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, 2024

or

□ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number **001-15771**

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

Delaware	**83-0221517**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer I.D. No.)

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer □
Non-accelerated filer ☒
Emerging growth company □

Accelerated filer □
Smaller reporting company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial 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 10, 2024 was 41,186,004 shares.

ABEONA THERAPEUTICS INC.
Form 10-Q
For the Quarter Ended March 31, 2024

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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, among other things: our ability to address the items raised in the FDA's complete response letter related to our Biologics License Application for pz-cel; the timing and outcome of our resubmission of a Biologics License Application for pz-cel; 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 pz-cel could potentially benefit patients with RDEB; our belief in the adequacy of the clinical trial data from our VIITAL™ clinical trial, together with the data generated in the program to date, to support regulatory approvals; 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, 2023, as updated from time to time in the Company's SEC filings, including this Quarterly Report on Form 10-Q. These factors include: the timing and outcome of our resubmission of the Biologics License Application for pz-cel; 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; 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 U.S. Food and Drug Administration ("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 potential 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)

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,558	$ 14,473
Short-term investments	44,786	37,753
Restricted cash	338	338
Other receivables	2,232	2,444
Prepaid expenses and other current assets	1,811	729
Total current assets	66,725	55,737
Property and equipment, net	3,767	3,533
Operating lease right-of-use assets	4,222	4,455
Other assets	114	277
Total assets	$ 74,828	$ 64,002
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 3,362	$ 1,858
Accrued expenses	2,791	5,985
Current portion of operating lease liability	1,044	998
Current portion of payable to licensor	4,691	4,580
Other current liabilities	1	1
Total current liabilities	11,889	13,422
Long-term operating lease liabilities	4,046	4,402
Long-term debt	18,079	—
Derivative liabilities	1,005	—
Warrant liabilities	48,690	31,352
Total liabilities	83,709	49,176
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock - $0.01 par value; authorized 2,000,000 shares; No shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	—	—
Common stock - $0.01 par value; authorized 200,000,000 shares; 27,550,593 and 26,523,878 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	276	265
Additional paid-in capital	772,129	764,151
Accumulated deficit	(781,102)	(749,524)
Accumulated other comprehensive loss	(184)	(66)
Total stockholders' (deficit) equity	(8,881)	14,826
Total liabilities and stockholders' equity	$ 74,828	$ 64,002

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)

	For the three months ended March 31,	
	2024	**2023**
Revenues:		
License and other revenues	$ —	$ —
Expenses:		
Research and development	7,207	8,041
General and administrative	7,123	3,997
Total expenses	14,330	12,038
Loss from operations	(14,330)	(12,038)
Interest income	843	364
Interest expense	(952)	(101)
Change in fair value of warrant and derivative liabilities	(17,301)	2,265
Other income	162	403
Net loss	$ (31,578)	$ (9,107)
Basic and diluted loss per common share	$ (1.16)	$ (0.54)
Weighted average number of common shares outstanding – basic and diluted	27,315,537	16,904,024
Other comprehensive income (loss):		
Change in unrealized (losses) gains related to available-for-sale debt securities	(118)	64
Comprehensive loss	$ (31,696)	$ (9,043)

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)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2023	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 income	—	—	—	—	(118)	(118)
Balance at March 31, 2024	27,550,693	$ 276	$ 772,129	$ (781,102)	$ (184)	$ (8,881)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	17,719,720	$ 177	$ 722,049	$ (695,336)	$ (129)	$ 26,761
Stock-based compensation expense	—	—	770	—	—	770
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement	111,064	1	(5)	—	—	(4)
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	98,560	1	255	—	—	256
Net loss	—	—	—	(9,107)	—	(9,107)
Other comprehensive income	—	—	—	—	64	64
Balance at March 31, 2023	17,929,344	$ 179	$ 723,069	$ (704,443)	$ (65)	$ 18,740

