UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2023

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 November 1, 2023 was 24,773,317 shares.

ABEONA THERAPEUTICS INC.
Form 10-Q
For the Quarter Ended September 30, 2023

INDEX

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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: the outcome of our submission of a Biologics License Application for EB-101 and the timing thereof; our plans to continue development of AAV-based gene therapies designed to treat ophthalmic and other diseases and next-generation AAV-based gene therapies; 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 EB-101 could potentially benefit patients with RDEB; development of our novel AAV-based gene therapy platform technology; 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 and related-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/A for the fiscal year ended December 31, 2022, as updated from time to time in the Company's SEC filings, including this Quarterly Report on Form 10-Q. These factors include: the outcome of our submission of a Biologics License Application for EB-101 and the timing thereof; 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 potentially future commercialization; the rate and degree of market acceptance of our product candidates for any indication once approved; and our ability to meet our obligations contained in license agreements to which we are party.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,712	$ 14,217
Short-term investments	49,042	37,932
Restricted cash	338	338
Other receivables	2,209	188
Prepaid expenses and other current assets	963	424
Total current assets	57,264	53,099
Property and equipment, net	3,999	5,741
Right-of-use lease assets	4,685	5,331
Other assets	139	43
Total assets	$ 66,087	$ 64,214
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,592	$ 1,811
Accrued expenses	3,972	3,991
Current portion of operating lease liability	1,649	1,773
Other current liabilities	199	204
Total current liabilities	8,412	7,779
Payable to licensor	4,472	4,163
Long-term operating lease liabilities	4,043	5,854
Warrant liabilities	27,122	19,657
Total liabilities	44,049	37,453
Commitments and contingencies		
Stockholders' equity:		
Preferred stock - $0.01 par value; authorized 2,000,000 shares; No shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	—	—
Common stock - $0.01 par value; authorized 200,000,000 shares; 24,713,908 and 17,719,720 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	247	177
Additional paid-in capital	754,823	722,049
Accumulated deficit	(732,933)	(695,336)
Accumulated other comprehensive loss	(99)	(129)
Total stockholders' equity	22,038	26,761
Total liabilities and stockholders' equity	$ 66,087	$ 64,214

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 September 30,		For the nine months ended September 30,	
	2023	2022	2023	2022
Revenues:				
License and other revenues	$ —	$ —	$ 3,500	$ 1,346
Expenses:				
Royalties	30	—	1,605	350
Research and development	7,148	5,490	23,712	22,693
General and administrative	4,156	3,890	13,174	11,574
Impairment of licensed technology	—	—	—	1,355
Loss/(gain) on right-of-use lease assets	—	—	(1,065)	1,561
Impairment of construction-in-progress	—	—	—	1,792
Total expenses	11,334	9,380	37,426	39,325
Loss from operations	(11,334)	(9,380)	(33,926)	(37,979)
Interest income	593	72	1,374	103
Interest expense	(105)	(157)	(309)	(558)
Change in fair value of warrant liabilities	(1,101)	3,050	(7,465)	5,995
Other income (expense)	111	(19)	2,729	(136)
Net loss	$ (11,836)	$ (6,434)	$ (37,597)	$ (32,575)
Deemed dividends related to Series A and Series B Convertible Redeemable Preferred Stock	—	—	—	(3,782)
Net loss attributable to Common Shareholders	$ (11,836)	$ (6,434)	$ (37,597)	$ (36,357)
Basic and diluted loss per common share	$ (0.48)	$ (1.00)	$ (1.89)	$ (6.05)
Weighted average number of common shares outstanding – basic and diluted	24,797,564	6,421,245	19,942,613	6,009,902
Other comprehensive income (loss):				
Change in unrealized gains (losses) related to available-for-sale debt securities	(33)	(4)	1	(11)
Foreign currency translation adjustments	29	(6)	29	(6)
Comprehensive loss	$ (11,840)	$ (6,444)	$ (37,567)	$ (36,374)

