	—
Shares of common stock underlying restricted stock	—	—	4,739,644	—
Shares of common stock issuable upon exercise of warrants	—	—	8,052,244	—
Shares of common stock issuable upon exercise of conversion feature of loan agreement	—	—	614,251	—
Dilutive potential common shares	—	—	13,582,360	—
Denominator for dilutive net income (loss) per share - adjusted weighted average shares used in computing net income (loss) per share - dilutive	54,242,507	48,081,758	65,780,650	38,504,273
Earnings per share:				
Basic income (loss) per common share	$ (0.10)	$ (0.63)	$ 1.76	$ (1.41)
Dilutive income (loss) per common share	$ (0.10)	$ (0.63)	$ 1.35	$ (1.41)

The following table sets forth the potential securities that could potentially dilute basic loss per share in the future that were not included in the computation of diluted net loss per share because to do so would have been anti-dilutive for the periods presented:

	For the three months ended September 30,		For the nine months ended September 30,	
	2025	2024	2025	2024
Shares of common stock issuable upon exercise of stock options	176,019	177,138	—	177,138
Shares of common stock underlying restricted stock	4,085,621	3,268,414	—	3,268,414
Shares of common stock issuable upon exercise of conversion feature of loan agreement	614,251	614,251	—	614,251
Shares of common stock issuable upon exercise of warrants	8,917,078	9,987,560	1,804,474	9,987,560
Total	13,792,969	14,047,363	1,804,474	14,047,363

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures*. ASU 2023-09 is intended to enhance the transparency and decision usefulness of income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. The standard is effective for annual reporting periods beginning after December 15, 2024, with early adoption permitted. The requirements of this ASU are disclosure related and did not have an impact on the Company's financial condition, results of operations, or cash flows. The Company adopted ASU 2023-09 effective January 1, 2025. Since ASU 2023-09 addresses only disclosures, the adoption of ASU 2023-09 did not have a significant impact on the Company's interim condensed consolidated financial statements.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU No. 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): *Disaggregation of Income Statement Expenses*. The amendments in ASU 2024-03 address investor requests for more detailed expense information and require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. This guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

NOTE 3 – SHORT-TERM INVESTMENTS

The following table provides a summary of the short-term investments (in thousands):

	September 30, 2025			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments:				
U.S. treasury securities	$ 50,668	—	(79)	$ 50,589
U.S. federal agency securities	23,555	—	(19)	23,536
Certificates of deposit	50,000	108	—	50,108
Total available-for-sale, short-term investments	$ 124,223	108	(98)	$ 124,233

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments:				
U.S. treasury securities	$ 23,990	—	(22)	$ 23,968
U.S. federal agency securities	40,365	10	—	40,375
Certificates of deposit	10,000	20	—	10,020
Total available-for-sale, short-term investments	$ 74,355	30	(22)	$ 74,363

As of September 30, 2025, the available-for-sale securities classified as short-term investments mature in one year or less. The Company carries its available-for-sale securities at fair value in the condensed consolidated balance sheets. Unrealized losses on available-for-sale securities as of September 30, 2025, were not significant and were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. None of the short-term investments have been in a continuous unrealized loss position for more than 12 months. Accordingly, no other-than-temporary impairment was recorded for the three and nine months ended September 30, 2025.

There were no significant realized gains or losses recognized on the sale or maturity of available-for-sale investments for the three and nine months ended September 30, 2025 or 2024.

NOTE 4 – PROPERTY AND EQUIPMENT, NET

Property and equipment are stated at cost and depreciated or amortized using the straight-line method based on useful lives as follows (in thousands):

	Useful lives (years)	September 30, 2025	December 31, 2024
Laboratory equipment	5	$ 10,008	$ 8,868
Furniture, software and office equipment	3 to 5	3,063	1,113
Leasehold improvements	Shorter of remaining lease term or useful life	8,603	8,805
Construction-in-progress		5,020	624
Subtotal		26,694	19,410
Less: accumulated depreciation		(16,356)	(14,980)
Total property and equipment, net		$ 10,338	$ 4,430

Construction-in-progress relates to leasehold improvements for the Company's new office space as well as for conversion of existing office space into additional manufacturing space to increase ZEVASKYN® manufacturing capacity.

Depreciation and amortization on property and equipment was $0.6 million and $0.5 million for the three months ended September 30, 2025 and 2024, respectively and $1.7 million and $1.5 million for the nine months ended September 30, 2025 and 2024, respectively. The Company capitalized into inventory $0.1 million and $0.3 million relating to depreciation associated with manufacturing equipment and production facilities for the three and nine months ended September 30, 2025, respectively. The capitalized costs associated are added to inventory and will be expensed through cost of sales product in the condensed consolidated statement of operations and comprehensive income (loss) upon our first commercial sale of ZEVASKYN®.

NOTE 5 – FAIR VALUE MEASUREMENTS

The Company calculates the fair value of the Company's assets and liabilities that qualify as financial instruments and includes additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of other receivables, prepaid expenses and other current assets, other assets, accounts payable, accrued taxes and accrued expenses approximate their carrying amounts due to the relatively short maturity of these instruments. The estimated fair value of the Loan Agreement (as Defined in Note 8 – Debt) as of September 30, 2025 and December 31, 2024, was $22.0 million and $24.7 million, respectively. Both observable and unobservable inputs were used to determine the fair value of long-term debt, which was classified within the Level 3 category.

U.S. GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. This guidance establishes a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

The Company has segregated all financial assets and liabilities that are measured at fair value on a recurring basis (at least annually) into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below.

The following table provides a summary of financial assets and liabilities measured at fair value on a recurring and non-recurring basis (in thousands):

Description	Fair Value at September 30, 2025	Level 1	Level 2	Level 3
Recurring Assets				
Cash equivalents				
Money market funds	$ 82,189	$ 82,189	$ —	$ —
Money market deposit account	180	180	—	—
Short-term investments				
U.S. treasury securities	50,589	50,589	—	—
U.S. federal agency securities	23,536	—	23,536	—
Certificates of deposit	50,108	—	50,108	—
Total assets measured at fair value	$ 206,602	$ 132,958	$ 73,644	$ —
Liabilities				
Warrant liabilities	$ 22,566	$ —	$ —	$ 22,566
Total liabilities measured at fair value	$ 22,566	$ —	$ —	$ 22,566

Description	Fair Value at December 31, 2024	Level 1	Level 2	Level 3
Recurring Assets				
Cash equivalents				
Money market funds	$ 17,627	$ 17,627	$ —	$ —
Money market deposit account	5,109	5,109	—	—
Short-term investments				
U.S. treasury securities	23,968	23,968	—	—
U.S. federal agency securities	40,375	—	40,375	—
Certificates of deposit	10,020	—	10,020	—
Total assets measured at fair value	$ 97,099	$ 46,704	$ 50,395	$ —
Liabilities				
Warrant liabilities	$ 32,014	$ —	$ —	$ 32,014
Total liabilities measured at fair value	$ 32,014	$ —	$ —	$ 32,014

Warrant Liabilities

As of September 30, 2025 and December 31, 2024, the Company had the following outstanding warrant liabilities:

	September 30, 2025	December 31, 2024
Warrants issued as part of the 2021 public offering, expiration date December 2026, exercise price of $9.75 per share	1,788,000	1,788,000
Warrants issued as part of the 2022 Private Placement Offering, expiration date November 2027, exercise price $4.75 per share	6,522,923	7,609,879
Warrants issued as part of the 2024 Loan Agreement, expiration date January 2029, exercise price $4.07 per share	589,681	589,681
Warrants issued as part of the 2024 Loan Agreement Amendment, expiration date July 2030, exercise price $6.07 per share	16,473	—

The common stock warrants related to the 2021 Public Offering and the 2022 Private Placement are not indexed to the Company's own stock and therefore have been classified as liabilities at their estimated fair value. The common stock warrants issued in connection with the Loan Agreement issuance were determined to be liability classified under ASC 815, *Derivatives and Hed*ging ("ASC 815"), as the common stock warrants were not considered indexed to the Company's stock. In January 2024, as part of the Loan Agreement, see Note 8, the Company issued warrants to purchase $2.4 million worth of shares of the Company's stock which have an exercise price of $4.07 per share and the shares issuable was calculated at 589,681 shares. In July 2025, as part of the Loan Agreement Amendment, see Note 8, the Company issued 16,473 common stock warrants. The July 2025 Avenue Warrants (as defined in Note 9 – Equity) expire on July 18, 2030 and have an exercise price per share equal to $6.07. The common stock warrants issued in connection with the Loan Agreement Amendment issuance were determined to be liability classified under ASC 815 as the common stock warrants were not considered indexed to the Company's stock.

Changes in the estimated fair value of the warrant liabilities is recorded as changes in fair value of warrant liabilities in the condensed consolidated statement of operations and comprehensive income (loss).

The following table provides a summary of the activity on the warrant liabilities (in thousands):

Warrant liabilities as of December 31, 2024	$	32,014
Issuance of warrants		80
Reclassification of warrants to equity as part of warrant exercise		(4,911)
Gain recognized in earnings from change in fair value		(4,617)
Warrant liabilities as of September 30, 2025	$	22,566

The warrant liabilities are valued using significant inputs not observable in the market. Accordingly, the warrant liability is measured at fair value on a recurring basis using unobservable inputs and are classified as Level 3 inputs within the fair value hierarchy. Fair value measurements categorized within Level 3 are sensitive to changes in the assumptions or methodology used to determine fair value and such changes could result in a significant increase or decrease in the fair value. The Company's valuation of the common stock warrants utilized the Black-Scholes option-pricing model, which incorporated assumptions and estimates to value the common stock warrants. The Company assessed these assumptions and estimates at the end of each reporting period.

The following table outlines the key inputs for the Black-Scholes option-pricing model:

	September 30, 2025	December 31, 2024
Common share price	$5.28	$5.57
Expected term (years)	1.21 – 4.80	1.96 – 4.02
Risk-free interest rate (%)	3.54% – 3.67%	4.16% – 4.24%
Volatility (%)	84.78% – 100.00%	92.64% – 100.00%
Expected dividend yield (%)	0%	0%

NOTE 6 – ACCRUED EXPENSES

The following table provides a summary of the components of accrued expenses (in thousands):

		September 30, 2025		December 31, 2024
Accrued employee compensation	$	4,700	$	4,392
Accrued contracted services and other		2,188		1,941
Total accrued expenses	$	6,888	$	6,333

NOTE 7 – LEASES

The Company leases space under operating leases for administrative, manufacturing and laboratory facilities in Cleveland, Ohio. The Company leased office space in New York, New York, which the Company sublet. The lease for the office space in New York, New York terminated in September 2025, which was the end of the lease term. The Company also leases certain office equipment under operating leases, which have a non-cancelable lease term of less than one year and the Company has elected the practical expedient to exclude these short-term leases from the Company's right-of-use assets and lease liabilities.

