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**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 March 31, 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**

(State or Other Jurisdiction of  
incorporation or Organization)

**83-0221517**

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

**6555 Carnegie Avenue, 4<sup>th</sup> 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 ☐

Accelerated filer ☐

Non-accelerated filer ☒

Smaller reporting company ☒

Emerging growth company ☐

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

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

The number of shares outstanding of the registrant's common stock as of May 9, 2025 was 51,156,736 shares.

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**ABEONA THERAPEUTICS INC.**  
**Form 10-Q**  
**For the Quarter Ended March 31, 2025**

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## 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 belief that ZEVASKYN™ could potentially benefit patients with RDEB; 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 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 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; and our ability to meet our obligations contained in license agreements to which we are party.*

**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)

	<u>March 31, 2025</u>	<u>December 31, 2024</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 15,936	\$ 23,357
Short-term investments	68,219	74,363
Restricted cash	338	338
Other receivables	1,617	1,652
Prepaid expenses and other current assets	2,011	1,143
Total current assets	88,121	100,853
Property and equipment, net	6,947	4,430
Operating lease right-of-use assets	4,239	3,552
Other assets	57	96
Total assets	<u>\$ 99,364</u>	<u>\$ 108,931</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,018	\$ 3,441
Accrued expenses	3,887	6,333
Current portion of long-term debt	8,148	5,926
Current portion of operating lease liability	613	823
Other current liabilities	317	64
Total current liabilities	17,983	16,587
Long-term operating lease liabilities	4,078	3,262
Long-term debt	11,138	13,037
Warrant liabilities	24,769	32,014
Total liabilities	57,968	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 March 31, 2025 and December 31, 2024, respectively	—	—
Common stock - \$0.01 par value; authorized 200,000,000 shares; 48,953,171 and 45,644,091 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	490	457
Additional paid-in capital	866,260	856,824
Accumulated deficit	(825,287)	(813,258)
Accumulated other comprehensive loss	(67)	8
Total stockholders' equity	41,396	44,031
Total liabilities and stockholders' equity	<u>\$ 99,364</u>	<u>\$ 108,931</u>

*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 Loss  
(\$ in thousands, except share and per share amounts)  
(Unaudited)

	<b>For the three months ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
Revenues:		
License and other revenues	\$ —	\$ —
Expenses:		
Research and development	9,941	7,207
General and administrative	9,786	7,123
Total expenses	19,727	14,330
Loss from operations	(19,727)	(14,330)
Interest income	1,310	843
Interest expense	(998)	(952)
Change in fair value of warrant and derivative liabilities	7,245	(17,301)
Other income	141	162
Net loss	<u>\$ (12,029)</u>	<u>\$ (31,578)</u>
Basic and diluted loss per common share	<u>\$ (0.24)</u>	<u>\$ (1.16)</u>
Weighted average number of common shares outstanding - basic and diluted	<u>49,778,801</u>	<u>27,315,537</u>
Other comprehensive income (loss):		
Change in unrealized gains related to available-for-sale debt securities	(75)	(118)
Comprehensive loss	<u>\$ (12,104)</u>	<u>\$ (31,696)</u>

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

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

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Total Stockholder's (Deficit) Equity</u>
	<u>Shares</u>	<u>Amount</u>				
<b>Balance at December 31, 2023</b>	26,523,878	\$ 265	\$ 764,151	\$ (749,524)	\$ (66)	\$ 14,826
Stock-based compensation expense	—	—	1,546	—	—	1,546
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement	137,500	2	(16)	—	—	(14)
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	889,315	9	6,448	—	—	6,457
Net loss	—	—	—	(31,578)	—	(31,578)
Other comprehensive loss	—	—	—	—	(118)	(118)
<b>Balance at March 31, 2024</b>	<u>27,550,693</u>	<u>\$ 276</u>	<u>\$ 772,129</u>	<u>\$ (781,102)</u>	<u>\$ (184)</u>	<u>\$ (8,881)</u>

  