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

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

Three months ended September 30, 2023

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at June 30, 2023	21,478,157	$ 215	$ 730,322	$ (721,097)	$ (95)	$ 9,345
Stock-based compensation expense	—	—	1,557	—	—	1,557
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement	(48,656)	—	(4)	—	—	(4)
Issuance of common stock, net of offering costs under direct placement offering	3,284,407	32	22,948	—	—	22,980
Net loss	—	—	—	(11,836)	—	(11,836)
Other comprehensive loss	—	—	—	—	(4)	(4)
Balance at September 30, 2023	24,713,908	$ 247	$ 754,823	$ (732,933)	$ (99)	$ 22,038

Nine months ended September 30, 2023

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at December 31, 2022	17,719,720	$ 177	$ 722,049	$ (695,336)	$ (129)	$ 26,761
Stock-based compensation expense	—	—	3,254	—	—	3,254
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement	1,719,460	18	(31)	—	—	(13)
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	1,990,321	20	6,603	—	—	6,623
Issuance of common stock, net of offering costs under direct placement offering	3,284,407	32	22,948	—	—	22,980
Net loss	—	—	—	(37,597)	—	(37,597)
Other comprehensive income	—	—	—	—	30	30
Balance at September 30, 2023	24,713,908	$ 247	$ 754,823	$ (732,933)	$ (99)	$ 22,038

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

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

Three months ended September 30, 2022

	Convertible Redeemable Preferred Stock									
	Series A		Series B		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at June 30, 2022	—	$ —	—	$ —	5,870,375	$ 1,467	$ 694,372	$ (681,781)	$ (34)	$ 14,024
Stock-based compensation expense	—	—	—	—	—	—	632	—	—	632
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	—	—	—	—	1,038,134	10	4,179	—	—	4,189
Issuance of common stock in connection with restricted share awards, net of cancellations	—	—	—	—	762,842	8	(8)	—	—	—
Reverse stock-split adjustment	—	—	—	—	—	(1,408)	1,408	—	—	—
Net loss	—	—	—	—	—	—	—	(6,434)	—	(6,434)
Other comprehensive loss	—	—	—	—	—	—	—	—	(10)	(10)
Balance at September 30, 2022	—	$ —	—	$ —	7,671,351	$ 77	$ 700,583	$ (688,215)	$ (44)	$ 12,401

Nine months ended September 30, 2022

	Convertible Redeemable Preferred Stock									
	Series A		Series B		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	—	$ —	—	$ —	5,888,217	$ 1,472	$ 696,563	$ (655,640)	$ (27)	$ 42,368
Stock-based compensation expense	—	—	—	—	—	—	2,218	—	—	2,218
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	—	—	—	—	1,038,134	10	4,179	—	—	4,189
Issuance of common stock in connection with restricted share awards, net of cancellations	—	—	—	—	745,000	3	(3)	—	—	—
Issuance of Series A and Series B Convertible Redeemable Preferred Stock	1,000,006	17,974	250,005	4,494	—	—	—	—	—	—
Deemed dividends related to Series A and Series B Convertible Redeemable Preferred Stock	—	3,026	—	756	—	—	(3,782)	—	—	(3,782)
Redemption of Series A and Series B Convertible Redeemable Preferred Stock	(1,000,006)	(21,000)	(250,005)	(5,250)	—	—	—	—	—	—
Reverse stock-split adjustment	—	—	—	—	—	(1,408)	1,408	—	—	—
Net loss	—	—	—	—	—	—	—	(32,575)	—	(32,575)
Other comprehensive loss	—	—	—	—	—	—	—	—	(17)	(17)
Balance at September 30, 2022	—	$ —	—	$ —	7,671,351	$ 77	$ 700,583	$ (688,215)	$ (44)	$ 12,401