During 2024, the Company signed a lease for 16,566 square feet of office space at 6700 Euclid Avenue, Cleveland, Ohio. Pursuant to the lease agreement, the lease term began on January 1, 2025 with an initial term through December 30, 2030. Annual lease payments during the term of the lease are approximately $0.3 million. The total lease payments over the duration of the lease term are approximately $1.5 million. The impact of this lease agreement was to increase the Company's operating right-of-use lease assets and operating lease liabilities by $1.0 million on January 1, 2025.

The Company had entered into two sublease agreements with unrelated third parties to occupy the Company's administrative offices in New York. The sublease agreements terminated in September 2025 at the same time the Company's lease terminated.

The following table provides a summary of the Company's operating lease liabilities (in thousands):

	September 30, 2025	December 31, 2024
Current operating lease liability	$ 102	$ 823
Non-current operating lease liability	4,254	3,262
Total operating lease liability	$ 4,356	$ 4,085

Lease costs and rent are reflected in general and administrative expenses and research and development expenses in the condensed consolidated statements of operations and comprehensive income (loss), as determined by the underlying activities.

The following table provides a summary of the components of lease costs and rent (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2025	2024	2025	2024
Operating lease cost	$ 385	$ 312	$ 1,137	$ 974
Variable lease cost	122	96	317	292
Short-term lease cost	13	8	32	42
Total operating lease costs	$ 520	$ 416	$ 1,486	$ 1,308

Cash paid for amounts included in the measurement of operating lease liabilities was $0.4 million and $0.3 million for the three months ended September 30, 2025 and 2024, respectively and $1.0 million and $0.9 million for the nine months ended September 30, 2025 and 2024, respectively.

Future minimum lease payments and obligations, which do not include short-term leases, related to the Company's operating lease liabilities as of September 30, 2025 were as follows (in thousands):

Future minimum lease payments and obligations	Operating Leases
2025, remainder	$ —
2026	419
2027	1,295
2028	1,325
2029	1,357
Thereafter	1,387
Total undiscounted operating lease payments	5,783
Less: imputed interest	1,427
Present value of operating lease liabilities	$ 4,356

The weighted-average remaining term of the Company's operating leases was 63 months, and the weighted-average discount rate used to measure the present value of the Company's operating lease liabilities was 8.7% as of September 30, 2025.

The Company received sublease income, which is recorded in other income on the condensed consolidated statement of operations and comprehensive income (loss), of $0.1 million during the three months ended September 30, 2025 and 2024 and $0.4 million during the nine months ended September 30, 2025 and 2024, respectively. The sublease ended on September 30, 2025 and there are no future cash receipts.

NOTE 8 – DEBT

The following table provides a summary of the Company's debt, net of debt issuance costs and discounts (in thousands):

	September 30, 2025	December 31, 2024
Loan Agreement Principal	$ 20,000	$ 20,000
Accreted final payment fee	625	354
Unamortized debt issuance costs and discounts	(874)	(1,391)
Total long-term debt	19,751	18,963
Less: current maturities	8,889	5,926
Long-term debt, net of current maturities	$ 10,862	$ 13,037

Loan and Security Agreement

On January 8, 2024 (the "Closing Date"), the Company entered into a Loan and Security Agreement, as supplemented by a Supplement, dated as of January 8, 2024 (collectively, the "Loan Agreement") with Avenue Venture Opportunities Fund, L.P., a Delaware limited partnership, as administrative agent and collateral agent ("Avenue" and the "Agent") and Avenue Venture Opportunities Fund II, L.P., a Delaware limited partnership ("Avenue 2" and, together with Avenue, the "Lenders"). The Loan Agreement provides for senior secured term loans (the "Loans") in an aggregate principal amount up to $50 million, with (i) a committed tranche of $20 million advanced on the Closing Date ("Tranche 1"), (ii) a committed tranche of up to $10 million which may be advanced upon the request of the Company between June 30, 2024 and September 30, 2024, subject to the Company obtaining FDA approval of ZEVASKYN® in RDEB, with the issuance of a Priority Review Voucher ("Tranche 2"), and (iii) a discretionary tranche of up to $20 million which may be advanced between March 31, 2025 and March 31, 2026 (the "Discretionary Tranche") provided at the discretion of the Lenders. The Loans are due and payable on July 1, 2027. As of September 30, 2024, the Tranche 2 was no longer available as the Company did not meet the Tranche 2 criteria.

The loan principal is repayable in equal monthly installments beginning on February 1, 2026. On April 28, 2025, with the FDA approval of ZEVASKYN® and in accordance with the Loan Agreement, the start date of the loan principal monthly installments was extended from May 1, 2025 to February 1, 2026. The Loans bear interest at a rate per annum (subject to increase during an event of default) equal to the greater of (i) the prime rate, as published by the Wall Street Journal from time to time, plus 5.00% and (ii) 13.50%. On July 18, 2025, the Company entered into an amendment (the "Amendment") to the Loan Agreement that reduces the interest rate for senior secured term loan owed under the Loan Agreement from 13.5% to a fixed rate of 11.75% per annum. The stated interest rate and effective interest rate as of September 30, 2025 was 11.75% and 18.40%, respectively. In connection with the Amendment, the Company issued the Lenders warrants to purchase up to an aggregate of 16,473 shares of Company common stock (collectively, the "July 2025 Avenue Warrants"). The July 2025 Avenue Warrants expire on July 18, 2030 and have an exercise price per share equal to $6.07.

The Company may, subject to certain parameters, voluntarily prepay the Loans, in whole, at any time. If prepayment occurs after January 8, 2025 and on or before January 8, 2026, the Company is required to pay a fee equal to 2.00% of the principal amount of the Loans; if prepayment occurs after January 8, 2026, the Company is required to pay a fee equal to 1.00% of the principal amount of the Loans. A final payment fee of 5.00% of the principal amount of the funded Tranche 1 Loans, Tranche 2 Loans and Discretionary Tranche Loans is also due upon maturity on July 1, 2027 or any earlier date of prepayment.

The Company's obligations under the Loan Agreement are secured by a pledge of substantially all of the Company's assets. Pursuant to the Loan Agreement, the Company is subject to a financial covenant requiring the Company to maintain at all times $5 million in unrestricted cash. The Loan Agreement also contains affirmative and negative covenants customary for financings of this type that, among other things, limit the ability of the Company and its subsidiaries to (i) incur additional debt, guarantees or liens; (ii) pay dividends; (iii) enter into certain change of control transactions; (iv) sell, transfer, lease, license, or otherwise dispose of certain assets; (v) make certain investments or loans; and (vi) engage in certain transactions with related persons, in each case, subject to certain exceptions. The Loan Agreement also includes events of default customary for financings of this type, in certain cases subject to customary periods to cure, following which the Agent may accelerate all amounts outstanding under the Loans.

Pursuant to the Supplement to the Loan and Security Agreement, Avenue also has the right to convert up to $3 million of the outstanding principal of the Loans into shares of Company common stock (the "Conversion Right") at a price per share equal to 120% of the exercise price of the Warrants (further discussed below) at any time while the Loans are outstanding, subject to certain terms and conditions, including ownership limitations. The Conversion Right required bifurcation as certain adjustments to the conversion price were not indexed to the Company's own stock and therefore the Conversion Right was recorded as a derivative liability. On January 8, 2024, the Conversion Right was recorded at the closing date fair value of $0.8 million which was based on a Monte Carlo simulation model. The derivative liability is remeasured at each reporting period with the change in fair value recorded to change in fair value of warrants and derivative liabilities in the condensed consolidated statement of operations until the derivative is exercised, expired, reclassified, or otherwise settled. On September 30, 2024, pursuant to the Loan Agreement, the conversion price was fixed at $4.88 and is considered indexed to the Company's own stock. On September 30, 2024, the Conversion Right no longer met the criteria of a derivative liability and the derivative liability of $1.1 million was reclassified to equity.

In addition, subject to applicable law and specified provisions set forth in the Supplement to the Loan and Security Agreement and solely to the extent permitted under applicable stock exchange rules without requiring stockholder approval, the Lenders may participate in certain equity financing transactions of the Company in an aggregate amount of up to $1 million on the same terms, conditions and pricing offered by the Company to other investors participating in such financing transactions (such right, the "Participation Right"). The Participation Right automatically terminates upon the earliest of (i) July 1, 2027, (ii) such time that the Lenders have purchased $1.0 million of the Company's equity securities in the aggregate pursuant to the Participation Right, and (iii) the repayment in full of all of the obligations under the Loan Agreement.

On the Closing Date and pursuant to the funding of Tranche 1 of the Loan Agreement, the Company issued to each of Avenue and Avenue 2 (collectively, the "Warrant Holders") warrants to purchase up to $480,000 and $1,920,000 of Company common stock, respectively which is more fully described in Note 9 – Equity below.

The future payment obligations of the principal are as follows as of September 30, 2025 (in thousands):

2025, remainder	$	—
2026		12,222
2027		7,778
Total principal	$	20,000

NOTE 9 – EQUITY

Preferred Stock

The aggregate number of authorized shares of the Company's preferred stock is 2,000,000 shares with a par value of one cent ($0.01). There is no preferred stock outstanding as of September 30, 2025 and December 31, 2024.

Common Stock and Warrants

Public Offerings

On December 21, 2021, the Company closed an underwritten public offering of 1,788,000 shares of common stock at a public offering price of $9.75 per share and stock purchase warrants to purchase 1,788,000 shares of common stock at an exercise price of $9.75. The net proceeds to the Company were $16.0 million, after deducting $1.5 million of underwriting discounts and commissions and offering expenses payable by the Company. The net proceeds were allocated to the warrant liability as noted below with the remainder of $7.0 million recorded in common stock and additional paid-in capital. In the event of certain fundamental transactions involving the Company, the holders of the stock purchase warrants may require the Company to make a payment based on a Black-Scholes valuation, using specific inputs that are not considered indexed to the Company's stock in accordance with ASC 815, *Derivatives and Hed*ging ("ASC 815"). Therefore, the Company accounted for the stock purchase warrants as liabilities, which were recorded at the closing date fair value of $9.0 million which was based on a Black-Scholes option pricing model. The remainder of the proceeds were allocated to common stock issued and recorded as a component of equity.