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

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

	For the three months ended March 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (31,578)	$ (9,107)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	491	661
Stock-based compensation expense	1,546	770
Change in fair value of warrant and derivative liabilities	17,301	(2,265)
Accretion and interest on short-term investments	(59)	(117)
Amortization of right-of-use lease assets	233	227
Non-cash interest	345	100
Change in operating assets and liabilities:		
Other receivables	252	(75)
Prepaid expenses and other current assets	(1,232)	(1,199)
Other assets	163	(56)
Accounts payable and accrued expenses	(1,690)	(376)
Lease liabilities	(310)	(308)
Other current liabilities	—	1
Net cash used in operating activities	(14,538)	(11,744)
Cash flows from investing activities:		
Capital expenditures	(725)	(218)
Purchases of short-term investments	(29,343)	(7,964)
Proceeds from maturities of short-term investments	22,251	10,393
Net cash (used in) provided by investing activities	(7,817)	2,211
Cash flows from financing activities:		
Proceeds from ATM sales of common stock, net of issuance costs	6,417	—
Payment from net settlement of restricted share awards	(14)	(4)
Proceeds from issuance of long-term debt	20,000	—
Payment of debt issuance costs	(963)	—
Net cash provided by (used in) financing activities	25,440	(4)
Net increase (decrease) in cash, cash equivalents and restricted cash	3,085	(9,537)
Cash, cash equivalents and restricted cash at beginning of period	14,811	14,555
Cash, cash equivalents and restricted cash at end of period	$ 17,896	$ 5,018
Supplemental cash flow information:		
Cash and cash equivalents	$ 17,558	$ 4,680
Restricted cash	338	338
Total cash, cash equivalents and restricted cash	$ 17,896	$ 5,018
Supplemental non-cash flow information:		
Derivative and warrant additions associated with loan and security agreement	$ 1,042	$ —
Cash paid for interest	$ 607	$ —
Cash paid for taxes	$ 8	$ 6

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

NOTE 1 – NATURE OF OPERATIONS AND SIGNIFICANT ACCOUNTING POLICIES

Background

Abeona Therapeutics Inc. (together with the Company's subsidiaries, "Abeona" or the "Company"), a Delaware corporation, is a clinical-stage biopharmaceutical company developing cell and gene therapies for life-threatening diseases. The Company's lead clinical program is for pz-cel, an autologous, engineered cell therapy currently in development for recessive dystrophic epidermolysis bullosa ("RDEB"). The Company's development portfolio also features adeno-associated virus ("AAV")-based gene therapies designed to treat highly unmet, medically needed ophthalmic diseases using the novel AIM™ capsids that the Company has exclusively licensed from the University of North Carolina at Chapel Hill, and internal AAV vector research programs.

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, 2023 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, 2023, which was filed with the SEC on March 18, 2024.

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 pz-cel 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 for the foreseeable future.

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 $31.6 million and $9.1 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, the Company had an accumulated deficit of approximately $781.1 million. To date the Company has not generated any significant revenues and expects to continue to generate operating losses for the foreseeable future. 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 $62.7 million as of March 31, 2024 plus the gross proceeds of $75.0 million from its underwritten offering that closed on May 7, 2024, 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 pz-cel; (4) 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.

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 unaudited interim condensed consolidated financial statements and the reported amounts of revenue and expenses during the reported period. 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. As of March 31, 2024 and December 31, 2023, the Company had ERC receivables of $2.1 million.

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, 2023 that are of significance, or potential significance, to the Company.

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, 2024, 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, 2024, the Company did not recognize a credit loss allowance for its investments or accounts receivable.

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, 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,	
	2024	2023
Shares of common stock issuable upon exercise of stock options	179,001	234,697
Shares of common stock underlying restricted stock	2,542,619	929,946
Shares of common stock issuable upon exercise of warrants	9,903,142	9,397,879
Total	12,624,762	10,562,522

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 (i) $4.75 and (ii) the price per share of the Company's net bona fide round of equity financing before September 30, 2024 (the "2024 Loan Agreement Warrants"). Utilizing the exercise price of $4.75, which is the only known price at March 31, 2024, the Company included 505,263 and nil of shares of common stock issuable upon exercise of the 2024 Loan Agreement Warrants for the three months ended March 31, 2024 and 2023, respectively, in the table above. In connection with the underwritten common stock financing consummated on May 7, 2024 pursuant to the terms of the 2024 Loan Agreement Warrants, the exercise price of the 2024 Loan Agreement Warrants was reduced to the lesser of (i) $4.07 per share 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.

Recently Adopted Accounting Pronouncements

The Company did not adopt any new accounting pronouncements during the three months ended March 31, 2024.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU No. 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 Company is currently assessing the impact that the adoption will have on its consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): *Improvements to Reportable Segment Disclosures,* which expands disclosures about a public entity's reportable segments and requires more enhanced information about a reportable segment's expenses, interim segment profit or loss, and how a public entity's chief operating decision maker uses reported segment profit or loss information in assessing segment performance and allocating resources. The standard is effective for annual reporting periods beginning after December 15, 2023, and interim periods within years beginning after December 15, 2024, with early adoption permitted. The Company is currently assessing the impact that the adoption will have on its consolidated financial statements.

NOTE 2 – SHORT-TERM INVESTMENTS

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

	March 31, 2024			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments:				
U.S. treasury securities	$ 36,999	—	(167)	$ 36,832
U.S. federal agency securities	7,970	—	(16)	7,954
Total available-for-sale, short-term investments	$ 44,969	—	(183)	$ 44,786

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments:				
U.S. treasury securities	$ 8,406	—	(13)	$ 8,393
U.S. federal agency securities	29,413	—	(53)	29,360
Total available-for-sale, short-term investments	$ 37,819	—	(66)	$ 37,753

As of March 31, 2024, 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, 2024, 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, 2024.