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

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

	For the nine months ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (37,597)	$ (32,575)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,797	2,364
Stock-based compensation expense	3,254	2,218
Change in fair value of warrant liabilities	7,465	(5,995)
Non-cash impairment of licensed technology	—	1,355
Non-cash loss/(gain) of right-of-use lease assets	(1,065)	1,561
Non-cash impairment of construction-in-progress	—	1,792
Accretion and interest on short-term investments	134	(206)
Amortization of right-of-use lease assets	680	1,204
Non-cash interest	309	558
Loss on disposal of property and equipment	52	121
Change in operating assets and liabilities:		
Accounts receivable	—	3,000
Other receivables	(2,021)	(1,047)
Prepaid expenses and other current assets	(539)	1,432
Other assets	(96)	148
Accounts payable, accrued expenses and lease liabilities	(142)	(5,125)
Other current liabilities	(5)	(296)
Net cash used in operating activities	(27,774)	(29,491)
Cash flows from investing activities:		
Capital expenditures	(294)	(105)
Proceeds from disposal of property and equipment	187	1,590
Purchases of short-term investments	(48,219)	(43,866)
Proceeds from maturities of short-term investments	37,005	43,707
Net cash provided by (used in) investing activities	(11,321)	1,326
Cash flows from financing activities:		
Proceeds from ATM sales of common stock, net of issuance costs	6,623	4,189
Proceeds from sales of common stock under direct placement offering, net of issuance costs	22,980	—
Proceeds from net settlement of restricted share awards	(13)	—
Proceeds from issuance of Series A and Series B Convertible Redeemable Preferred Stock, net of issuance costs	—	22,468
Redemption of Series A and Series B Convertible Redeemable Preferred Stock	—	(26,250)
Net cash provided by financing activities	29,590	407
Net decrease in cash, cash equivalents and restricted cash	(9,505)	(27,758)
Cash, cash equivalents and restricted cash at beginning of period	14,555	38,829
Cash, cash equivalents and restricted cash at end of period	$ 5,050	$ 11,071
Supplemental cash flow information:		
Cash and cash equivalents	$ 4,712	$ 5,733
Restricted cash	338	5,338
Total cash, cash equivalents and restricted cash	$ 5,050	$ 11,071
Supplemental non-cash flow information:		
Right-of-use asset obtained in exchange for new operating lease liabilities	$ 419	$ —

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 EB-101, 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™ capsid platform 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, 2022 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/A for the year ended December 31, 2022, which was filed with the SEC on April 10, 2023.

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 EB-101 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 $11.8 million and $6.4 million for the three months ended September 30, 2023 and 2022, respectively, and net losses of $37.6 million and $36.4 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, the Company had an accumulated deficit of approximately $732.9 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 $54.1 million as of September 30, 2023, 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 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 its EB-101; (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. The Company's significant estimates include, but are not limited to, fair value of warrant liabilities and stock-based compensation. Due to the uncertainty inherent in such estimates, actual results could differ from these estimates and assumptions.

Other receivables

Other receivables include employee retention credits ("ERC"), sublease rent receivables and other miscellaneous receivables. As of September 30, 2023 and December 31, 2022, the Company had ERC receivables of $2.1 million and nil, respectively.

Summary of Significant Accounting Policies

There have been no new, anticipated or material changes to the significant accounting policies disclosed in the Company's Annual Report on Form 10-K/A for the year ended December 31, 2022 other than those identified below.

Correction of Error

During the fourth quarter of 2022, the Company identified errors in the accounting for certain common stock warrants that were issued in 2021. The common stock warrants were not indexed to the Company's own stock and therefore should have been classified as liabilities at their estimated fair value instead of additional paid-in capital. Although the errors were immaterial to prior periods, the 2021 financial statements were restated in accordance with Staff Accounting Bulletin No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements", due to the significance of the out-of-period correction to the 2021 period. There was no impact to the Company's consolidated statements of operations and comprehensive loss for 2021. The correction of the error resulted in the Company adjusting its quarterly information presented for the three and nine months ended September 30, 2022. The matter was correctly presented in the fiscal year end December 31, 2022 consolidated financial statements included in the Company's 2022 Annual Report on Form 10-K/A.