As of September 30, 2025, there were 1,788,000 stock purchase warrants outstanding related to this public offering. These stock purchase warrants expire on December 21, 2026. During such time as each warrant is outstanding, the holder of the warrant is entitled to participate in any dividends or other distribution of assets to holders of shares of common stock. There was no warrant activity during the three and nine months ended September 30, 2025, other than the change in fair value of the warrants for the stock purchase warrants issued as part of this public offering.

On May 7, 2024, the Company sold 12,285,056 shares of its common stock and, in lieu of common stock, pre-funded warrants to purchase 6,142,656 shares of its common stock (the "2024 Pre-Funded Warrants"), for an aggregate purchase price of $75.0 million gross, or $70.2 million net of related costs. The offering price for each share of common stock was $4.07, and the offering price for the 2024 Pre-Funded Warrants was $4.0699, which represents the per share offering price for the Company's common stock less a $0.0001 per share exercise price for each 2024 Pre-Funded Warrant. The 2024 Pre-Funded Warrants are immediately exercisable at a nominal exercise price of $0.0001 per share and may be exercised at any time until the pre-funded warrants are exercised in full. On June 24, 2024, 700,000 of the 2024 Pre-Funded Warrants were exercised and on December 2, 2024, 1,228,531 of the 2024 Pre-Funded Warrants were exercised, leaving 4,214,125 2024 Pre-Funded Warrants outstanding as of September 30, 2025. The 2024 Pre-Funded Warrants are classified as equity in accordance with ASC 815, given the prefunded warrants are indexed to the Company's own shares of common stock and meet the requirements to be classified in equity. The 2024 Pre-Funded warrants were recorded at their relative fair value at issuance in the stockholders' equity section of the consolidated balance sheet and the 2024 Pre-Funded Warrants are considered outstanding shares in the basic and diluted earnings per share calculation for the three and nine months ended September 30, 2025 given their nominal exercise price.

Open Market Sale Agreement

On August 17, 2018, the Company entered into an open market sale agreement (as amended, the "ATM Agreement") with Jefferies LLC ("Jefferies") pursuant to which, the Company may sell from time to time, through Jefferies, shares of its common stock for an aggregate sales price of up to $75.0 million. Any sales of shares pursuant to this agreement are made under the Company's effective "shelf" registration statement on Form S-3 that is on file with and has been declared effective by the SEC.

The Company sold 3,510,889 and 1,902,376 shares of its common stock under the ATM Agreement during the nine months ended September 30, 2025 and 2024, respectively, resulting in net proceeds of $17.3 million and $10.0 million during the nine months ended September 30, 2025 and 2024, respectively. There were no sales under the ATM Agreement during the three months ended September 30, 2025 and 2024.

Private Placement Offerings

On November 3, 2022, the Company sold 7,065,946 shares of its common stock, and in lieu of shares of common stock, pre-funded warrants exercisable for 543,933 shares of common stock and accompanying warrants to purchase 7,609,879 shares of its common stock to a group of new and existing institutional investors in a private placement. The offering price for each share of common stock and accompanying warrant was $4.60, and the offering price for each pre-funded warrant and accompanying warrant was $4.59, which equaled the offering price per share of the common stock and accompanying warrant, less the $0.01 per share exercise price of each pre-funded warrant. Each accompanying warrant represents the right to purchase one share of the Company's common stock at an exercise price of $4.75 per share of common stock. The pre-funded warrants were exercised in December 2022 and converted to 543,933 shares of common stock. Total shares sold and converted during the year ended December 31, 2022 were 7,609,879 for an aggregate purchase price of $35.0 million gross, or $32.6 million net of related costs of $1.5 million which was expensed to general and administrative expenses and $0.9 million which was recorded as a reduction to additional paid-in-capital. The net proceeds were allocated to the warrant liability as noted below with the remainder of $12.9 million and $0.1 million recorded in additional paid-in capital and common stock, respectively.

In the event of certain fundamental transactions involving the Company, the holders of the stock purchase warrants may require the Company to make a payment based on a Black-Scholes valuation, using specific inputs that are not considered indexed to the Company's stock in accordance with ASC 815. Therefore, the Company is accounting for the stock purchase warrants as liabilities. On November 3, 2022, the stock purchase warrants were recorded at the closing date fair value of $22.0 million which was based on a Black-Scholes option pricing model. The remainder of the proceeds were allocated to common stock issued and recorded as a component of equity.

As of September 30, 2025, there were 6,522,923 warrants outstanding related to this private placement offering. The warrants expire on November 3, 2027. During such time as each warrant is outstanding, the holder of the warrant is entitled to participate in any dividends or other distribution of assets to holders of shares of common stock. In August 2025, 1,086,956 warrants were exercised for proceeds of $5.2 million. There was no warrant activity during the three and nine months ended September 30, 2025, other than the exercise and change in fair value of the warrants related to warrants issued as part of this private placement offering.

Direct Placement Offering

On July 6, 2023, the Company sold 3,284,407 shares of its common stock, and in lieu of shares of common stock, pre-funded warrants exercisable for 2,919,140 shares of common stock (the "2023 Pre-Funded Warrants"), to a group of existing institutional investors for an aggregate purchase price of $25.0 million gross, or $23.0 million net of related costs. The offering price for each share of common stock was $4.03, and the offering price for the 2023 Pre-Funded Warrants was $4.0299, which represents the per share offering price for the Company's common stock less a $0.0001 per share exercise price for each such 2023 Pre-Funded Warrant. The 2023 Pre-Funded Warrants are immediately exercisable at a nominal exercise price of $0.0001 per share, may be exercised at any time and do not have an expiration date. On May 9, 2024, 300,000 of the 2023 Pre-Funded Warrants were exercised, leaving 2,619,140 2023 Pre-Funded Warrants outstanding as of September 30, 2025. The 2023 Pre-Funded Warrants are classified as equity in accordance with ASC 815, given the 2023 Pre-Funded Warrants are indexed to the Company's own shares of common stock and meet the requirements to be classified in equity. The 2023 Pre-Funded Warrants were recorded at their relative fair value at issuance in the stockholders' equity section of the consolidated balance sheet and the 2023 Pre-Funded Warrants are considered outstanding shares in the basic and diluted earnings per share calculation for the three and nine months ended September 30, 2025 given their nominal exercise price.

Common Stock Warrants related to the Loan and Security Agreement

On January 8, 2024, in connection with entering into the Loan and Security Agreement, the Company issued to the Warrant Holders warrants to purchase up to $0.5 million and $1.9 million worth of shares, respectively, of Company common stock (collectively, the "January Warrants"). The January Warrants expire on January 8, 2029 and upon issuance, had an exercise price per share equal to the lesser of (i) $4.75 and (ii) the price per share of the Company's next bona fide round of equity financing before September 30, 2024 in which the Company sells or issues shares of its common stock, excluding certain excluded issuances as defined in the Supplement. In connection with the underwritten common stock offering consummated on May 7, 2024, and pursuant to the term of the January Warrants, the exercise price of the January Warrants was reduced to $4.07 per share for 589,681 shares. In addition, upon a change of control where the per share price of the Company common stock is less than or equal to two times that of the exercise price, the Warrant Holders would be entitled to receive the shares of common stock underlying the January Warrants without payment of the exercise price. On January 8, 2024, the January Warrants did not include an explicit share limit and the number of shares issuable under the warrant agreements were variable based on the exercise price, therefore, the January Warrants were liability classified based on a Black-Scholes valuation in accordance with ASC 815 and were recorded at the closing date fair value of $0.2 million which was based on a Black-Scholes option pricing model. On September 30, 2024, per the terms of the January Warrants, the exercise price and the number of shares issuable became set at $4.07 per share and 589,681 shares, respectively.

The Warrant Holders may exercise the January Warrants at any time, or from time to time up to and including January 8, 2029, by making a cash payment equal to the exercise price multiplied by the quantity of shares. The Warrant Holders may also exercise the January Warrants on a cashless basis by receiving a net number of shares calculated pursuant to the formula set forth in the January Warrants. The January Warrants are subject to anti-dilution adjustments for stock dividends, stock splits, and reverse stock splits.

On July 18, 2025, in connection with entering into the Loan Agreement Amendment, the Company issued the Lenders warrants to purchase up to an aggregate of 16,473 shares of Company common stock (collectively, the "July 2025 Avenue Warrants"). The July 2025 Avenue Warrants expire on July 18, 2030 and have an exercise price per share equal to $6.07. In the event of certain fundamental transactions involving the Company, the holders of the stock purchase warrants may require the Company to make a payment based on a Black-Scholes valuation, using specific inputs that are not considered indexed to the Company's stock in accordance with ASC 815. Therefore, the Company accounted for the stock purchase warrants as liabilities, which were recorded at the closing date fair value of $0.1 million which was based on a Black-Scholes option pricing model.

NOTE 10 – STOCK-BASED COMPENSATION

Prior to May 17, 2023, the Company had previously granted stock options and stock awards under the Abeona Therapeutics Inc. 2015 Equity Incentive Plan (the "2015 Incentive Plan"). As of May 17, 2023, no further grants can be made under the 2015 Incentive Plan. The Company now grants stock options and stock awards under the Abeona Therapeutics Inc. 2023 Equity Incentive Plan (the "2023 Incentive Plan") which was approved by stockholders on May 17, 2023. On April 24, 2024, stockholders approved an amendment to the 2023 Incentive Plan to increase the shares authorized for issuance from 1,700,000 shares to 3,200,000 shares. On December 20, 2024, stockholders approved an additional increase in the shares authorized for issuance under the 2023 Incentive Plan from 3,200,000 shares to 8,400,000 shares. As of September 30, 2025, there were 3,280,169 shares available to be granted under the 2023 Incentive Plan. In addition, in 2023, the Company's board of directors approved various restricted stock awards granted to certain new hires as inducement grants. On October 10, 2023, the Company's board of directors approved the Abeona Therapeutics Inc. 2023 Employment Inducement Equity Incentive Plan (the "Inducement Plan"). As of September 30, 2025, there were 394,921 shares available to be granted under the Inducement Plan.