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>				
<b>Balance at December 31, 2024</b>	45,644,091	\$ 457	\$ 856,824	\$ (813,258)	\$ 8	\$ 44,031
Stock-based compensation expense	—	—	2,701	—	—	2,701
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement	1,996,797	20	(51)	—	—	(31)
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	1,312,283	13	6,786	—	—	6,799
Net loss	—	—	—	(12,029)	—	(12,029)
Other comprehensive loss	—	—	—	—	(75)	(75)
<b>Balance at March 31, 2025</b>	<u>48,953,171</u>	<u>\$ 490</u>	<u>\$ 866,260</u>	<u>\$ (825,287)</u>	<u>\$ (67)</u>	<u>\$ 41,396</u>

*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)

	<b>For the three months ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (12,029)	\$ (31,578)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	534	491
Stock-based compensation expense	2,701	1,546
Change in fair value of warrant and derivative liabilities	(7,245)	17,301
Accretion and interest on short-term investments	455	(59)
Amortization of right-of-use lease assets	281	233
Non-cash interest	323	345
Change in operating assets and liabilities:		
Other receivables	35	252
Prepaid expenses and other current assets	(868)	(1,232)
Other assets	39	163
Accounts payable and accrued expenses	(2,378)	(1,690)
Lease liabilities	(362)	(310)
Other current liabilities	112	—
Net cash used in operating activities	(18,402)	(14,538)
<b>Cash flows from investing activities:</b>		
Capital expenditures	(1,401)	(725)
Purchases of short-term investments	(48,645)	(29,343)
Proceeds from maturities of short-term investments	54,259	22,251
Net cash provided by (used in) investing activities	4,213	(7,817)
<b>Cash flows from financing activities:</b>		
Proceeds from ATM sales of common stock, net of issuance costs	6,799	6,417
Payments related to net settlement of restricted share awards	(31)	(14)
Proceeds from issuance of long-term debt	—	20,000
Payment of debt issuance costs	—	(963)
Net cash provided by financing activities	6,768	25,440
Net (decrease) increase in cash, cash equivalents and restricted cash	(7,421)	3,085
Cash, cash equivalents and restricted cash at beginning of period	23,695	14,811
Cash, cash equivalents and restricted cash at end of period	\$ 16,274	\$ 17,896
<b>Supplemental cash flow information:</b>		
Cash and cash equivalents	\$ 15,936	\$ 17,558
Restricted cash	338	338
Total cash, cash equivalents and restricted cash	\$ 16,274	\$ 17,896
<b>Supplemental non-cash flow information:</b>		
Right-of-use asset obtained in exchange for new operating lease liabilities	\$ 968	\$ —
Derivative and warrant additions associated with loan and security agreement	\$ —	\$ 1,042
Changes in accrued property and equipment	\$ 1,179	\$ —
Cash paid for interest	\$ 675	\$ 607
Cash paid for taxes	\$ —	\$ 8

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

## ABEONA THERAPEUTICS INC. AND SUBSIDIARIES

### Notes to Unaudited Condensed Consolidated Financial 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 that the Company has exclusively licensed from the University of North Carolina at Chapel Hill and developed internally through its AAV vector research programs.

##### Liquidity

In accordance with Accounting Standards Codification ("ASC") 205-40, *Going Concern*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the accompanying unaudited interim condensed consolidated financial statements were issued.

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 and 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.

Since its inception, the Company has funded its operations primarily with proceeds from sales of shares of its stock. The Company has incurred recurring losses since its inception, including net losses of \$12.0 million and \$31.6 million for the three months ended March 31, 2025 and 2024, respectively. As of March 31, 2025, the Company had an accumulated deficit of approximately \$825.3 million. To date the Company has not generated any significant revenues and may continue to generate operating losses for the until ZEVASKYN™ can provide sufficient revenue for the Company to be profitable. As of the issuance date of these unaudited interim condensed consolidated financial statements, the Company expects that its existing cash, cash equivalents, restricted cash and short-term investments of \$84.5 million as of March 31, 2025 in addition to the \$10.5 million in net proceeds from the Company's subsequent sale of common stock under the ATM Agreement and the gross proceeds of \$155 million upon the closing of our asset purchase agreement for the sale of our Rare Disease Priority Review Voucher, will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months from the issuance date of these condensed consolidated financial statements.