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, 2024 or 2023.

NOTE 3 – 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, 2024	December 31, 2023
Laboratory equipment	5	$ 7,498	$ 6,935
Furniture, software and office equipment	3 to 5	1,045	986
Leasehold improvements	Shorter of remaining lease term or useful life	8,706	8,603
Subtotal		17,249	16,524
Less: accumulated depreciation		(13,482)	(12,991)
Total property and equipment, net		$ 3,767	$ 3,533

Depreciation and amortization on property and equipment was $0.5 million and $0.7 million for the three months ended March 31, 2024 and 2023, respectively.

NOTE 4 – FAIR VALUE MEASUREMENTS

The Company calculates the fair value of the Company's assets and liabilities that qualify as financial instruments and includes additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of other receivables, prepaid expenses and other current assets, other assets, accounts payable, accrued expenses, and payables to licensor approximate their carrying amounts due to the relatively short maturity of these instruments.

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 as of March 31, 2024 and December 31, 2023 (in thousands):

Description	Fair Value at March 31, 2024	Level 1	Level 2	Level 3
Recurring Assets				
Cash equivalents				
Money market fund	$ 17,558	$ 17,558	$ —	$ —
Short-term investments				
U.S. treasury securities	36,832	36,832	—	—
U.S. federal agency securities	7,954	—	7,954	—
Total assets measured at fair value	$ 62,344	$ 54,390	$ 7,954	$ —
Liabilities				
Payable to licensor	$ 4,691	$ —	$ —	$ 4,691
Derivative liabilities	1,005	—	—	1,005
Warrant liabilities	48,690	—	—	48,690
Total liabilities measured at fair value	$ 54,386	$ —	$ —	$ 54,386

Description	Fair Value at December 31, 2023	Level 1	Level 2	Level 3
Recurring Assets				
Cash equivalents				
Money market fund	$ 1,034	$ 1,034	$ —	$ —
Short-term investments				
U.S. treasury securities	8,393	8,393	—	—
U.S. federal agency securities	29,360	—	29,360	—
Total assets measured at fair value	$ 38,787	$ 9,427	$ 29,360	$ —
Liabilities				
Payable to licensor	$ 4,580	$ —	$ —	$ 4,580
Warrant liabilities	31,352	—	—	31,352
Total liabilities measured at fair value	$ 35,932	$ —	$ —	$ 35,932

Warrant Liabilities

As of March 31, 2024 and December 31, 2023, the Company had the following outstanding warrant liabilities:

	March 31, 2024	December 31, 2023
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, 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 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	505,263	—

For the warrants issued as part of the 2024 loan agreement, the Company utilized the exercise price of $4.75, which is the only known price at March 31, 2024, to calculate the number of warrants in the table above. The Company included the calculated warrants of 505,263 and nil for the three months ended March 31, 2024 and 2023, respectively, in the table above.

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 related to the Loan Agreement were determined to be liability classified under ASC 815 as the common stock warrants do not include an explicit share limit and the number of shares issuable under the warrant agreements are variable based on the exercise price. Changes in the estimated fair value of the warrant liabilities is recorded as changes in fair value of warrant liabilities in the consolidated statement of operations and comprehensive loss.

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

Warrant liabilities as of December 31, 2023	$	31,352
Fair value of warrants issued in connection with Loan Agreement		220
Loss recognized in earnings from change in fair value		17,118
Warrant liabilities as of March 31, 2024	$	48,690

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.

	March 31, 2024	December 31, 2023
Common share price	$ 7.25	$ 5.01
Expected term (years)	2.71 – 4.77	2.96 – 3.84
Risk-free interest rate (%)	4.12% – 4.34%	3.84% – 3.92%
Volatility (%)	100.00% - 103.15%	100%
Expected dividend yield (%)	0%	0%

Derivative Liabilities

The Conversion Right embedded within the Loan Agreement (see Note 8 below) 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. The derivative liability is remeasured at each reporting period with the change in fair value recorded to changes 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.

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

Derivative liabilities as of December 31, 2023	$	—
Fair value of derivatives issued in connection with Loan Agreement		822
Loss recognized in earnings from change in fair value		183
Derivative liabilities as of March 31, 2024	$	1,005

The derivative liabilities are valued using significant inputs not observable in the market. Accordingly, the derivative 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 derivatives utilized the Monte Carlo simulation model, which incorporated assumptions and estimates to value the derivatives. The Company assessed these assumptions and estimates at the end of each reporting period.