The following tables present the effects of the correction of the prior period error to the condensed consolidated statement of operations and comprehensive loss (in thousands, except for per share data):

	For the three months ended September 30, 2022		
Condensed Consolidated Statement of Operations and Comprehensive Loss	**As Reported**	**Adjustment**	**As Revised**
Change in fair value of warrant liabilities	$ —	$ 3,050	$ 3,050
Net loss	$ (9,484)	$ 3,050	$ (6,434)
Net loss attributable to Common Shareholders	$ (9,484)	$ 3,050	$ (6,434)
Basic and diluted loss per common share	$ (1.48)	$ 0.48	$ (1.00)
Comprehensive loss	$ (9,494)	$ 3,050	$ (6,444)

	For the nine months ended September 30, 2022		
Condensed Consolidated Statement of Operations and Comprehensive Loss	**As Reported**	**Adjustment**	**As Revised**
Change in fair value of warrant liabilities	$ —	$ 5,995	$ 5,995
Net loss	$ (38,570)	$ 5,995	$ (32,575)
Net loss attributable to Common Shareholders	$ (42,352)	$ 5,995	$ (36,357)
Basic and diluted loss per common share	$ (7.05)	$ 1.00	$ (6.05)
Comprehensive loss	$ (42,369)	$ 5,995	$ (36,374)

The following tables present the effects of the correction of the prior period error to the condensed consolidated statement of stockholders' equity (in thousands):

	As of September 30, 2022		
Condensed Consolidated Statement of Stockholders' Equity	**As Reported**	**Adjustment**	**As Revised**
Additional paid-in capital, December 31, 2021	$ 705,570	$ (9,007)	$ 696,563
Total stockholders' equity, December 31, 2021	$ 51,375	$ (9,007)	$ 42,368
Additional paid-in capital, June 30, 2022	$ 703,379	$ (9,007)	$ 694,372
Accumulated deficit, June 30, 2022	$ (684,726)	$ 2,945	$ (681,781)
Total stockholders' equity, June 30, 2022	$ 20,086	$ (6,062)	$ 14,024
Net loss for the three months ended September 30, 2022	$ (9,484)	$ 3,050	$ (6,434)
Net loss for the nine months ended September 30, 2022	$ (38,570)	$ 5,995	$ (32,575)
Additional paid-in capital, September 30, 2022	$ 709,590	$ (9,007)	$ 700,583
Accumulated deficit, September 30, 2022	$ (694,210)	$ 5,995	$ (688,215)
Total stockholders' equity, September 30, 2022	$ 15,413	$ (3,012)	$ 12,401

The following tables present the effects of the correction of the prior period error to the condensed consolidated cash flow statement (in thousands):

Condensed Consolidated Cash Flow Statement	For the nine months ended September 30, 2022		
	As Reported	Adjustment	As Revised
Net loss	$ (38,570)	$ 5,995	$ (32,575)
Adjustments to reconcile net loss to cash used in operating activities:			
Change in fair value of warrant liabilities	$ —	$ (5,995)	$ (5,995)
Net cash used in operating activities	$ (29,491)	$ —	$ (29,491)

Credit Losses

The Company reviews its available-for-sale investments for credit losses on a collective basis by major security type and in line with the Company's investment policy. As of September 30, 2023, 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 September 30, 2023, 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. The weighted average number of shares of common stock include 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 and nine months ended September 30,	
	2023	2022
Stock options	223,323	242,644
Restricted stock	2,308,924	821,269
Warrants	9,397,879	1,788,000
Total	11,930,126	2,851,913

New Accounting Pronouncements

No new accounting pronouncements issued is expected to have a material impact on the Company's condensed consolidated financial statements.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13 (Topic 326), Financial Instruments—Credit Losses: *Measurement of Credit Losses on Financial Instruments*, which replaces the existing incurred loss impairment model with an expected credit loss model and requires a financial asset measured at amortized cost to be presented at the net amount expected to be collected. The new guidance was effective for the Company on January 1, 2023, and the adoption did not have a material impact on the Company's consolidated financial statements.