The following table summarizes stock-based compensation expense (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2025	2024	2025	2024
Research and development	$ 223	$ 485	$ 1,125	$ 1,055
Selling, general and administrative	2,466	1,319	7,095	3,618
Total stock-based compensation expense	$ 2,689	$ 1,804	$ 8,220	$ 4,673

Stock Options

The Company estimates the fair value of each option award on the date of grant using the Black-Scholes option-pricing model. The Company then recognizes the grant date fair value of each option as compensation expense ratably using the straight-line attribution method over the service period (generally the vesting period). The Black-Scholes model incorporates the following assumptions:

- Expected volatility – the Company estimates the volatility of the share price at the date of grant using a "look-back" period which coincides with the expected term, defined below. The Company believes using a "look-back" period which coincides with the expected term is the most appropriate measure for determining expected volatility.

- Expected term – the Company estimates the expected term using the "simplified" method, as outlined in SEC Staff Accounting Bulletin No. 107, "Share-Based Payment."

- Risk-free interest rate – the Company estimates the risk-free interest rate using the U.S. Treasury yield curve for periods equal to the expected term of the options in effect at the time of grant.

- Dividends – the Company uses an expected dividend yield of zero because the Company has not declared nor paid a cash dividend, nor are there any plans to declare a dividend.

The Company did not grant any stock options in the three and nine months ended September 30, 2025 and 2024.

The Company accounts for forfeitures as they occur, which may result in the reversal of compensation costs in subsequent periods as the forfeitures arise.

The following table summarizes stock option activity during the nine months ended September 30, 2025:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	176,587	$ 38.64	5.83	$ 6
Granted	—	$ —	—	$ —
Cancelled/forfeited	(568)	$ 14.21	—	$ —
Exercised	—	$ —	—	$ —
Outstanding at September 30, 2025	176,019	$ 38.72	5.10	$ 5
Exercisable	174,792	$ 38.93	5.09	$ 4
Unvested	1,227	$ 8.81	6.47	$ 1

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. As of September 30, 2025, the total compensation cost related to non-vested option awards not yet recognized was approximately $6,000 with a weighted average remaining vesting period of 0.3 years.

Restricted Stock

The following table summarizes restricted stock award activity during the nine months ended September 30, 2025:

	Number of Awards	Weighted Average Grant Date Fair Value Per Unit
Outstanding at December 31, 2024	3,320,811	$ 4.60
Granted	2,208,927	$ 5.33
Cancelled/forfeited	(48,697)	$ 5.09
Vested	(1,395,420)	$ 4.68
Outstanding at September 30, 2025	4,085,621	$ 4.96

As of September 30, 2025, there was $15.5 million of total unrecognized compensation expense related to unvested restricted stock awards, which is expected to be recognized over a weighted average vesting period of 1.9 years. The total fair value of restricted stock awards that vested during the nine months ended September 30, 2025 and 2024 was $6.5 million and $4.5 million, respectively.

NOTE 11 – LICENSE/SUPPLIER AGREEMENT

License Agreement Relating to Recessive Dystrophic Epidermolysis Bullosa (RDEB)

In 2016, the Company entered into two licensing agreements between the Company and The Board of Trustees of Leland Stanford Junior University ("Stanford") to develop EB-101 (LZRSE-Col7A1 Engineered Autologous Epidermal Sheets (LEAES)) and EB-201 (AAV DJ COL7A1) and to license the invention "Gene Therapy for Recessive Dystrophic EB using Genetically Corrected Autologous Keratinocytes." Under the terms of the licensing agreements, the Company paid an upfront of licensing fees in cash and is subject to annual license maintenance fees. In addition, the Company is subject to the achievement of certain milestones, regulatory approval milestone payments, and royalty payments in the low single digits on annual net sales of the licensed product. As of September 30, 2025, the Company paid the remaining milestone payments of $0.3 million which became due upon FDA approval of ZEVASKYN® on April 28, 2025 and is included in selling, general and administrative costs in the condensed consolidated statement of operations and comprehensive income (loss).

License Agreement Relating to Novel AAV Capsids ("AIM™ capsids")

In 2016, the Company licensed an international patent family from The University of North Carolina at Chapel Hill ("UNC") covering novel AAV capsids ("AIM™ capsids") that may potentially be used to deliver a wide variety of therapeutic transgenes to human cells to treat genetic diseases. Under the terms of the licensing agreements, the Company paid an upfront licensing fee in cash and is subject to on-going patent expenses incurred in relation to the patents licensed under this agreement and annual license maintenance fees. In addition, the Company is subject to the achievement of certain milestones, regulatory approval milestone payments, and royalty payments in the low single digits on annual net sales of the licensed product. As of September 30, 2025, as a result of exercise of the option to license certain of the Company's AAV capsids, the Company paid $0.1 million to UNC as a royalty payment under this agreement.

License Agreement Relating to CLN1 Disease

In 2016, the Company licensed from UNC rights to two patent families directed to treating CLN1 disease (also known as infantile Batten disease). Under the terms of the licensing agreements, the Company paid an upfront of licensing fees in cash and is subject to on-going patent expenses incurred in relation to the patents licensed under this agreement and annual license maintenance fees. In addition, the Company is subject to the achievement of certain milestones, regulatory approval milestone payments, and royalty payments in the low single digits on annual net sales of the licensed product. The Company subsequently sublicensed the license to Taysha Gene Therapies ("Taysha"), see detail of the sublicense agreement below. As part of the agreement with UNC, the Company is obligated to pay to UNC a percentage of any sublicense revenue that the Company receives under the agreement. The Company recognizes any payments under this agreement as royalties in the consolidated statement of operations and comprehensive income (loss). During the three and nine months ended September 30, 2025 and 2024, no milestone or royalty payments under this agreement have been made.

License Agreement Relating to Rett Syndrome

In 2019, the Company licensed rights to one patent family from UNC and two patent families from The University Court of the University of Edinburgh ("U. Edinburgh") and The University Court of the University of Glasgow ("U. Glasgow") relating to gene therapy for the treatment of Rett Syndrome. Under the terms of the licensing agreements, the Company paid an upfront of licensing fees in cash and is subject to on-going patent expenses incurred in relation to the patents licensed under this agreement and annual license maintenance fees. In addition, the Company is subject to the achievement of certain milestones, regulatory approval milestone payments, and royalty payments in the low single digits on annual net sales of the licensed product. The Company subsequently sublicensed the license to Taysha, see detail of the sublicense agreement below. As part of the agreement with UNC, the Company is obligated to pay to UNC and U. Edinburgh a percentage of any sublicense revenue that the Company receives under the agreement. The Company recognizes any payments under this agreement as royalties in the consolidated statement of operations and comprehensive income (loss). During the three and nine months ended September 30, 2025 and 2024, no milestone or royalty payments under this agreement have been made.

License Agreement Relating to AAV Capsids

In 2024, the Company entered into a license agreement with a third party for certain of the Company's AAV capsids. This agreement had an option to exercise before the terms of the agreement were activated. In June 2025, the third party exercised its option as per the agreement with a payment of $0.4 million included as license and other revenues in the statement of operations and comprehensive income (loss).

The Company assessed the nature of the promised license to determine whether the license has significant stand-alone functionality and evaluated whether such functionality can be retained without ongoing activities by the Company and determined that the license has significant stand-alone functionality. Furthermore, the Company has no ongoing activities associated with the license to support or maintain the license's utility. Based on this, the Company determined that the pattern of transfer of control of the license to the third party was at a point in time.

The transaction price of the contract includes (i) $0.4 million of fixed consideration, (ii) up to $24.0 million of variable consideration in the form of event-based milestone payments, (iii) up to $45.0 million of variable consideration in the form of sales-based milestone payments, and (iv) low single-digit royalty-based payments based on net sales. The Company is obligated to pay a portion of milestone payments and royalties on net sales received from the third party to UNC. The event-based milestone payments are based on certain development and regulatory events occurring. The Company evaluated whether the milestone conditions have been achieved and if it is probable that a significant cumulative revenue reversal would not occur before recognizing the associated revenue. The Company determined that these milestone payments are not within the Company's control or the licensee's control, such as regulatory approvals, and are not considered probable of being achieved until those approvals are received. Accordingly, the Company has fully constrained the $24.0 million in event-based milestone payments until such time that it is probable that a significant cumulative revenue reversal would not occur. The sales-based milestone payments and other royalty-based payments are based on a level of sales for which the license is deemed to be the predominant item to which the royalties relate. The Company will recognize revenue for these payments at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any sales-based or royalty revenue resulting from this licensing arrangement.

Under this arrangement, the Company recognized nil and $0.4 million in revenue during the three and nine months ended September 30, 2025, respectively and no revenue for the three and nine months ended September 30, 2024. As of September 30, 2025 and December 31, 2024, the Company does not have any contract assets or contract liabilities as a result of this transaction.

Sublicense and Inventory Purchase Agreements Relating to CLN1 Disease

In August 2020, the Company entered into sublicense and inventory purchase agreements with Taysha relating to a potential gene therapy for CLN1 disease. Under the sublicense agreement, Taysha received worldwide exclusive rights to intellectual property and know-how relating to the research, development, and manufacture of the potential gene therapy, which the Company had referred to as ABO-202. Under the inventory purchase agreement, the Company sold to Taysha certain inventory and other items related to ABO-202. The Company assessed the nature of the promised license to determine whether the license has significant stand-alone functionality and evaluated whether such functionality can be retained without ongoing activities by the Company and determined that the license has significant stand-alone functionality. Furthermore, the Company has no ongoing activities associated with the license to support or maintain the license's utility. Based on this, the Company determined that the pattern of transfer of control of the license to Taysha was at a point in time.

The transaction price of the contract includes (i) $7.0 million of fixed consideration, (ii) up to $26.0 million of variable consideration in the form of event-based milestone payments, (iii) up to $30.0 million of variable consideration in the form of sales-based milestone payments, and (iv) high single-digit royalty-based payments based on net sales. The Company is obligated to pay a portion of milestone payments and royalties on net sales received from Taysha to UNC. The event-based milestone payments are based on certain development and regulatory events occurring. At inception, the Company evaluated whether the milestone conditions had been achieved and if it was probable that a significant cumulative revenue reversal would not occur before recognizing the associated revenue and determined that these milestone payments were not within the Company's control or the licensee's control, such as regulatory approvals, and were not considered probable of being achieved until those approvals were received. Accordingly, at inception, the Company fully constrained the $26.0 million of event-based milestone payments until such time that it is probable that significant cumulative revenue reversal would not occur. The sales-based milestone payments and other royalty-based payments are based on a level of sales for which the license is deemed to be the predominant item to which the royalties relate. The Company will recognize revenue for these payments at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any sales-based or royalty revenue resulting from this licensing arrangement.