	March 31, 2024	December 31, 2023
Common share price	$ 7.25	—
Expected term (years)	3.25	—
Risk-free interest rate (%)	4.27%	—
Volatility (%)	89.70%	—

NOTE 5 – SETTLEMENT LIABILITY

On November 12, 2021, the Company entered into a settlement agreement ("Settlement Agreement") with the Company's prior licensor REGENXBIO Inc. ("REGENXBIO") to resolve all existing disputes between the parties. In accordance with the Settlement Agreement, the Company agreed to pay REGENXBIO a total of $30.0 million, payable as follows: (1) $20.0 million paid in November 2021 after execution of the Settlement Agreement, (2) $5.0 million on the first anniversary of the effective date of the Settlement Agreement (paid in November 2022), and (3) $5.0 million upon the earlier of (i) the third anniversary of the effective date of the Settlement Agreement or (ii) the closing of a Strategic Transaction, as defined in the Settlement Agreement.

As of March 31, 2024, the Company recorded the payable due to REGENXBIO in the condensed consolidated balance sheets based on the present value of the remaining payments due to REGENXBIO under the Settlement Agreement using an effective interest rate of 9.6%. The present value of the amount due in November 2024 was $4.7 million and $4.6 million as of March 31, 2024 and December 31, 2023, respectively.

NOTE 6 – ACCRUED EXPENSES

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

	March 31, 2024	December 31, 2023
Accrued employee compensation	$ 1,328	$ 3,688
Accrued contracted services and other	1,463	2,297
Total accrued expenses	$ 2,791	$ 5,985

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 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.

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 Company expects to receive $1.0 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):

	March 31, 2024	December 31, 2023
Current operating lease liability	$ 1,044	$ 998
Non-current operating lease liability	4,046	4,402
Total operating lease liability	$ 5,090	$ 5,400

Lease costs and rent are reflected in general and administrative expenses and research and development expenses in the 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):

	For the three months ended March 31,	
	2024	2023
Operating lease cost	$ 334	$ 415
Variable lease cost	74	39
Short-term lease cost	23	18
Total operating lease costs	$ 431	$ 472

Cash paid for amounts included in the measurement of operating lease liabilities was $0.3 million for the three months ended March 31, 2024 and 2023.

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, 2024 were as follows (in thousands):

Future minimum lease payments and obligations	Operating Leases
2024, remainder	$ 591
2025	1,555
2026	791
2027	807
2028	823
Thereafter	1,693
Total undiscounted operating lease payments	6,260
Less: imputed interest	1,170
Present value of operating lease liabilities	$ 5,090

The weighted-average remaining term of the Company's operating leases was 63 months and the weighted-average discount rate used to measure the present value of the Company's operating lease liabilities was 7.3% as of March 31, 2024.

The Company received $0.1 million during the three months ended March 31, 2024 and 2023, 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, 2024 are as follows (in thousands):

Future cash receipts	Operating Subleases
2024, remainder	$ 477
2025	485
Total future cash receipts	$ 962

NOTE 8 – DEBT

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

	March 31, 2024	December 31, 2023
Loan Agreement principal	$ 20,000	$ —
Accreted final payment fee	74	—
Unamortized debt issuance costs and discounts	(1,995)	—
Total debt	$ 18,079	$ —

Loan and Security Agreement

On January 8, 2024 (the "Closing Date"), the Company entered into a Loan and Security Agreement (the "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"). Also on January 8, 2024, the Company entered into a Supplement to the Agreement (collectively with the Agreement, the "Loan Agreement") with the Agent and 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 pz-cel 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").

The Loan principal is repayable in equal monthly installments beginning on April 8, 2025, with the possibility of deferring principal payments an additional nine to fifteen months contingent upon (i) the Company obtaining FDA approval of pz-cel in recessive dystrophic epidermolysis bullosa, with the issuance of a Priority Review Voucher and (ii) the Company raising $90 million of cumulative equity and/or non-dilutive capital subsequent to the Closing Date. 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 interest rate as of March 31, 2024 was 13.50%.

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.

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 "Warrantholders") warrants to purchase up to $480,000 and $1,920,000 of Company common stock, respectively which is more fully described in Note 9 below.

The future payment obligations of the principal are as follows (in thousands):

2024, remainder	$	—
2025		6,667
2026		8,889
2027		4,444
Total principal	$	20,000

NOTE 9 – EQUITY

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 Hedg*ing ("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, 2024, 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, 2024, other than the change in fair value of the warrants for the stock purchase warrants issued as part of this public offering.