While the Company believes its capital resources are sufficient to fund the Company's on-going operations for the next 12 months from the issuance date of these unaudited condensed consolidated financial statements, the Company's liquidity could be materially affected over this period by: (1) its ability to raise additional capital through equity offerings, debt financings, or other non-dilutive third-party funding; (2) costs associated with new or existing strategic alliances, or licensing and collaboration arrangements; (3) negative regulatory events or unanticipated costs related to ZEVASKYN™; (4) its ability to generate revenue through its sales of ZEVASKYN™; or (5) any other unanticipated material negative events or costs. One or more of these events or costs could materially affect the Company's liquidity. If the Company is unable to meet its obligations when they become due, the Company may have to delay expenditures, reduce the scope of its research and development programs, or make significant changes to its operating plan. The accompanying unaudited interim condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

## **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 that are of significance, or potential significance, to the Company.

### **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.

### **Other receivables**

Other receivables include employee retention credits ("ERC"), sublease rent receivables and other miscellaneous receivables that are expected to be collected within the next twelve months. As of March 31, 2025 and December 31, 2024, the Company had ERC 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 March 31, 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, and the credit quality of its significant customers, the current economic environment/macroeconomic trends, supportable forecasts, and other relevant factors. The Company's accounts receivable are with customers that do not have a history of uncollectibility nor a history of significantly aged accounts receivables. As of March 31, 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 clinical-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 Loss Per Share

Basic and diluted net loss per share is computed by dividing net 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. 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. Potential dilutive securities result from outstanding restricted stock, stock options, conversion features of loan agreements, and stock purchase warrants.

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 March 31,	
	2025	2024
Shares of common stock issuable upon exercise of stock options	176,179	179,001
Shares of common stock underlying outstanding restricted stock	5,250,307	2,542,619
Shares of common stock issuable upon exercise of conversion feature of loan agreement	614,251	505,263
Shares of common stock issuable upon exercise of warrants	9,987,560	9,397,879
Total	16,028,297	12,624,762

## 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 will 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):

March 31, 2025				
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments:				
U.S. treasury securities	\$ 35,462	—	(26)	\$ 35,436
U.S. federal agency securities	32,823	—	(40)	32,783
Total available-for-sale, short-term investments	<u>\$ 68,285</u>	<u>—</u>	<u>(66)</u>	<u>\$ 68,219</u>

  

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	<u>\$ 74,355</u>	<u>30</u>	<u>(22)</u>	<u>\$ 74,363</u>

As of March 31, 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 March 31, 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 months ended March 31, 2025.

There were no significant realized gains or losses recognized on the sale or maturity of available-for-sale investments for the three months ended March 31, 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)	March 31, 2025	December 31, 2024
Laboratory equipment	5	\$ 9,186	\$ 8,868
Furniture, software and office equipment	3 to 5	1,189	1,113
Leasehold improvements	Shorter of remaining lease term or useful life	8,805	8,805
Construction-in-progress		3,280	624
Subtotal		22,460	19,410
Less: accumulated depreciation		(15,513)	(14,980)
Total property and equipment, net		<u>\$ 6,947</u>	<u>\$ 4,430</u>

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

Depreciation and amortization on property and equipment was \$0.5 million for the three months ended March 31, 2025 and 2024.

## 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, 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 of March 31, 2025 and December 31, 2024, was \$24.3 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 measured at fair value on a recurring and non-recurring basis (in thousands):

Description	Fair Value at March 31, 2025	Level 1	Level 2	Level 3
<b>Recurring Assets</b>				
Cash equivalents				
Money market funds	\$ 9,554	\$ 9,554	\$ —	\$ —
Money market deposit account	5,145	5,145	—	—
Short-term investments				
U.S. treasury securities	35,436	35,436	—	—
U.S. federal agency securities	32,783	—	32,783	—
Total assets measured at fair value	<u>\$ 82,918</u>	<u>\$ 50,135</u>	<u>\$ 32,783</u>	<u>\$ —</u>
<b>Liabilities</b>				
Warrant liabilities	\$ 24,769	\$ —	\$ —	\$ 24,769
Total liabilities measured at fair value	<u>\$ 24,769</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 24,769</u>

Description	Fair Value at December 31, 2024	Level 1	Level 2	Level 3
<b>Recurring Assets</b>				
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	<u>\$ 97,099</u>	<u>\$ 46,704</u>	<u>\$ 50,395</u>	<u>\$ —</u>
<b>Liabilities</b>				
Warrant liabilities	\$ 32,014	\$ —	\$ —	\$ 32,014
Total liabilities measured at fair value	<u>\$ 32,014</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 32,014</u>

#### Warrant Liabilities

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

	March 31, 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	7,609,879	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

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 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 loss.