Under this arrangement, the Company has not recognized any revenue during the three and nine months ended September 30, 2025 and 2024, respectively, based on event-based-milestone payments. The Company has no contract assets or liabilities as of September 30, 2025 and December 31, 2024 as a result of this transaction.

Sublicense Agreement Relating to Rett Syndrome

In October 2020, the Company entered into a sublicense agreement with Taysha for a gene therapy for Rett syndrome, including intellectual property related to MECP2 gene constructs and regulation of their expression. The agreement grants Taysha worldwide exclusive rights to intellectual property developed by scientists at UNC, U. Edinburgh and the Company, and the Company's know-how relating to the research, development, and manufacture of the gene therapy for Rett syndrome and MECP2 gene constructs and regulation of their expression.

The Company assessed the nature of the promised license to determine whether the license has significant stand-alone functionality and evaluated whether such functionality can be retained without ongoing activities by the Company and determined that the license has significant stand-alone functionality. Furthermore, the Company has no ongoing activities associated with the license to support or maintain the license's utility. Based on this, the Company determined that the pattern of transfer of control of the license to Taysha was at a point in time.

The transaction price of the contract includes (i) $3.0 million of fixed consideration, (ii) up to $26.5 million of variable consideration in the form of event-based milestone payments, (iii) up to $30.0 million of variable consideration in the form of sales-based milestone payments, and (iv) high single-digit royalty-based payments based on net sales. The Company is obligated to pay a portion of milestone payments and royalties on net sales received from Taysha to UNC and U. Edinburgh. The event-based milestone payments are based on certain development and regulatory events occurring. The Company evaluated whether the milestone conditions have been achieved and if it is probable that a significant cumulative revenue reversal would not occur before recognizing the associated revenue. The Company determined that these milestone payments are not within the Company's control or the licensee's control, such as regulatory approvals, and are not considered probable of being achieved until those approvals are received. Accordingly, the Company fully constrained the $26.5 million in event-based milestone payments until such time that it is probable that a significant cumulative revenue reversal would not occur. The sales-based milestone payments and other royalty-based payments are based on a level of sales for which the license is deemed to be the predominant item to which the royalties relate. The Company will recognize revenue for these payments at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any sales-based or royalty revenue resulting from this licensing arrangement.

Under this arrangement, the Company recognized no revenue during the three and nine months ended September 30, 2025 and 2024. As of September 30, 2025 and December 31, 2024, the Company does not have any contract assets or contract liabilities as a result of this transaction.

Ultragenyx License Agreement

On May 16, 2022, the Company and Ultragenyx Pharmaceutical Inc. ("Ultragenyx") entered into an exclusive license agreement (the "License Agreement") for AAV gene therapy, ABO-102, for the treatment of Sanfilippo syndrome type A (MPS IIIA). Under the License Agreement, Ultragenyx assumed responsibility for the ABO-102 program from the Company, with the exclusive right to develop, manufacture, and commercialize ABO-102 worldwide. Also pursuant to the License Agreement, following regulatory approval, the Company is eligible to receive tiered royalties from mid-single-digit up to 10% on net sales and up to $30.0 million in commercial milestone payments. Both forms of consideration comprise the transaction price to which the Company expects to be entitled in exchange for transferring the related intellectual property and certain, contractually-specified, transition services to Ultragenyx. The sales-based royalty and milestone payments are subject to the royalty recognition constraint. As such, these fees are not recognized as revenue until the later of: (a) the occurrence of the subsequent sale, and (b) the performance obligation to which they relate has been satisfied. As of September 30, 2025 and December 31, 2024, the Company does not have any contract assets or contract liabilities as a result of this transaction.

NOTE 12 – SEGMENT INFORMATION

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the Chief Operating Decision Maker ("CODM"), or decision making group, in deciding how to allocate resources in assessing performance. The Company is a commercial-stage biopharmaceutical company developing cell and gene therapies for life-threatening diseases and has one reportable segment. The Company's CODM is the chief executive officer.

The accounting policies of the clinical-stage biopharmaceutical segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the commercial-stage biopharmaceutical segment based on net income (loss), which is reported on the consolidated statements of operations and comprehensive income (loss) as consolidated net income (loss). The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets. Expenditures for additions to long-lived assets, which include purchases of property and equipment, are included in total consolidated assets reviewed by the chief operating decision maker and are reported on the consolidated statements of cash flows.

To date, the Company has not generated any product revenue. The Company will continue to incur significant expenses and operating losses until ZEVASKYN® can provide sufficient revenue for the Company to be profitable. As such, the CODM uses cash forecast models in deciding how to invest into the commercial-stage biopharmaceutical segment. Such cash forecast models are reviewed to make decisions about allocating resources and assessing the entity-wide operating results and performance. Net income (loss) is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used to make decisions about allocating resources, assessing the performance of the segment and in establishing management's compensation, along with cash forecast models.

The table below summarizes the significant expense categories regularly reviewed by the CODM (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2025	2024	2025	2024
License and other revenues	$ —	$ —	$ 400	$ —
Research and development costs				
Salaries & related costs	$ 1,689	$ 3,492	$ 8,605	$ 11,488
Non-cash stock-based compensation	223	485	1,125	1,055
Other research and development costs (a)	2,304	4,964	10,370	12,823
Total research and development costs	$ 4,216	$ 8,941	$ 20,100	$ 25,366
Selling, general and administrative costs				
Salaries & related costs	$ 6,975	$ 2,235	$ 18,084	$ 7,931
Non-cash stock-based compensation	2,466	1,320	7,095	3,619
Pre-commercial preparation costs	2,138	814	5,635	3,625
Other selling, general and administrative costs (b)	7,735	2,035	15,435	6,998
Total selling, general and administrative costs	$ 19,314	$ 6,404	$ 46,249	$ 22,173
Other segment items (c)	(18,369)	14,924	(157,592)	6,902
Net income (loss)	$ (5,161)	$ (30,269)	$ 91,643	$ (54,441)

(a) Other research and development costs include, but are not limited to preclinical lab supplies, preclinical and development costs, clinical trial costs, preclinical manufacturing and manufacturing facility costs, costs associated with preclinical regulatory approvals, preclinical depreciation on lab supplies and manufacturing facilities, and preclinical consultant-related expenses.

(b) Other selling, general and administrative costs primarily consist of office facility costs, public reporting company related costs, professional fees (e.g., legal expenses), regulatory costs, production costs not attributable to cost of sales and other general operating expenses not otherwise included in research and development expenses.

(c) Other segment items includes cost of sales, royalties, interest income, interest expense, change in fair value of warrant and derivative liabilities, gain on sale of priority review voucher, other income and income tax (benefit) expense.

NOTE 13 – INCOME TAXES

The Company recorded a current income tax benefit of $15.2 million for the three months ended September 30, 2025 and a current income tax expense of $0.3 million for the nine months ended September 30, 2025. The Company did not record an income tax expense for the three and nine months ended September 30, 2024 as it generated sufficient tax losses, after consideration of discrete items, during each of the periods.

The significant decrease from the $15.5 million income tax expense recorded for the six months ended June 30, 2025 is primarily due to the favorable impact of the One Big Beautiful Bill Act, enacted on July 4, 2025. The legislation restored immediate expensing of domestic R&D expenditures, reinstated 100% bonus depreciation, and provided more favorable rules for determining the limitation on business interest expense, which collectively reduced the Company's taxable income and resulted in a current tax benefit for the three months ended September 30, 2025.

As previously disclosed, the Company's ability to utilize its net operating loss ("NOL") carryforwards are subject to limitation under Section 382 of the Internal Revenue Code of 1986, as amended. Per Section 382, a change in ownership greater than 50% within a three-year period results in annual limitations on the utilization of NOL carryforwards. The Company is currently in the process of determining if a Section 382 change has occurred and to what extent the use of its NOL carryforwards may be limited. Preliminary results indicate that the Company has experienced multiple ownership changes and may have a material limitation on the use of its NOL carryforwards. The Company expects to complete its Section 382 analysis by December 31, 2025.

NOTE 14 – SALE OF NONFINANCIAL ASSETS

On May 9, 2025, the Company entered into a definitive asset purchase agreement that transferred the rights to a PRV awarded to the Company following the FDA approval of ZEVASKYN®. The PRV sale was subject to customary closing conditions and was completed in June 2025 following the expiration of applicable U.S. antitrust requirements. The Company accounted for this transaction under ASC Topic 610-20, *Gains and Losses from the Derecognition of Nonfinancial Assets* ("ASC 610-20"). The Company received the gross proceeds of $155.0 million during the three months ended June 30, 2025 and recognized a gain, net of transaction costs of $2.6 million, from sale of priority review voucher of $152.4 million on the Company's condensed consolidated statement of operations and comprehensive income (loss) as it did not have a carrying value at the time of sale.

NOTE 15 – SUBSEQUENT EVENTS

In October 2025, 1,719,944 of the May 2024 Pre-Funded Warrants were exercised and were net settled for 1,719,911 of common shares.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis together with our unaudited condensed consolidated financial statements and accompanying notes included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2024 (the "Annual Report"). This discussion and analysis contains forward-looking statements, which involve risks and uncertainties. As a result of many factors, such as those described under "Forward-Looking Statements," "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report, our actual results may differ materially from those anticipated in these forward-looking statements.

OVERVIEW

Abeona is a commercial-stage biopharmaceutical company developing cell and gene therapies for life-threatening diseases. On April 28, 2025, the U.S. Food and Drug Administration ("FDA") approved ZEVASKYN® (prademagene zamikeracel) gene-modified cellular sheets, also known as pz-cel, as the first and only autologous cell-based gene therapy for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa ("RDEB"), a serious and debilitating genetic skin disease. There is no cure for RDEB, and ZEVASKYN® is the only FDA-approved product to treat RDEB wounds with a single application. ZEVASKYN® was granted Orphan Drug and Rare Pediatric Disease designations by the FDA.

ZEVASKYN® is manufactured at our current Good Manufacturing Practices ("cGMP") manufacturing facility in Cleveland, Ohio, and is made available through ZEVASKYN® Qualified Treatment Centers ("QTCs").

Our development portfolio also features adeno-associated virus ("AAV") based gene therapies designed to treat ophthalmic diseases with high unmet need using novel AIM™ capsids. Abeona's novel, next-generation AAV capsids are being evaluated to improve tropism profiles for a variety of devastating diseases.