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 $150.0 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 889,315 and 98,560 shares of its common stock under the ATM Agreement during the three months ended March 31, 2024 and 2023, respectively, resulting in net proceeds of $6.5 million and $0.3 million during the three months ended March 31, 2024 and 2023, respectively. Subsequent to March 31, 2024 and through April 24, 2024, the Company sold 1,013,061 shares of common stock under the ATM Agreement resulting in $3.5 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 commons 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, 2024, 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, 2024, 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. None of the 2023 Pre-Funded Warrants have been exercised as of March 31, 2024. The prefunded 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 prefunded warrants were recorded at their relative fair value at issuance in the stockholders' equity (deficit) section of the consolidated balance sheet and the prefunded warrants are considered outstanding shares in the basic earnings per share calculation for the three months ended March 31, 2024 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 "Warrantholders") 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. Assuming an exercise price of $4.75 per share, 505,263 shares of common stock would be issued in connection with the exercise in full of the January Warrants. The January 204 warrants do not include an explicit share limit and the number of shares issuable under the warrant agreements are variable based on the exercise price and therefore the warrants were liability classified based on a Black-Scholes valuation in accordance with ASC 815. On January 8, 2024, the warrants were recorded at the closing date fair value of $0.2 million which was based on a Black-Scholes option pricing model.

In connection with the underwritten common stock financing consummated on May 7, 2024, and pursuant to the term of the January Warrants, the exercise price of the January Warrants was reduced to the lesser of (i) $4.07 per share 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. Assuming an exercise at $4.07 per share, 589,680 shares of common stock would be issued in connection with the exercise in full of the January Warrants. 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 Warrantholders would be entitled to receive the shares of common stock underlying the Warrant without payment of the exercise price.

The Warrantholders may exercise the 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 Warrantholders may also exercise the Warrants on a cashless basis by receiving a net number of shares calculated pursuant to the formula set forth in the Warrants. The Warrants are subject to anti-dilution adjustments for stock dividends, stock splits, and reverse stock splits.

NOTE 10 – STOCK-BASED COMPENSATION

The Company previously granted stock options under its 2005 Equity Incentive Plan (the "2005 Incentive Plan"), under which no further grants can be made. In addition, 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. As of March 31, 2024, there were 156,591 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, 2024, there were 721,900 shares available to be granted under the Inducement Plan.

The following table summarizes stock-based compensation expense for the three months ended March 31, 2024 and 2023 (in thousands):

	For the three months ended March 31,	
	2024	2023
Research and development	$ 346	$ 584
General and administrative	1,220	186
Total stock-based compensation expense	$ 1,546	$ 770

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, 2024 and 2023.

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, 2024:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	179,001	$ 38.58	6.83	$ 3
Granted	—	$ —	—	$ —
Cancelled/forfeited	—	$ —	—	$ —
Exercised	—	$ —	—	$ —
Outstanding at March 31, 2024	179,001	$ 38.58	6.58	$ 14
Exercisable	143,907	$ 38.58	6.42	$ 6
Unvested	35,094	$ 38.59	7.24	$ 8

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, 2024, the total compensation cost related to non-vested option awards not yet recognized was approximately $1.0 million with a weighted average remaining vesting period of 1.1 years.

Restricted Stock

The following table summarizes restricted stock award activity during the three months ended March 31, 2024:

	Number of Awards	Weighted Average Grant Date Fair Value Per Unit
Outstanding at December 31, 2023	2,448,169	$ 4.25
Granted	137,500	$ 5.31
Cancelled/forfeited	—	$ —
Vested	(43,050)	$ 7.56
Outstanding at March 31, 2024	2,542,619	$ 4.18

As of March 31, 2024, there was $7.4 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, 2024 and 2023 was $0.5 million.

NOTE 11 – LICENSE/SUPPLIER AGREEMENT

Sublicense and Inventory Purchase Agreements Relating to CLN1 Disease

In August 2020, the Company entered into sublicense and inventory purchase agreements with Taysha Gene Therapies ("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) other royalty-based payments based on net sales. 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, 2024 and 2023, respectively based on event-based-milestone payments. The Company has no contract assets or contract liabilities as of March 31, 2024 and December 31, 2023 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 the University of North Carolina at Chapel Hill, the University of 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) other royalty-based payments based on net sales. 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 for the three months ended March 31, 2024 and 2023, As of March 31, 2024 and December 31, 2023, 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, 2024 and December 31, 2023, the Company does not have any contract assets or contract liabilities as a result of this transaction.

NOTE 12 – SUBSEQUENT EVENTS

On May 7, 2024, the Company closed on an underwritten offering of 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, at an offering price of $4.07 per share, which is equal to the closing price on Thursday, May 2, 2024, or $4.0699 per pre-funded warrant, which represents the per share offering price for the common stock less the $0.0001 per share exercise price for each pre-funded warrant. The pre-funded warrants will be 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. The Company estimates that the net proceeds from the Offering will be approximately $70.2 million, after deducting the underwriting discounts and commissions and paying estimated offering expenses.