In January 2024, as part of the Loan and Security Agreement, see Note 8, the Company issued warrants to purchase \$2,400,000 worth of shares of the Company's stock which have an exercise price equal to the lesser of \$4.07 per share and the shares issuable was calculated at 589,681 shares.

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

Warrant liabilities as of December 31, 2024	\$ 32,014
Gain recognized in earnings from change in fair value	(7,245)
Warrant liabilities as of March 31, 2025	<u>\$ 24,769</u>

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:

	March 31, 2025	December 31, 2024
Common share price	\$4.76	\$5.57
Expected term (years)	1.71 – 3.78	1.96 – 4.02
Risk-free interest rate (%)	3.81% – 3.85%	4.16% – 4.24%
Volatility (%)	89.60% - 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):

	March 31, 2025	December 31, 2024
Accrued employee compensation	\$ 1,848	\$ 4,392
Accrued contracted services and other	2,039	1,941
Total accrued expenses	<u>\$ 3,887</u>	<u>\$ 6,333</u>

#### NOTE 7 – LEASES

The Company leases space under operating leases for administrative, manufacturing and laboratory facilities in Cleveland, Ohio. The Company also leases office space in New York, New York, that the Company sublets. The lease for the office space in New York, New York will terminate in September of 2025, which is 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 commences 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 additional space at the 6700 Euclid Avenue facility will allow the Company to convert office space at the 6555 Carnegie Avenue facility into additional manufacturing space to increase ZEVASKYN™ manufacturing capacity. 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 has entered into two sublease agreements with unrelated third parties to occupy the Company's administrative offices in New York, New York. The sublease agreements terminate in September of 2025 at the same time the Company's lease terminates. The Company expects to receive \$0.3 million in future sublease income through September 2025 from the two subleases noted above.

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

	<u>March 31, 2025</u>	<u>December 31, 2024</u>
Current operating lease liability	\$ 613	\$ 823
Non-current operating lease liability	4,078	3,262
Total operating lease liability	<u>\$ 4,691</u>	<u>\$ 4,085</u>

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 loss, as determined by the underlying activities.

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

	<u>For the three months ended March 31,</u>	
	<u>2025</u>	<u>2024</u>
Operating lease cost	\$ 372	\$ 334
Variable lease cost	116	74
Short-term lease cost	8	23
Total operating lease costs	<u>\$ 496</u>	<u>\$ 431</u>

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 March 31, 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 March 31, 2025 were as follows (in thousands):

<u>Future minimum lease payments and obligations</u>	<u>Operating Leases</u>
2025, remainder	\$ 400
2026	1,044
2027	1,114
2028	1,140
2029	1,166
Thereafter	1,191
Total undiscounted operating lease payments	6,055
Less: imputed interest	1,364
Present value of operating lease liabilities	<u>\$ 4,691</u>

The weighted-average remaining term of the Company's operating leases was 62 months and the weighted-average discount rate used to measure the present value of the Company's operating lease liabilities was 8.2% as of March 31, 2025.

The Company received \$0.1 million during the three months ended March 31, 2025 and 2024, of sublease income which is recorded in other income on the condensed consolidated statement of operations and comprehensive loss.

Future cash receipts from the Company's sublease agreements as of March 31, 2025 are as follows (in thousands):

<b>Future cash receipts</b>	<b>Operating Subleases</b>
2025, remainder	\$ 302
Total future cash receipts	<u>\$ 302</u>

#### NOTE 8 – DEBT

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

	<b>March 31, 2025</b>	<b>December 31, 2024</b>
Loan Agreement Principal	\$ 20,000	\$ 20,000
Accreted final payment fee	457	354
Unamortized debt issuance costs and discounts	(1,171)	(1,391)
Total long-term debt	19,286	18,963
Less: current maturities	8,148	5,926
Long-term debt, net of current maturities	<u>\$ 11,138</u>	<u>\$ 13,037</u>

#### 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 recessive dystrophic epidermolysis bullosa, 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 (the "Maturity Date"). 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 May 1, 2025. 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%. The stated interest rate and effective interest rate as of March 31, 2025 was 13.50% and 22.09%, respectively. 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, which will require reclassification of \$5.9 million from current portion of long-term debt to long-term debt as of April 28, 2025.