Preclinical Pipeline

Our preclinical programs are investigating the use of novel AAV capsids in AAV-based therapies for serious genetic eye diseases, including ABO-504 for Stargardt disease, ABO-503 for X-linked retinoschisis ("XLRS") and ABO-505 for autosomal dominant optic atrophy ("ADOA"). We completed pre-Investigational New Drug Application ("pre-IND") meetings with the FDA regarding the preclinical development plans and regulatory requirements to support first-in-human trials.

Recent Updates

During the third quarter, we manufactured a full batch of drug product following patient biopsy collection in August 2025. Although we produced bonafide drug product, it could not be released because a rapid sterility assay, mandated by the FDA as a release assay during the final stage of the Biologics License Application (BLA) review, initially yielded a false positive result for sterility. We immediately implemented a temporary pause on collecting patient biopsies and worked diligently to optimize the release assay to ensure reliable results and avoid any unnecessary future lot rejections. Upon completion of assay optimization and the necessary regulatory submission for its implementation, we resumed biopsy collection in November 2025.

On October 8, 2025, we announced the activation of the newest QTC for ZEVASKYN® at Children's Hospital Colorado. As a result, RDEB patients will be able to access ZEVASKYN® at Lucile Packard Children's Hospital Stanford, Lurie Children's Hospital of Chicago and Children's Hospital Colorado.

On October 13, 2025, we announced that ABO-503 for XLRS was selected by the FDA for Rare Disease Endpoint Advancement Pilot ("RDEA") Program. The RDEA program facilitates the development and timely approval of rare disease therapies by supporting the use of novel efficacy endpoints in clinical trials. As part of the RDEA program, Abeona will have opportunities for enhanced communication and collaboration with the FDA, including frequent advice and regular ad-hoc conversations to accelerate the development and validation of product-specific novel efficacy endpoints for Abeona's XLRS program.

On October 20, 2025, we announced the appointment of James A. Gow, MD, MBA, MS, MHCM, as the Senior Vice President, Head of Clinical Development & Medical Affairs, effective immediately. Dr. Gow has over 20 years of industry experience in clinical development and medical affairs and is a recognized expert in gene therapy, especially in ophthalmology.

On October 30, 2025, we announced that the Centers for Medicare and Medicaid Services ("CMS") has established a permanent Healthcare Common Procedure Coding System ("HCPCS") J-code for ZEVASKYN®. The new J-code for ZEVASKYN®, J3389 (Topical administration, prademagene zamikeracel, per treatment) becomes effective on January 1, 2026.

RESULTS OF OPERATIONS

Comparison of Three Months Ended September 30, 2025 and September 30, 2024

($ in thousands)	For the three months ended September 30, 2025	2024	Change $	Change %
Costs and expenses:				
Cost of sales	$ 488	$ —	$ 488	100%
Research and development	4,216	8,941	(4,725)	(53)%
Selling, general and administrative	19,314	6,404	12,910	202%
Total costs and expenses	24,018	15,345	8,673	57%
Loss from operations	(24,018)	(15,345)	(8,673)	57%
Interest income	1,672	1,189	483	41%
Interest expense	(901)	(1,102)	201	(18)%
Change in fair value of warrant and derivative liabilities	2,760	(15,156)	17,916	(118)%
Other income	129	145	(16)	(11)%
Loss before income taxes	(20,358)	(30,269)	9,911	(33)%
Income tax benefit	(15,197)	—	(15,197)	100%
Net loss	$ (5,161)	$ (30,269)	$ 25,108	(83)%

Cost of sales

Cost of sales during the three months ended September 30, 2025 primarily includes costs associated with the August 2025 production of a full batch of ZEVASKYN® that could not be released due to technical issues that arose in implementing the rapid sterility lot release assay, mandated by the FDA during BLA review. There was no cost of sales in the same period of 2024, as ZEVASKYN® was approved by the FDA in April 2025.

Research and development

Research and development expenses include, but are not limited to, payroll and personnel expenses, preclinical lab supplies, preclinical and development costs, clinical trial costs, preclinical manufacturing and manufacturing facility costs, costs associated with regulatory approvals, preclinical depreciation on lab supplies and manufacturing facilities, and preclinical consultant-related expenses.

Total research and development spending for the three months ended September 30, 2025 was $4.2 million, as compared to $8.9 million for the same period of 2024, a decrease of $4.7 million. The reduction in expenses was primarily due to costs capitalized into inventory and engineering runs and other production costs that are no longer considered research and development due to FDA approval of ZEVASKYN® in April of 2025.

We expect our research and development activities to continue as we work towards advancing other product candidates towards potential regulatory approval, reflecting costs associated with the following:

- employee and consultant-related expenses;
- preclinical and developmental costs;
- clinical trial costs;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with regulatory approvals.

Selling, general and administrative

Selling, general and administrative expenses primarily consist of payroll and personnel costs, office facility costs, public reporting company related costs, professional fees (e.g., legal expenses), selling and other costs for commercial launch and other general operating expenses not otherwise included in research and development expenses. We expect our selling, general, and administrative costs to continue to increase as we launch ZEVASKYN® and advance other product candidates toward potential regulatory approval.

Total selling, general and administrative expenses were $19.3 million for the three months ended September 30, 2025, as compared to $6.4 million for the same period of 2024, an increase of $12.9 million. The increase in expenses was primarily due to increases in commercial costs related to our continued commercialization efforts, increased legal costs associated with commercialization, increases of salaries and stock-based compensation due to new hires, and costs related to engineering runs and other production costs that are no longer considered research and development due to FDA approval in April of 2025.

Interest income

Interest income was $1.7 million for the three months ended September 30, 2025, as compared to $1.2 million in the same period of 2024. The increase resulted from higher earnings on short-term investments driven by increased average short-term investment balances.

Interest expense

Interest expense was $0.9 million for the three months ended September 30, 2025 compared to $1.1 million in the same period of 2024. Interest expense was due to the credit facility entered into by the Company in January 2024 and decreased as a result of the July 2025 Loan Agreement Amendment.

Change in fair value of warrant and derivative liabilities

The change in fair value of warrant liabilities was a gain of $2.8 million for the three months ended September 30, 2025. We issued stock purchase warrants that are required to be classified as a liability and valued at fair market value at each reporting period. The gain in the fair value of warrant liabilities was primarily due to the decrease in our stock price over the quarter and a shorter term of the outstanding warrants.

The change in fair value of warrant and derivative liabilities was a loss of $15.2 million for the three months ended September 30, 2024. We issued stock purchase warrants that are required to be classified as a liability and valued at fair market value at each reporting period. In addition, the conversion feature in our loan agreement is required to be classified as a liability and valued at fair market value at each reporting period. The loss in the fair value of warrant and derivative liabilities was primarily due to the increase in our stock price over the quarter offset by the reduced term of each of the warrants and derivative liabilities.

Other income

Other income, which consists primarily of sublease income, was $0.1 million for the three months ended September 30, 2025, as compared to $0.1 million in the same period of 2024.

Income tax benefit

We recorded a current income tax benefit of $15.2 million for the three months ended September 30, 2025. We did not record an income tax expense for the three months ended September 30, 2024 as we generated sufficient tax losses, after consideration of discrete items. The current income tax benefit for the three months ended September 30, 2025 was by the favorable impact of the One Big Beautiful Bill Act, enacted on July 4, 2025. The legislation restored immediate expensing of domestic R&D expenditures, reinstated 100% bonus depreciation, and provided more favorable rules for determining the limitation on business interest expense, which collectively reduced our taxable income and resulted in a current tax benefit for the three months ended September 30, 2025.

Comparison of Nine Months Ended September 30, 2025 and September 30, 2024

($ in thousands)	For the nine months ended September 30, 2025	2024	Change $	Change %
Revenues:				
License and other revenues	$ 400	$ —	$ 400	100%
Costs and expenses:				
Cost of sales	$ 488	$ —	$ 488	100%
Royalties	100	—	100	100%
Research and development	20,100	25,366	(5,266)	(21)%
Selling, general and administrative	46,249	22,173	24,076	109%
Total costs and expenses	66,937	47,539	19,398	41%
Loss from operations	(66,537)	(47,539)	(18,998)	40%
Interest income	4,009	3,223	786	24%
Interest expense	(2,856)	(3,126)	270	(9)%
Change in fair value of warrant and derivative liabilities	4,617	(7,530)	12,147	(161)%
Gain from sale of priority review voucher, net	152,366	—	152,366	100%
Other income	359	531	(172)	(32)%
Income (loss) before income taxes	91,958	(54,441)	146,399	(269)%
Income tax expense	315	—	315	100%
Net income (loss)	$ 91,643	$ (54,441)	$ 146,084	(268)%

License and other revenues

License and other revenues for the nine months ended September 30, 2025 was $0.4 million as compared to nil for the same period of 2024. The revenue in 2025 of $0.4 million consists of revenue resulting from a third party exercising its option to license certain of our AAV capsids.

Cost of sales

Cost of sales during the nine months ended September 30, 2025 primarily includes costs associated with the August 2025 production of a full batch of ZEVASKYN® that could not be released due to technical issues that arose in implementing the rapid sterility lot release assay, mandated by the FDA during BLA review. There was no cost of sales in the same period of 2024, as ZEVASKYN® was approved by the FDA in April 2025.

Royalties

Total royalty expense for the nine months ended September 30, 2025 was $0.1 million as compared to nil for the same period of 2024. The increase in expense was due to royalties owed to the University of North Carolina at Chapel Hill resulting from the milestones due from the exercise of an option by a third party to license certain of our AAV capsids.

Research and development

Total research and development spending for the nine months ended September 30, 2025 was $20.1 million, as compared to $25.4 million for the same period of 2024, a decrease of $5.3 million. The reduction in expenses was primarily due to costs capitalized into inventory and engineering runs and other production costs that are no longer considered research and development due to FDA approval of ZEVASKYN® in April of 2025.

We expect our research and development activities to continue as we work towards advancing our product candidates towards potential regulatory approval, reflecting costs associated with the following:

- employee and consultant-related expenses;
- preclinical and developmental costs;
- clinical trial costs;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with regulatory approvals.

Selling, general and administrative

Total selling, general and administrative expenses were $46.2 million for the nine months ended September 30, 2025, as compared to $22.2 million for the same period of 2024, an increase of $24.0 million. The increase in expenses was primarily due to increases in commercial costs related to our continued commercialization efforts, increased legal costs associated with commercialization, increases of salaries and stock-based compensation due to new hires, and to costs related to engineering runs and other production costs that are no longer considered research and development due to FDA approval in April of 2025.