NOTE 2 – SHORT-TERM INVESTMENTS

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

	September 30, 2023			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments:				
U.S. treasury securities	$ 4,916	—	(22)	$ 4,894
U.S. federal agency securities	44,225	—	(77)	44,148
Total available-for-sale, short-term investments	$ 49,141	—	(99)	$ 49,042

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments:				
U.S. treasury and federal agency securities	$ 38,032	—	(100)	$ 37,932
Total available-for-sale, short-term investments	$ 38,032	—	(100)	$ 37,932

As of September 30, 2023, the available-for-sale securities classified as short-term investments mature in one year or less. The Company carries its available-for-sale securities at fair value in the condensed consolidated balance sheets. Unrealized losses on available-for-sale securities as of September 30, 2023, were not significant and were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. None of the short-term investments have been in a continuous unrealized loss position for more than 12 months. Accordingly, no other-than-temporary impairment was recorded for the three and nine months ended September 30, 2023.

There were no significant realized gains or losses recognized on the sale or maturity of available-for-sale investments for the three and nine months ended September 30, 2023 or 2022.

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)	September 30, 2023	December 31, 2022
Laboratory equipment	5	$ 7,182	$ 7,636
Furniture, software and office equipment	3 to 5	960	1,379
Leasehold improvements	Shorter of remaining lease term or useful life	8,602	8,605
Subtotal		16,744	17,620
Less: accumulated depreciation		(12,745)	(11,879)
Total property and equipment, net		$ 3,999	$ 5,741

Depreciation expense was $0.5 million and $0.8 million for the three months ended September 30, 2023 and 2022, respectively, and $1.8 million and $2.3 million for the nine months ended September 30, 2023 and 2022, respectively.

On March 31, 2022, the Company announced that it was pursuing a strategic partner to take over development activities of ABO-102 and that it was discontinuing development of ABO-101. As a result, the Company determined the construction-in-progress that was dedicated to the ABO-101 and ABO-102 programs had no future value, and thus recorded an impairment charge of $1.8 million for the nine months ended September 30, 2022.

NOTE 4 – LICENSED TECHNOLOGY

On May 15, 2015, we acquired Abeona Therapeutics LLC, which had an exclusive license through Nationwide Children's Hospital to the AB-101 and AB-102 patent portfolios for developing treatments for patients with Sanfilippo Syndrome Type B and Sanfilippo Syndrome Type A, respectively. The license was being amortized to expense over the life of the license of 20 years. On March 31, 2022, the Company announced that it was pursuing a strategic partner to take over development activities of ABO-102 and that it was discontinuing development of ABO-101. As a result of this shift in priorities, the Company determined the remaining value of the licensed technology had no future value and thus recorded an impairment charge of $1.4 million for the nine months ended September 30, 2022. There is no remaining net value of licensed technology as of September 30, 2023 and December 31, 2022.

Amortization expense on licensed technology was nil and $29,000 for the nine months ended September 30, 2023 and 2022, respectively. There was no amortization expense for the three months ended September 30, 2023 or 2022.

NOTE 5 – FAIR VALUE MEASUREMENTS

The Company calculates the fair value of the Company's assets and liabilities that qualify as financial instruments and includes additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of other receivables, prepaid expenses and other current assets, other assets, accounts payable, accrued 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 September 30, 2023 and December 31, 2022 (in thousands):

Description	Fair Value at September 30, 2023	Level 1	Level 2	Level 3
Recurring Assets				
Cash equivalents				
Money market fund	$ 1,021	$ 1,021	$ —	$ —
Short-term investments				
U.S. treasury securities	4,894	4,894	—	—
U.S. federal agency securities	44,148	—	44,148	—
Total assets measured at fair value	$ 50,063	$ 5,915	$ 44,148	$ —
Liabilities				
Payable to licensor	$ 4,472	—	—	$ 4,472
Warrant liabilities	27,122	—	—	27,122
Total liabilities measured at fair value	$ 31,594	$ —	$ —	$ 31,594

Description	Fair Value at December 31, 2022	Level 1	Level 2	Level 3
Recurring Assets:				
Cash equivalents				
Money market fund	$ 12,923	$ 12,923	$ —	$ —
Short-term investments				
U.S. treasury securities and federal agency securities	37,932	—	37,932	—
Total assets measured at fair value	$ 50,855	$ 12,923	$ 37,932	$ —
Liabilities				
Warrant liabilities	19,657	—	—	19,657
Total liabilities measured at fair value	$ 19,657	$ —	$ —	$ 19,657