The Company may, subject to certain parameters, voluntarily prepay the Loans, in whole, at any time. If prepayment occurs on or before the one-year anniversary of the Closing Date, the Company is required to pay a prepayment fee equal to 3.00% of the principal amount of the Loans prepaid; if prepayment occurs after the one-year anniversary of the Closing Date and on or before the two-year anniversary of the Closing Date, the Company is required to pay a fee equal to 2.00% of the principal amount of the Loans; if prepayment occurs after the two-year anniversary of the Closing Date, 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, Tranche 2 Loans and Discretionary Tranche Loans is also due upon the Maturity Date 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. At 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 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 March 31, 2025 (in thousands):

2025, remainder	\$	5,926
2026		8,889
2027		5,185
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 March 31, 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 Hedging* ("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 March 31, 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 months ended March 31, 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 March 31, 2025. The 2024 Pre-Funded Warrants are classified as equity in accordance with ASC 815, *Derivatives and Hedging*, 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 three months ended March 31, 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 1,312,283 and 889,315 shares of its common stock under the ATM Agreement during the three months ended March 31, 2025 and 2024, respectively, resulting in net proceeds of \$6.8 million and \$6.5 million during the three months ended March 31, 2025 and 2024, respectively. Subsequent to March 31, 2025 and through April 28, 2025, the Company sold 2,198,606 shares of common stock under the ATM Agreement resulting in \$10.5 million of net proceeds.

### 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 March 31, 2025, there were 7,609,879 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. There was no warrant activity during the three months ended March 31, 2025, other than the 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 March 31, 2025. The 2023 Pre-Funded Warrants are classified as equity in accordance with ASC 815, *Derivatives and Hedging*, 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 months ended March 31, 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 each of Avenue and Avenue 2 (collectively, the "Warrant Holders") warrants to purchase up to \$480,000 and \$1,920,000 worth of shares, respectively, of Company common stock (collectively, the "January Warrants"). The Warrants expire on January 8, 2029 (the "Expiration Date") 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 and 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 the Expiration Date, 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.

#### 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 March 31, 2025, there were 3,306,588 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 March 31, 2025, there were 531,700 shares available to be granted under the Inducement Plan.

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

	For the three months ended March 31,	
	2025	2024
Research and development	\$ 670	\$ 346
General and administrative	2,031	1,200
Total stock-based compensation expense	<u>\$ 2,701</u>	<u>\$ 1,546</u>

#### 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 recognize 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 months ended March 31, 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 three months ended March 31, 2025:

	<u>Number of Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (years)</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Outstanding at December 31, 2024	176,587	\$ 38.64	5.83	\$ 6
Granted	—	\$ —	—	\$ —
Cancelled/forfeited	(408)	\$ 17.25	—	\$ —
Exercised	—	\$ —	—	\$ —
Outstanding at March 31, 2025	<u>176,179</u>	<u>\$ 38.69</u>	<u>5.60</u>	<u>\$ 3</u>
Exercisable	169,544	\$ 39.29	5.56	\$ 2
Unvested	6,635	\$ 23.42	6.60	\$ 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 March 31, 2025, the total compensation cost related to non-vested option awards not yet recognized was approximately \$0.1 million with a weighted average remaining vesting period of 0.5 years.

#### Restricted Stock

The following table summarizes restricted stock award activity during the three months ended March 31, 2025:

	<u>Number of Awards</u>	<u>Weighted Average Grant Date Fair Value Per Unit</u>
Outstanding at December 31, 2024	3,320,811	\$ 4.60
Granted	2,009,280	\$ 5.24
Cancelled/forfeited	(11,617)	\$ 4.73
Vested	(68,167)	\$ 8.25
Outstanding at March 31, 2025	<u>5,250,307</u>	<u>\$ 4.79</u>

As of March 31, 2025, there was \$19.8 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 2.2 years. The total fair value of restricted stock awards that vested during the three months ended March 31, 2025 and 2024 was \$0.6 million and \$0.5 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 March 31, 2025, the Company is subject to remaining milestone payments totaling approximately \$0.2 million which became due upon FDA approval of ZEVASKYN™ on April 28, 2025.

### **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 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. As of March 31, 2025, no milestone or royalty payments under this agreement have been made.

### **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. As of March 31, 2025, no milestone or royalty payments under this agreement have been made. 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.