Interest income

Interest income was $4.0 million for the nine months ended September 30, 2025, as compared to $3.2 million in the same period of 2024. The increase resulted from higher earnings on short-term investments driven by increased average short-term investment balances.

Interest expense

Interest expense was $2.9 million for the nine months ended September 30, 2025, as compared to $3.1 million in the same period of 2024. Interest expense was due to the credit facility entered into by the Company in January 2024 and decreased as a result of the July 2025 Loan Agreement Amendment.

Change in fair value of warrant and derivative liabilities

The change in fair value of warrant liabilities was a gain of $4.6 million for the nine months ended September 30, 2025. We issued stock purchase warrants that are required to be classified as a liability and valued at fair market value at each reporting period. The gain in the fair value of warrant liabilities was primarily due to the decrease in our stock price as of September 30, 2025 compared to December 31, 2024 and to the shorter term period over period.

The change in fair value of warrant and derivative liabilities was a loss of $7.5 million for the nine months ended September 30, 2024. In 2024, we issued stock purchase warrants that are required to be classified as a liability and valued at fair market value at each reporting period. In addition, the conversion feature in our loan agreement was required to be classified as a liability through September 30, 2024 and was valued at fair market value at each reporting period during the nine-month period ending September 30, 2024. The change in the fair value of warrant and derivative liabilities was primarily due to the increase in our stock price as of September 30, 2024 compared to December 31, 2023.

Gain from sale of priority review voucher, net

In May 2025, we sold our PRV awarded to us following the FDA approval of ZEVASKYN®. We received gross proceeds of $155.0 million during the nine months ended September 30, 2025 and recognized a gain from the PRV sale of $152.4 million, net of transaction costs of $2.6 million, as it did not have a carrying value at the time of sale.

Other income

Other income, which consists primarily of sublease income, was $0.4 million for the nine months ended September 30, 2025, as compared to $0.5 million in the same period of 2024.

Income tax expense

We recorded a current income tax expense of $0.3 million for the nine months ended September 30, 2025. We did not record an income tax expense for the nine months ended September 30, 2024 as we generated sufficient tax losses, after consideration of discrete items. The current income tax expense for the nine months ended September 30, 2025 was driven by pre-tax income from the gain on sale of the PRV, offset by the favorable impact of the One Big Beautiful Bill Act, enacted on July 4, 2025. The legislation restored immediate expensing of domestic R&D expenditures, reinstated 100% bonus depreciation, and provided more favorable rules for determining the limitation on business interest expense, which collectively reduced the Company's taxable income and resulting income tax expense for the nine months ended September 30, 2025.

LIQUIDITY AND CAPITAL RESOURCES

Cash Flows for the Nine Months Ended September 30, 2025 and 2024

	For the nine months ended September 30,	
($ in thousands)	**2025**	**2024**
Total cash, cash equivalents and restricted cash provided by (used in):		
Operating activities	$ (58,373)	$ (39,456)
Investing activities	95,474	(58,116)
Financing activities	22,426	98,825
Net increase in cash, cash equivalents and restricted cash	$ 59,527	$ 1,253

Operating activities

Net cash used in operating activities was $58.4 million for the nine months ended September 30, 2025, primarily comprised of our net income of $91.6 million, offset by a decrease in operating assets and liabilities of $4.8 million and net non-cash charges of $145.2 million. Non-cash charges consisted primarily of $152.4 million gain on sale of priority review voucher for which the cash proceeds are recorded in investing activities, $4.6 million of gain as a result of the change in fair value of warrant and derivative liabilities, $8.2 million of stock-based compensation and $1.7 million of depreciation and amortization.

Net cash used in operating activities was $39.5 million for the nine months ended September 30, 2024, primarily comprised of our net loss of $54.4 million and decreases in operating assets and liabilities of $0.5 million and net non-cash charges of $15.5 million. Non-cash charges consisted primarily of $7.5 million of the change in fair value of warrant and derivative liabilities, $4.7 million of stock-based compensation, $1.1 million of non-cash interest expense and $1.5 million of depreciation and amortization.

Investing activities

Net cash provided by investing activities was $95.5 million for the nine months ended September 30, 2025, primarily comprised of net proceeds from sale of priority review voucher of $152.4 million, proceeds from maturities of short-term investments of $118.8 million, offset by purchases of short-term investments of $168.9 million and capital expenditures of $6.8 million.

Net cash used in investing activities was $58.1 million for the nine months ended September 30, 2024, primarily comprised of proceeds from maturities of short-term investments of $90.2 million, offset by purchases of short-term investments of $146.5 million and capital expenditures of $1.8 million.

Financing activities

Net cash provided by financing activities was $22.4 million for the nine months ended September 30, 2025, primarily comprised of proceeds of $17.3 million from open market sales of common stock pursuant to the ATM Agreement (as defined below) and proceeds of $5.2 million from the exercise of stock purchase warrants.

Net cash provided by financing activities was $98.8 million for the nine months ended September 30, 2024, primarily comprised of $70.2 million in net proceeds from sales of common stock, $10.0 million from open market sales of common stock pursuant to the ATM Agreement (as defined below) and net proceeds of $19.0 million from our January 2024 Loan Agreement.

We have historically funded our operations primarily through our sale of equity securities, our most recent gain on sale of our PRV, and strategic collaboration arrangements.

Our principal source of liquidity is cash, cash equivalents, restricted cash and short-term investments, collectively referred to as our cash resources. As of September 30, 2025, our cash resources were $207.5 million. We believe that our current cash and cash equivalents, restricted cash and short-term investments are sufficient to fund operations through at least the next 12 months from the date of this report on Form 10-Q. We may need to secure additional funding to carry out all of our planned research and development and potential commercialization activities. If we are unable to obtain additional financing or generate license or product revenue, the lack of liquidity and sufficient capital resources could have a material adverse effect on our future prospects.

We have an open market sale agreement with Jefferies LLC (as amended, the "ATM Agreement") pursuant to which, we may sell from time to time, through Jefferies LLC, shares of our common stock for an aggregate sales price of up to $75.0 million. Any sales of shares pursuant to this agreement are made under our effective "shelf" registration statement on Form S-3 that is on file with and has been declared effective by the SEC. We sold 3,510,889 shares of our common stock under the ATM Agreement and received $17.3 million of net proceeds during the nine months ended September 30, 2025. We sold 1,902,376 shares of our common stock under the ATM Agreement and received $10.0 million of net proceeds during the nine months ended September 30, 2024. Under the ATM Agreement and as of September 30, 2025, we have remaining shares of our common stock for an aggregate sales price of up to $51.5 million.

Since our inception and excluding the gain on sale of our priority review voucher, we have incurred negative cash flows from operations and have expended, and expect to continue to expend, substantial funds to complete our planned product development and commercialization efforts. Excluding the gain on sale of our priority review voucher, we have not been profitable since inception and to date have received limited revenues from the sale of products or licenses. As a result, we have incurred significant operating losses and negative cash flows from operations since our inception and anticipate such losses and negative cash flows will continue until ZEVASKYN® can provide sufficient revenue for us to be profitable and cash flow generating.

We may incur losses for the next several years as we continue to invest in commercialization, product research and development, preclinical studies, clinical trials, and regulatory compliance and cannot provide assurance that we will ever be able to generate sufficient product sales or royalty revenue to achieve profitability on a sustained basis, or at all.

If we raise additional funds by selling additional equity securities, the relative equity ownership of our existing investors will be diluted, and the new investors could obtain terms more favorable than previous investors. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Our future capital requirements and adequacy of available funds depend on many factors, including:

- the successful commercialization of ZEVASKYN®;
- the successful development, regulatory approval and commercialization of our cell and gene therapy and other product candidates;
- the ability to establish and maintain collaborative arrangements with corporate partners for the research, development, and commercialization of products;
- continued scientific progress in our research and development programs;
- the magnitude, scope and results of preclinical testing and clinical trials;
- the costs involved in filing, prosecuting, and enforcing patent claims;
- the costs involved in conducting clinical trials;
- competing technological developments;
- the cost of manufacturing and scale-up;
- the ability to establish and maintain effective commercialization arrangements and activities; and
- the successful outcome of our regulatory filings.

Due to uncertainties and certain of the risks described above, under "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report, it is not possible to reliably predict future spending or time to completion by project or product category or the period in which material net cash inflows from significant projects are expected to commence. If we are unable to timely complete a particular project, our research and development efforts could be delayed or reduced, our business could suffer depending on the significance of the project and we might need to raise additional capital to fund operations, as discussed above.

We plan to continue our policy of investing any available funds in suitable certificates of deposit, money market funds, government securities and investment-grade, interest-bearing securities. We do not invest in derivative financial instruments.

Critical Accounting Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

- it requires assumptions to be made that were uncertain at the time the estimate was made, and
- changes in the estimate or different estimates that could have been selected could have a material impact in our results of operations or financial condition.

While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results could differ from those estimates and the differences could be material. For a discussion of the critical accounting estimates that affect the unaudited condensed consolidated financial statements, see "Critical Accounting Estimates" included in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report.

See Note 2 to our unaudited condensed consolidated financial statements for a discussion of our significant accounting policies.

Recently Issued Accounting Standards Not Yet Effective or Adopted

See Note 2 to our unaudited condensed consolidated financial statements for a discussion of recently issued accounting standards not yet effective or adopted.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management and consultants, including the Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer), we have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures ("Disclosure Controls and Procedures"), as of September 30, 2025, as such term is defined in Rules 13a-15(e) or 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Conclusion of Evaluation — Based on this Disclosure Controls and Procedures evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our Disclosure Controls and Procedures as of September 30, 2025 were effective.

Changes in Internal Control Over Financial Reporting – There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act) that occurred during the quarter ended September 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

None.

ITEM 1A. RISK FACTORS

Our business and financial results are subject to numerous risks and uncertainties. As a result, the risks and uncertainties discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2024 should be carefully considered. There have been no material changes in the assessment of our risk factors from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2024 except as set forth below.

Changes in and uncertainty surrounding U.S. trade policy could have a material adverse impact on our business, financial condition and results of operations.

The U.S. government has announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely affect our business, results of operations, financial conditions and prospects.

Current or future tariffs or other trade restrictions may result in increased research and development expenses, including with respect to increased costs associated with raw materials, laboratory equipment, and research materials and components. In addition, such tariffs may increase our supply chain complexity and could also potentially disrupt our existing supply chain. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Tariffs and trade restrictions affecting the import of materials necessary for manufacturing or clinical trials could result in manufacturing delays for ZEVASKYN® or hinder our ability to establish cost-effective production capabilities, as well as in delays to our development timelines for our pre-clinical product candidates, negatively affecting our growth prospects. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. Tariffs and trade restrictions.