Warrant Liabilities

As of September 30, 2023 and December 31, 2022, the Company had outstanding warrant liabilities related to the 2022 private placement that allow the holders to purchase 7,609,879 shares of common stock at an exercise price of $4.75 per share. The expiration date for these warrant liabilities is November 2027. As of September 30, 2023 and December 31, 2022, the Company had outstanding warrant liabilities related to the 2021 public offering that allow the holders to purchase 1,788,000 shares of common stock at an exercise price of $9.75 per share. The expiration date for these warrant liabilities is December 2026. The common stock warrants are not indexed to the Company's own stock and therefore have been classified as liabilities at their estimated fair value. Changes in the estimated fair value of the warrant liabilities is recorded as changes in fair value of warrant liabilities in the condensed consolidated statement of operations and comprehensive loss.

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

Warrant liabilities as of December 31, 2022	$ 19,657
Loss recognized in earnings from change in fair value	7,465
Warrant liabilities as of September 30, 2023	$ 27,122

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. Assumptions used to estimate the fair value of the warrants in the Black-Scholes option-pricing model are as follows:

	September 30, 2023	December 31, 2022
Common share price	$4.21	$1.72-$2.18
Expected term (years)	3.21 – 4.09	3.96 – 4.84
Risk-free interest rate (%)	4.56% – 4.65%	3.91% – 4.01%
Volatility (%)	100.00% – 106.99%	102.40% – 107.55%
Expected dividend yield (%)	0%	0%

NOTE 6 – 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, 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 September 30, 2023, 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 long-term portion due in November 2024 was $4.5 million and $4.2 million as of September 30, 2023 and December 31, 2022, respectively.

NOTE 7 – ACCRUED EXPENSES

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

	September 30, 2023	December 31, 2022
Accrued employee compensation	$ 2,126	$ 2,593
Accrued contracted services and other	1,846	1,398
Total accrued expenses	$ 3,972	$ 3,991

NOTE 8 – 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, therefore, the Company has elected the practical expedient to exclude these short-term leases from the Company's right-of-use assets and lease liabilities.

In June 2023, the Company terminated one of its operating leases for office space. The termination resulted in a gain of $1.1 million representing the difference between the carry value of the right-of-use assets and the related lease liabilities. This gain was recorded in the nine months ended September 30, 2023, and is included in loss/(gain) on right-of-use lease assets in the condensed consolidated statement of operations and comprehensive loss.

On March 31, 2022, the Company announced that they were pursuing a strategic partner to take over development activities of ABO-102 and that the Company was discontinuing development of ABO-101. As a result of this shift in priorities, the Company determined the portion of the lease that was dedicated to the future facility for the ABO-101 and ABO-102 programs, had no future value and thus, the Company recorded an impairment charge of $1.6 million for the nine months ended September 30, 2022.

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

	September 30, 2023	December 31, 2022
Current operating lease liability	$ 1,649	$ 1,773
Non-current lease liability	4,043	5,854
Total lease liability	$ 5,692	$ 7,627

Lease costs and rent are reflected in general and administrative expenses and research and development expenses in the condensed consolidated statements of operations and comprehensive loss, as determined by the underlying activities. The following table provides a summary of the components of lease costs and rent (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2023	2022	2023	2022
Operating lease cost	$ 340	$ 467	$ 1,048	$ 1,400
Variable lease cost	66	154	281	366
Short-term lease cost	19	17	50	58
Total operating lease costs	$ 425	$ 638	$ 1,379	$ 1,824

Cash paid for amounts included in the measurement of operating lease liabilities was $0.3 million and $0.2 million for the three months ended September 30, 2023 and 2022, respectively and $0.9 million and $1.1 million for the nine months ended September 30, 2023 and 2022, respectively.

Future minimum lease payments and obligations, which do not include short-term leases, of the Company's operating lease liabilities as of September 30, 2023 were as follows (in thousands):

Future minimum lease payments and obligations	Operating Leases
2023, remainder	$ 403
2024	993
2025	1,552
2026	791
2027	807
Thereafter	2,516
Total undiscounted operating lease payments	7,062
Less: imputed interest	1,370
Present value of operating lease liabilities	$ 5,692

The weighted-average remaining term of the Company's operating leases was 66 months and the weighted-average discount rate used to measure the present value of the Company's operating lease liabilities was 7.4% as of September 30, 2023.