### **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. As of March 31, 2025, no milestone or royalty payments under this agreement have been made. 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.

### **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 the 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 months ended March 31, 2025 and 2024, respectively, based on event-based-milestone payments. The Company has no contract assets or liabilities as of March 31, 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 the 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 has 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 months ended March 31, 2025 and 2024. As of March 31, 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.

Additionally, pursuant to the License Agreement, Ultragenyx will reimburse the Company for certain development and transition costs actually incurred by the Company. These costs are passed through to Ultragenyx without mark-up. The Company has determined that these costs are not incurred for the purpose of satisfying any performance obligation under the License Agreement. Accordingly, the reimbursement of these costs is recognized as a reduction of research and development costs. As of March 31, 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 loss, which is reported on the consolidated statements of operations and comprehensive loss as consolidated net 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 ZEVAKSYN™ 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 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:

	For the three months ended March 31,	
	2025	2024
License and other revenues	\$ —	\$ —
Research and development costs		
Salaries & related costs	\$ 4,681	\$ 3,555
Non-cash stock-based compensation	670	346
Other research and development costs (a)	4,590	3,306
Total research and development costs	\$ 9,941	\$ 7,207
General and administrative costs		
Salaries & related costs	\$ 3,653	\$ 2,262
Non-cash stock-based compensation	2,031	1,200
Pre-commercial preparation costs	1,207	1,351
Other general and administrative costs (b)	2,895	2,310
Total general and administrative costs	\$ 9,786	\$ 7,123
Other segment items (c)	(7,698)	17,248
Net loss	\$ (12,029)	\$ (31,578)

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

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

(c) Other segment items includes royalties, interest income, interest expense, change in fair value of warrant and derivative liabilities and other income.

#### NOTE 13 – SUBSEQUENT EVENTS

##### FDA Approval

On April 28, 2025, the 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 RDEB, a serious and debilitating genetic skin disease.

##### Loans Principal Payments

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, which will require reclassification of \$5.9 million from current portion of long-term debt to long-term debt as of April 28, 2025.

##### Sale of Priority Review Voucher

On May 9, 2025 the Company entered into a definitive asset purchase agreement to sell its Rare Pediatric Disease Priority Review Voucher (“PRV”) for gross proceeds of \$155 million upon the closing of the transaction. The Company was awarded the PRV following the FDA approval of ZEVASKYN™ (prademagene zamikeracel) on April 28, 2025. The transaction is subject to customary closing conditions, including expiration of the applicable waiting period under the Hart-Scott Rodino (“HSR”) Antitrust Improvements Act.

## 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 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. In connection with the FDA approval of ZEVASKYN™, Abeona received a Rare Pediatric Disease Priority Review Voucher ("PRV"). ZEVASKYN™ has been granted Orphan Drug and Rare Pediatric Disease ("RPD") designations by the FDA and Orphan Drug Designation by the European Medicines Agency ("EMA").

We established a current Good Manufacturing Practices ("cGMP") commercial facility in Cleveland, Ohio for manufacturing ZEVASKYN™ drug product to support our commercial launch. ZEVASKYN™ will be made available beginning in the third quarter of 2025 through ZEVASKYN™ Qualified Treatment Centers ("QTCs"). The QTCs are well-recognized epidermolysis bullosa treatment centers with cell and gene therapy experience, situated across the U.S. to ensure patients nationwide have access to this important treatment.

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 exclusively licensed from the University of North Carolina at Chapel Hill and developed internally through our AAV vector research programs. 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

#### Sale of Priority Review Voucher

On May 9, 2025, we entered into a definitive asset purchase agreement to sell its Rare Pediatric Disease Priority Review Voucher ("PRV") for gross proceeds of \$155 million upon the closing of the transaction. We were awarded the PRV following the FDA approval of ZEVASKYN™ on April 28, 2025. The transaction is subject to customary closing conditions, including expiration of the applicable waiting period under the Hart-Scott Rodino ("HSR") Antitrust Improvements Act.

#### First Qualified Treatment Center Activation

On May 14, 2025, we announced that Ann & Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's") is now activated as the first QTC for ZEVASKYN™. Lurie Children's has completed QTC start-up activities enabling it to begin patient identification for scheduling of ZEVASKYN treatment. Treatments are expected to begin in the third quarter of 2025.