If we are unable to obtain necessary raw materials or product components in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, the development, testing and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

We recently received approval to market our first product, ZEVASKYN®, and will begin commercial sales, which make it difficult to assess our future viability.

We are a commercial-stage biopharmaceutical company. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. On April 28, 2025, the United States Food and Drug Administration ("FDA") approved our Biologics License Application ("BLA") for ZEVASKYN® for treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa ("RDEB"), a series and debilitating genetic skin disease. To date we have not recorded any revenue from ZEVASKYN® and recorded minimal other revenue and may recognize minimal revenue in the foreseeable future. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have limited experience in generating revenue from product sales.

Although ZEVASKYN® has been approved by the FDA, our ability to generate significant revenue from product sales depends on ZEVASKYN® successful commercialization. Successful commercialization requires success in many areas, including, but not limited to:

- launching ZEVASKYN® and enrolling new patients;
- obtaining market acceptance of ZEVASKYN® as a viable treatment option;
- obtaining adequate market share, reimbursement and pricing for ZEVASKYN®;
- our ability to find patients who have been diagnosed with RDEB and wish to begin receiving treatment;
- addressing any competing products and technological and market developments;
- negotiating favorable terms, including commercial rights, in any collaboration, licensing, or other arrangements into which we may enter, any amendments thereto, or extensions thereof;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

If the patient demand is not as significant as we estimate, or the reasonably predicted population for treatment is narrowed by competition, physician choice, or treatment guidelines, or for any other reason, we may not generate significant revenue from the sale of ZEVASKYN®.

Our financial performance depends on the commercial success of ZEVASKYN®.

Our financial performance depends heavily on the commercial success of ZEVASKYN®, which received FDA approval on April 28, 2025. If ZEVASKYN® faces problems such as unexpected side effects, loss of intellectual property protection, data integrity issues, manufacturing or supply chain issues or other product shortages, regulatory proceedings, changes in labeling, publicity affecting doctor or patient confidence in the product, material product liability litigation, or pressure from new competitive products, the adverse impact on our revenue could be significant. Our revenues could be significantly affected by the timing and rate of commercial acceptance of our product. The commercial success of our approved product also requires significant attention and focus from key members of our management.

Even if we succeed in commercializing ZEVASKYN®, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of any future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses before we become profitable have had and may continue to have an adverse effect on our stockholders' equity and working capital.

Our ability to use our net operating loss carryforwards to offset future taxable income and taxes may be subject to certain limitations.

As of December 31, 2024, we had $416.1 million of U.S. federal net operating loss carryforwards and $6.0 million of general business credit carryforwards, which may be utilized against future federal and state income taxes. Federal NOL carryforwards we generated in tax years through December 31, 2017 generally may be carried forward for 20 years and may fully offset taxable income in the year utilized, and federal NOLs we generated in tax years beginning after December 31, 2017 generally may be carried forward indefinitely but may only be used to offset 80% of our taxable income annually for tax years beginning after December 31, 2017.

Generally, a change of more than 50% in the ownership of a company's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes or applicable state tax law. An ownership change may limit our ability to use our NOL carryforwards attributable to the period prior to the change. We are currently in the process of determining if a Section 382 change has occurred and to what extent the use of our NOL carryforwards may be limited. Preliminary results indicate that we have experienced multiple ownership changes and may have a material limitation on the use of our NOL carryforwards. We expect to complete our Section 382 analysis by December 31, 2025.

If we are limited in our ability to use our NOLs and tax credits this year or in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs and tax credits, and we could be required to pay taxes earlier than we would otherwise be required, which could cause such NOLs to expire unused. This could adversely affect our results of operations.

Disruptions at FDA and other government agencies, such as those that may be caused by funding shortages, could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. Disruptions at FDA and other agencies may also increase the time necessary to meet with and provide feedback to entities developing drug products, review and/or approve our submissions, conduct inspections, issue regulatory guidance, or otherwise authorize our actions requiring regulatory approval, which would adversely affect our business. In addition, government funding of FDA 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. For example, the executive branch recently established the Department of Government Efficiency ("DOGE"), which implemented a federal government hiring freeze and large scale layoffs of current federal employees and also announced additional efforts to reduce federal government employee headcount and the size of the federal government. It is unclear how these executive actions or other potential actions by the executive branch will impact the regulatory authorities that oversee our business. These budgetary pressures may reduce FDA's ability to perform its responsibilities. If a significant reorganization or reduction in FDA's workforce occurs, FDA's budget is significantly reduced, or there are other disruptions at FDA and other agencies, more time may be necessary for biological products, or biologics, or modifications to approved biologics to be reviewed and/or approved by necessary government agencies, which could increase our costs and would adversely affect our business. In addition, if the current government shutdown continues, it could significantly impact the ability of FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. For example, over the last several years, the United States government has shut down several times and certain regulatory agencies, such as FDA, have had to furlough critical employees and stop critical activities. Additionally, Congress may introduce and ultimately pass healthcare-related legislation that could impact the drug approval process.

We are subject to extensive governmental regulation, which increases our cost of doing business and may affect our ability to commercialize any new products that we may develop.

The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of pharmaceutical products through lengthy and detailed laboratory, preclinical and clinical testing procedures and other costly and time-consuming procedures to establish safety and efficacy. All of our drugs and drug candidates require receipt and maintenance of governmental approvals for commercialization. Preclinical and clinical trials and manufacturing of our drug candidates will be subject to the rigorous testing and approval processes of the FDA and corresponding foreign regulatory authorities. Satisfaction of these requirements typically takes a significant number of years and can vary substantially based upon the type, complexity, and novelty of the product.

Due to the time-consuming and uncertain nature of the drug candidate development process and the governmental approval process described above, we cannot be certain when we, independently or with our collaborative partners, might submit a BLA for FDA or other regulatory review. Further, our ability to commence and/or complete development projects will be subject to our ability to raise enough funds to pay for the development costs of these projects. Government regulation also affects the manufacturing and marketing of pharmaceutical products. Government regulations may delay marketing of our potential drugs for a considerable or indefinite period of time, impose costly procedural requirements upon our activities and furnish a competitive advantage to larger companies or companies more experienced in regulatory affairs. Delays in obtaining governmental regulatory approval could adversely affect our marketing as well as our ability to generate significant revenues from commercial sales.

Our drug candidates may not receive FDA or other regulatory approvals on a timely basis or at all. Moreover, if regulatory approval of a drug candidate is granted, such approval may impose limitations on the indicated use for which such drug may be marketed. Even if we obtain initial regulatory approvals for our drug candidates, our drugs and our manufacturing facilities would be subject to continual review and periodic inspection, and later discovery of previously unknown problems with a drug, manufacturer or facility may result in restrictions on the marketing or manufacture of such drug, including withdrawal of the drug from the market. The FDA and other regulatory authorities stringently apply regulatory standards and failure to comply with regulatory standards can, among other things, result in fines, denial or withdrawal of regulatory approvals, product recalls or seizures, operating restrictions, and criminal prosecution.

Further, the current federal administration has announced that it is looking for opportunities to improve efficiency and identify fraud and ineffective use of resources at government agencies, including through DOGE. This includes government agencies we may interact with like the FDA. There is a possibility that changes will be made at the FDA, and other governmental agencies that we may interact with, and that these changes could have a material adverse impact on our business.

ITEM 5. OTHER INFORMATION

Securities Trading Arrangements of Directors and Executive Officers

During the fiscal quarter ended September 30, 2025, none of our directors or officers (as defined in Rule 16a-1 under the Exchange Act) adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 105b-1 trading arrangement" (as those terms are defined in Item 408 of Regulation S-K).

ITEM 6. EXHIBITS

See Exhibit Index below, which is incorporated by reference herein.

Exhibit Index

Exhibits:	Description of Document
4.1	Warrant to Purchase Common Stock, by and between Abeona Therapeutics Inc. and Avenue Venture Opportunities Fund, L.P., dated as of July 18, 2025 (incorporated by reference to Exhibit 4.1 of our Form 8-K filed on July 18, 2025).
4.2	Warrant to Purchase Common Stock, by and between Abeona Therapeutics Inc. and Avenue Venture Opportunities Fund II, L.P., dated as of July 18, 2025 (incorporated by reference to Exhibit 4.2 of our Form 8-K filed on July 18, 2025).
10.1	First Amendment to Loan and Security Agreement and Supplement, by and among Abeona Therapeutics Inc., MacroChem Corporation, Abeona Therapeutics LLC, Avenue Venture Opportunities Fund, L.P., as Agent, and Avenue Venture Opportunities Fund II, L.P., dated as of July 18, 2025 (incorporated by reference to Exhibit 10.1 of our Form 8-K filed on July 18, 2025).
31.1	Principal Executive Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.*
31.2	Principal Financial Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934. *
32**	Certification 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 Abeona's Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, formatted in Inline XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at September 30, 2025 and December 31, 2024 (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2025 and 2024 (unaudited), (iii) Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the three and nine months ended September 30, 2025 and 2024 (unaudited), (iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2025 and 2024 (unaudited), and (v) Notes to Condensed Consolidated Financial Statements (unaudited).
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
** Pursuant to Item 601(b)(32)(ii) of Regulation S-K, this exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filing.

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.

ABEONA THERAPEUTICS INC.

Date: November 12, 2025

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2025

By: */s/ Joseph Vazzano*
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 31.1

PRINCIPAL EXECUTIVE OFFICER CERTIFICATION PURSUANT TO 18 U.S.C.
SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Vishwas Seshadri, certify that:

1. I have reviewed this report on Form 10-Q for the quarterly period ended September 30, 2025, of Abeona Therapeutics Inc.;
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: November 12, 2025

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

PRINCIPAL FINANCIAL OFFICER CERTIFICATION PURSUANT TO 18 U.S.C.
SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph Vazzano, certify that:

1. I have reviewed this report on Form 10-Q for the quarterly period ended September 30, 2025, of Abeona Therapeutics Inc.;
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: November 12, 2025

By: */s/ Joseph Vazzano*
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32

CERTIFICATION PURSUANT TO 18 U.S.C.
SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Abeona Therapeutics Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Vishwas Seshadri, President and Chief Executive Officer of the Company, and Joseph Vazzano, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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: November 12, 2025

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2025

By: */s/ Joseph Vazzano*
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)