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/A for the year ended December 31, 2023 (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 clinical-stage biopharmaceutical company developing cell and gene therapies for life-threatening diseases. Our lead clinical program is pz-cel, investigational autologous, COL7A1 gene-corrected epidermal sheets, currently in development for recessive dystrophic epidermolysis bullosa ("RDEB"). We have announced positive data from the VIITAL™ study evaluating the efficacy, safety and tolerability of pz-cel. The VIITAL™ study met both its two co-primary efficacy endpoints demonstrating statistically significant, clinically meaningful improvements in wound healing and pain reduction in large chronic RDEB wounds. On September 25, 2023, we submitted a Biologics License Application ("BLA") for pz-cel to the U.S. Food and Drug Administration ("FDA").

In November 2023, the FDA accepted and granted priority review for our BLA for pz-cel, and subsequently, under the Prescription Drug User Fee Act ("PDUFA"), the FDA set a target action date of May 25, 2024. In April 2024, the FDA issued a Complete Response Letter ("CRL") in response to the BLA. The CRL follows the completion of Abeona's Late Cycle Review Meeting with the FDA in March 2024. At the Late Cycle Review Meeting and in a subsequent information request, the FDA noted that certain additional information needed to satisfy the Chemistry Manufacturing and Controls ("CMC") requirements of the pz-cel BLA must be satisfactorily resolved before the application can be approved. In response, we submitted plans to the FDA with the commitment to provide certain CMC data prior to BLA approval, and full validation reports after approval in mid-2024. We discussed these plans with the FDA in a subsequent informal meeting. In the CRL, the FDA indicated that the proposed timing of the data submission by us would not have allowed sufficient time for the FDA to complete its review by the May 25, 2024 PDUFA date.

The information needed to satisfy the CMC requests in the CRL pertains to validation requirements for certain manufacturing and release testing methods, including some that were captured in observations made during the FDA's pre-license inspection ("PLI"). The CRL did not identify any deficiencies related to the clinical efficacy or clinical safety data in the BLA, and the FDA did not request any new clinical trials or clinical data to support the approval of pz-cel.

We have continued to prepare our current Good Manufacturing Practices ("cGMP") commercial facility in Cleveland, Ohio for manufacturing pz-cel drug product to support our planned commercial launch of pz-cel, if approved. Pz-cel study drug product for all our VIITAL™ study participants has been manufactured at our Cleveland facility. As part of our commercial planning, we continue to engage with stakeholders across the healthcare system, including public and private payors, and healthcare providers to better understand market access and potential pricing for pz-cel. We have also begun discussions with high volume treatment centers of excellence to onboard them for pz-cel application upon potential FDA approval.

Our development portfolio also features adeno-associated virus ("AAV") based gene therapies designed to treat ophthalmic diseases using the novel AIM™ capsids that we have exclusively licensed from the University of North Carolina at Chapel Hill, and internal AAV vector research programs.

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.

Other Recent Developments

On January 8, 2024, we entered into a $50 million credit facility with the Avenue Venture Opportunities Fund, L.P. The credit agreement, which has a term of three and a half years, includes a first tranche of $20 million at closing, a second tranche of $10 million of committed capital, and an additional accordion option to upsize the credit facility by an additional $20 million upon satisfaction of certain terms and conditions.

On May 7, 2024, we closed on an underwritten offering of 12,285,056 shares of our common stock and, in lieu of common stock, pre-funded warrants to purchase 6,142,656 shares of our common stock, at an offering price of $4.07 per share, which is equal to the closing price on Thursday, May 2, 2024, or $4.0699 per pre-funded warrant, which represents the per share offering price for the common stock less the $0.0001 per share exercise price for each pre-funded warrant. The pre-funded warrants will be 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. We estimate that the net proceeds from the Offering will be approximately $70.2 million, after deducting the underwriting discounts and commissions and paying estimated offering expenses.

RESULTS OF OPERATIONS

Comparison of Three Months Ended March 31, 2024 and March 31, 2023

	For the three months ended		Change	
($ in thousands)	**March 31, 2024**	**March 31, 2023**	**$**	**%**
Revenues:				
License and other revenues	$ —	$ —	$ —	N/A
Expenses:				
Research and development	7,207	8,041	(834)	(10)%
General and administrative	7,123	3,997	3,126	78%
Total expenses	14,330	12,038	2,292	19%
Loss from operations	(14,330)	(12,038)	(2,292)	19%
Interest income	843	364	479	132%
Interest expense	(952)	(101)	(851)	843%
Change in fair value of warrant and derivative liabilities	(17,301)	2,265	(19,566)	(864)%
Other income	162	403	(241)	(60)%
Net loss	$ (31,578)	$ (9,107)	$ (22,471)	247%

N/A – not applicable or not meaningful

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, 2024 was $7.2 million, as compared to $8.0 million for the same period of 2023, a decrease of $0.8 million. The decrease in expenses was primarily due to:

- decreased clinical and development work for our cell and gene therapy product candidates and other related costs of $1.9 million which was due to the reduction in number of clinical trials ongoing;
- decreased other costs of $0.3 million; partially offset by
- increased salary and related costs of $1.2 million; and
- increased stock compensation expenses of $0.2 million.