## RESULTS OF OPERATIONS

### Comparison of Three Months Ended March 31, 2025 and March 31, 2024

(\$ in thousands)	For the three months ended March 31,		Change	
	2025	2024	\$	%
Expenses:				
Research and development	\$ 9,941	\$ 7,207	\$ 2,734	38%
General and administrative	9,786	7,123	2,663	37%
Total expenses	19,727	14,330	5,397	38%
Loss from operations	(19,727)	(14,330)	(5,397)	38%
Interest income	1,310	843	467	55%
Interest expense	(998)	(952)	(46)	5%
Change in fair value of warrant and derivative liabilities	7,245	(17,301)	24,546	(142)%
Other income	141	162	(21)	(13)%
Net loss	\$ (12,029)	\$ (31,578)	\$ 19,549	(62)%

#### Research and development

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

Total research and development spending for the three months ended March 31, 2025 was \$9.9 million, as compared to \$7.2 million for the same period of 2024, an increase of \$2.7 million. The increase in expenses was primarily due to a \$1.1 million increase in salaries and \$0.3 million in non-cash stock-based compensation costs due to increased headcount related to scale up of manufacturing capacity in preparation for the planned launch of ZEVASKYN™ and \$0.9 million in pre-clinical development work.

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.

#### General and administrative

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), costs for planned commercial launch and other general operating expenses not otherwise included in research and development expenses.

Total general and administrative expenses were \$9.8 million for the three months ended March 31, 2025, as compared to \$7.1 million for the same period of 2024, an increase of \$2.7 million. The increase in expenses was primarily due to:

- increased salary and related costs of \$1.4 million;
- increased non-cash stock-based compensation of \$0.8 million; and
- increased other costs such as professional fees, rent, and recruiting of \$0.5 million.

#### Interest income

Interest income was \$1.3 million for the three months ended March 31, 2025, as compared to \$0.8 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 \$1.0 million for the three months ended March 31, 2025 and 2024. Interest expense is due to the credit facility entered into by the Company in January 2024.

#### Change in fair value of warrant and derivative liabilities

The change in fair value of warrant liabilities was a gain of \$7.2 million for the three months ended March 31, 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 year over the year and a shorter term.

The change in fair value of warrant and derivative liabilities was a loss of \$17.3 million for the three months ended March 31, 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 year as of March 31, 2024 compared to December 31, 2023.

#### Other income

Other income was \$0.1 million for the three months ended March 31, 2025, as compared to \$0.2 million in the same period of 2024. Other income includes sublease income and saw a minor reduction period over period.

## LIQUIDITY AND CAPITAL RESOURCES

### Cash Flows for the Three Months Ended March 31, 2025 and 2024

(\$ in thousands)	For the three months ended March 31,	
	2025	2024
Total cash, cash equivalents and restricted cash (used in) provided by:		
Operating activities	\$ (18,402)	\$ (14,538)
Investing activities	4,213	(7,817)
Financing activities	6,768	25,440
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (7,421)</u>	<u>\$ 3,085</u>

#### Operating activities

Net cash used in operating activities was \$18.4 million for the three months ended March 31, 2025, primarily comprised of our net loss of \$12.0 million and decreases in operating assets and liabilities of \$3.4 million and net non-cash charges of \$3.0 million. Non-cash charges consisted primarily of \$7.2 million of gain as a result of the change in fair value of warrant and derivative liabilities, \$2.7 million of stock-based compensation and \$0.5 million of depreciation and amortization.

Net cash used in operating activities was \$14.5 million for the three months ended March 31, 2024, primarily comprised of our net loss of \$31.6 million and decreases in operating assets and liabilities of \$2.8 million and net non-cash charges of \$19.9 million. Non-cash charges consisted primarily of \$17.3 million of the change in fair value of warrant and derivative liabilities, \$1.5 million of stock-based compensation and \$0.5 million of depreciation and amortization.

#### Investing activities

Net cash provided by investing activities was \$4.2 million for the three months ended March 31, 2025, primarily comprised of proceeds from maturities of short-term investments of \$54.2 million, offset by purchases of short-term investments of \$48.6 million and capital expenditures of \$1.4 million.

Net cash used in investing activities was \$7.8 million for the three months ended March 31, 2024, primarily comprised of proceeds from maturities of short-term investments of \$22.3 million, offset by purchases of short-term investments of \$29.3 million and capital expenditures of \$0.7 million.

#### Financing activities

Net cash provided by financing activities was \$6.8 million for the three months ended March 31, 2025, primarily comprised of proceeds of \$6.8 million from open market sales of common stock pursuant to the ATM Agreement (as defined below).

Net cash provided by financing activities was \$25.4 million for the three months ended March 31, 2024, primarily comprised of proceeds of \$6.4 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 sales of common stock.

Our principal source of liquidity is cash, cash equivalents, restricted cash and short-term investments, collectively referred to as our cash resources. As of March 31, 2025, our cash resources were \$84.5 million. We believe that our current cash and cash equivalents, restricted cash and short-term investments in addition to the \$10.5 million in net proceeds from our subsequent sale of common stock under the ATM and the gross proceeds of \$155 million upon the closing of our definite asset purchase agreement to sell our PRV, 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 1,312,283 shares of our common stock under the ATM Agreement and received \$6.8 million of net proceeds during the three months ended March 31, 2025. We sold 889,315 shares of our common stock under the ATM Agreement and received \$6.4 million of net proceeds during the three months ended March 31, 2024. Subsequent to March 31, 2025 and through April 28, 2025, we sold 2,198,606 shares of our common stock under the ATM Agreement resulting in \$10.5 million in net proceeds.

Since our inception, 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. 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 anticipates 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 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, our ability to successfully commercialize our product candidates, our ability to obtain applicable regulatory approval to market our product candidates, our ability to obtain necessary additional capital to fund operations in the future, our ability to successfully manufacture our products and our product candidates in clinical quantities or for commercial purposes, government regulation to which we are subject, the uncertainty associated with preclinical and clinical testing, intense competition that we face, the potential necessity of licensing technology from third parties and protection of our intellectual property, 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 in the risks 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 March 31, 2025, as such term is defined in Rules 13a-151 and 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 March 31, 2025 were effective.

**Changes in Internal Control Over Financial Reporting** – There were no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 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.

***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.

***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 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 a prolonged government shutdown occurs, 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 FDA 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 the 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(c) The following table provides information about purchases of equity securities that are registered pursuant to Section 12 of the Exchange Act for the quarter ended March 31, 2025:

	Total number of shares (or units) purchased <sup>(a)</sup>	Average price paid per share (or unit)
<i>Shares delivered or withheld pursuant to restricted stock awards</i>		
January 1, 2025 - January 31, 2025	—	\$ —
February 1, 2025 - February 28, 2025	—	\$ —
March 1, 2025 - March 31, 2025	866	\$ 5.28
	<u>866</u>	<u>\$ 5.28</u>

(a) Reflects shares of common stock surrendered to the Company for payment of tax withholding obligations in connection with the vesting of restricted stock.

## ITEM 5. OTHER INFORMATION

### Securities Trading Arrangements of Directors and Executive Officers

During the fiscal quarter ended March 31, 2025, Leila Alland, M.D., a member of the Company's board of directors, adopted a "Rule 10b5-1 trading arrangement" as defined in Regulation S-K Item 408 providing for the sale from time to time of an aggregate of up to 64,800 shares of our common stock. The duration of the trading arrangement is until June 22, 2026, or earlier if all transactions under the trading arrangement are completed.

## ITEM 6. EXHIBITS

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

### Exhibit Index

Exhibits: Description of Document

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 March 31, 2025, formatted in Inline XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at March 31, 2025 and December 31, 2024 (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2025 and 2024 (unaudited), (iii) Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the three months ended March 31, 2025 and 2024 (unaudited), (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 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)

\* 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: May 15, 2025

By: /s/ Vishwas Seshadri

Vishwas Seshadri  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: May 15, 2025

By: /s/ Joseph Vazzano

Joseph Vazzano  
Chief Financial Officer  
(Principal Financial Officer)

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 March 31, 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: May 15, 2025

By: /s/ Vishwas Seshadri

Vishwas Seshadri  
President and Chief Executive Officer  
(Principal Executive Officer)

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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 March 31, 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: May 15, 2025

By: /s/ Joseph Vazzano

Joseph Vazzano  
Chief Financial Officer  
(Principal Financial Officer)

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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 March 31, 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: May 15, 2025

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

Date: May 15, 2025

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

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