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), pre-commercial launch activity costs and other general operating expenses not otherwise included in research and development expenses.

Total general and administrative expenses were $7.1 million for the three months ended March 31, 2024, as compared to $4.0 million for the same period of 2023, an increase of $3.1 million. The increase in expenses was primarily due to:

- increased salary and related costs of $0.9 million;

- increased pre-commercial preparation costs of $1.3 million;
- increased non-cash stock-based compensation of $0.6 million; and
- increased other costs such as professional fees, rent, and recruiting of $0.3 million.

Interest income

Interest income was $0.8 million for the three months ended March 31, 2024, as compared to $0.4 million in the same period of 2023. The increase resulted from higher earnings on short-term investments driven by higher interest rates and increased average short-term investment balances.

Interest expense

Interest expense was $1.0 million for the three months ended March 31, 2024, as compared to $0.1 million in the same period of 2023. The increase was primarily due to the credit facility entered into by the Company in January 2024, resulting in recognized interest expense of $0.8 million.

Change in fair value of warrant and derivative liabilities

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, as compared to a gain of $2.3 million for the same period in 2023.

We issued stock purchase warrants that are required to be classified as a liability and valued at fair market value at each reporting period. In addition, the conversion feature in our loan agreement is required to be classified as a liability and valued at fair market value at each reporting period. The change in the fair value of warrant and derivative liabilities was primarily due to the increase in our stock price year over the year and a shorter term.

Other income

Other income was $0.2 million for the three months ended March 31, 2024, as compared to $0.4 million in the same period of 2023. The change was primarily a result of other income related to a refund of overpayment of franchise taxes that was received in 2023.

LIQUIDITY AND CAPITAL RESOURCES

Cash Flows for the Three Months Ended March 31, 2024 and 2023

	For the three months ended	
($ in thousands)	**March 31, 2024**	**March 31, 2023**
Total cash, cash equivalents and restricted cash (used in) provided by:		
Operating activities	$ (14,538)	$ (11,744)
Investing activities	(7,817)	2,211
Financing activities	25,440	(4)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 3,085	$ (9,537)

Operating activities

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.

Net cash used in operating activities was $11.7 million for the three months ended March 31, 2023, primarily comprised of our net loss of $9.1 million and decreases in operating assets and liabilities of $2.0 million and net non-cash charges of $0.6 million.

Investing activities

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.

Net cash provided by investing activities was $2.2 million for the three months ended March 31, 2023, primarily comprised of proceeds from maturities of short-term investments of $10.4 million, partially offset by purchases of short-term investments of $8.0 million and capital expenditures of $0.2 million.

Financing activities

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.

Net cash used in financing activities was $4,000 for the three months ended March 31, 2023, primarily comprised of the net settlement of restricted share awards.

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, 2024, our cash resources were $62.7 million. We believe that our current cash and cash equivalents, restricted cash and short-term investments and accounting for the gross proceeds from our $75.0 million underwritten offering that closed on May 7, 2024, 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 $150.0 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 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.

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 potential commercialization efforts. We have not been profitable since inception and to date have received limited revenues from the sale of products or licenses. We expect to 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 as well as the discussion below related to our derivative liability.

See Note 1 to our unaudited condensed consolidated financial statements for a discussion of our significant accounting policies.

Derivative Liability

We account for the fair value of the conversion right embedded within the loan agreement in accordance with the guidance in ASC 815, which requires us to bifurcate and separately account for the conversion feature as an embedded derivative contained in our loan agreement. Accordingly, we account for the conversion feature as a derivative liability in our condensed consolidated balance sheet. Derivatives are measured at their fair value on the balance sheet. In determining the appropriate fair value, we use a Monte Carlo simulation model, which incorporated assumptions and estimates to value the derivatives. The derivative liability is remeasured at each reporting period with the change in fair value recorded to change in fair value of warrant and derivative liabilities in the condensed consolidated statement of operations until the derivative is exercised, expired, reclassified, or otherwise settled.

Recently Issued Accounting Standards Not Yet Effective or Adopted

See Note 1 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, 2024, as such term is defined in Rules 13a-15I 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, 2024 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, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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, 2023 should be carefully considered.

In addition, on April 16, 2024 we received a Complete Response Letter (a "CRL") related to our Biologics License Application (BLA) for pz-cel for the treatment of patients with recessive dystrophic epidermolysis bullosa (RDEB). In the CRL, the FDA noted that certain additional information needed to satisfy Chemistry Manufacturing and Controls ("CMC") requirements must be satisfactorily resolved before the application can be approved. In response, the Company submitted plans to the FDA with the commitment to provide CMC data prior to BLA approval, and full validation reports after approval in mid-2024. There can be no assurance that we will be able to satisfy the requirements of the CRL or the timeline on which we will be able to do so. A delay in receiving approval of the BLA could shorten any periods during which we may have the exclusive right to commercialize our pz-cel or allow our competitors to bring products to market before we do. This may impair our ability to successfully commercialize pz-cel. If any of the foregoing were to occur, our business, financial condition, results of operations, and prospects will be materially harmed.

Other than as set forth above, 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, 2023.

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, 2024:

	Total number of shares (or units) purchased [(a)]	Average price paid per share (or unit)
Shares delivered or withheld pursuant to restricted stock awards		
January 1, 2024 - January 31, 2024	—	$ —
February 1, 2024 - February 29, 2024	—	$ —
March 1, 2024 - March 31, 2024	—	$ —
	—	$ —

(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, 2024, the following officers, as defined in Rule 16a-1(f) under the Exchange Act, as amended, adopted a "Rule 10b5-1 trading arrangement" as defined in Regulation S-K Item 408, as follows:

On February 9, 2024, Vishwas Seshadri, the Company's President and Chief Executive Officer and a member of the Company's board of directors, adopted a Rule 10b5-1 trading arrangement providing for the sale from time to time of an aggregate of (i) up to 20,000 shares of our common stock and (ii) up to (a) 100% of the shares of our common stock issued upon the settlement of 2,700 outstanding restricted stock units, (b) up to 21% of the shares of our common stock issued upon the settlement of 23,280 outstanding restricted stock units and (c) up to 30% of the shares of our common stock issued upon the settlement of 134,730 outstanding restricted stock units, in each case, less the number of shares traded to cover tax withholding obligations in connection with the vesting and settlement of such restricted stock units. The duration of the trading arrangement is until October 30, 2025, or earlier if all transactions under the trading arrangement are completed.

Joseph Vazzano, the Company's Chief Financial Officer, adopted two Rule 10b5-1 trading arrangements on February 9, 2024 and February 12, 2024:

- The arrangement adopted on February 9, 2024 provides for the sale from time to time of an aggregate of (i) up to 14,979 shares of our common stock and (ii) up to 47,302 of the shares of our common stock issued upon the settlement of 141,908 outstanding restricted stock units, less the number of shares traded to cover tax withholding obligations in connection with the vesting and settlement of such restricted stock units. The duration of the trading arrangement is until December 31, 2024, or earlier if all transactions under the trading arrangement are completed.

- The arrangement adopted on February 12, 2024 provides for the sale from time to time of an aggregate of up to 5,500 shares of our common stock. The duration of the trading arrangement is until December 31, 2024, or earlier if all transactions under the trading arrangement are completed.

Each trading arrangement described is intended to satisfy the affirmative defense in Rule 10b5-1(c).

ITEM 6. EXHIBITS

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

Exhibit Index

Exhibits:

4.1	Warrant to Purchase Common Stock, by and between Abeona Therapeutics, Inc. and Avenue Venture Opportunities Fund, L.P., dated as of January 8, 2024 (incorporated by reference from our Form 8-K filed with the SEC on January 8, 2024).
4.2	Warrant to Purchase Common Stock, by and between Abeona Therapeutics, Inc. and Avenue Venture Opportunities Fund II, L.P., dated as of January 8, 2024 (incorporated by reference from our Form 8-K filed with the SEC on January 8, 2024).
10.1	Loan and Security Agreement, by and among Abeona Therapeutics, Inc., MacroChem Corporation, Abeona Therapeutics LLC, Avenue Venture Opportunities Fund, L.P., as Agent, and Avenue Venture Opportunities Fund II, L.P., dated as of January 8, 2024 (incorporated by reference from our Form 8-K filed with the SEC on January 8, 2024).
10.2	Supplement to the Loan and Security Agreement, by and among Abeona Therapeutics, Inc., MacroChem Corporation, Abeona Therapeutics LLC, Avenue Venture Opportunities Fund, L.P., as Agent, and Avenue Venture Opportunities Fund II, L.P., dated as of January 8, 2024 (incorporated by reference from our Form 8-K filed with the SEC on January 8, 2024).
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, 2024, formatted in Inline XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at March 31, 2024 and December 31, 2023 (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2024 and 2023 (unaudited), (iii) Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the three months ended March 31, 2024 and 2023 (unaudited), (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2024 and 2023 (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, 2024

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

Date: May 15, 2024

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

EXHIBIT 31.1

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

I, Vishwas Seshadri, certify that:

1. I have reviewed this report on Form 10-Q for the quarterly period ended March 31, 2024, 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, 2024

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

EXHIBIT 31.2

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

I, Joseph Vazzano, certify that:

1. I have reviewed this report on Form 10-Q for the quarterly period ended March 31, 2024, 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, 2024

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

EXHIBIT 32

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

In connection with the Quarterly Report of Abeona Therapeutics Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2024 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, 2024

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

Date: May 15, 2024

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