Future cash receipts from the Company's sublease agreements as of September 30, 2023 are as follows (in thousands):

Future cash receipts	Operating Subleases
2023, remainder	$ 156
2024	634
2025	485
Total future cash receipts	$ 1,275

NOTE 9 – EQUITY

Reverse Stock Split

Effective July 1, 2022, the Company's stock underwent a 25:1 Reverse Stock Split. The number of authorized shares of Common Stock immediately after the Reverse Stock Split remained at 200,000,000 shares.

Public Offerings

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

As of September 30, 2023, there were 1,788,000 post-split stock purchase warrants outstanding. 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 or nine months ended September 30, 2023.

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 1,990,321 shares of its common stock under the ATM Agreement resulting in net proceeds of $6.6 million during the nine months ended September 30, 2023. There were no sales under the ATM Agreement during the three months ended September 30, 2023. The Company sold 1,038,134 shares of its common stock under the ATM Agreement and received $4.2 million of net proceeds during the three and nine months ended September 30, 2022.

Private Placement Offering

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 September 30, 2023, 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.

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 and may be exercised at any time. None of the 2023 Pre-Funded Warrants have been exercised as of September 30, 2023.

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 September 30, 2023, 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.

The following table summarizes stock-based compensation expense for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2023	2022	2023	2022
Research and development	$ 339	$ 173	$ 743	$ 729
General and administrative	1,218	459	2,511	1,489
Total stock-based compensation expense	$ 1,557	$ 632	$ 3,254	$ 2,218

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 estimated the fair value of stock options granted in the periods presented utilizing a Black-Scholes option-pricing model utilizing the following assumptions:

	For the nine months ended September 30,	
	2023*	2022
Expected volatility (%)	n/a	95.1% - 96.0%
Expected term (years)	n/a	6.07 - 6.08 years
Risk-free interest rate (%)	n/a	1.7% - 3.3%
Expected dividend yield (%)	n/a	0%

** the Company did not grant any stock options in the nine months ended September 30, 2023.*

The following table summarizes stock option activity for the 2015 Incentive Plan and the 2005 Incentive Plan during the nine months ended September 30, 2023 (there were no stock options granted under the 2023 Incentive Plan during the nine months ended September 30, 2023):

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	240,770	$ 37.04	6.42	$ —
Granted	—	$ —	—	$ —
Cancelled/forfeited	(17,447)	$ 33.40	—	$ —
Exercised	—	$ —	—	$ —
Outstanding at September 30, 2023	223,323	$ 37.33	5.69	$ —
Exercisable	170,958	$ 36.81	5.09	$ —
Unvested	52,365	$ 39.03	7.65	$ —

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. As of September 30, 2023, the total compensation cost related to non-vested option awards not yet recognized was approximately $1.7 million with a weighted average remaining vesting period of 1.5 years.

Restricted Stock

The following table summarizes restricted stock award activity for the 2023 Incentive Plan, 2015 Incentive Plan and Inducement Grants during the nine months ended September 30, 2023:

	Number of Awards	Weighted Average Grant Date Fair Value Per Unit
Outstanding at December 31, 2022	816,958	$ 5.35
Granted	1,817,559	$ 3.96
Cancelled/forfeited	(56,398)	$ 4.32
Vested	(269,195)	$ 5.44
Outstanding at September 30, 2023	2,308,924	$ 4.27

As of September 30, 2023, there was approximately $8.5 million of total unrecognized compensation expense related to unvested restricted stock awards, which is expected to be recognized over a weighted average vesting period of 2.4 years. The total fair value of restricted stock awards that vested during the nine months ended September 30, 2023 was $1.5 million.

NOTE 11 – LICENSE/SUPPLIER AGREEMENT

Sublicense Agreement Relating to Rett Syndrome

In October 2020, the Company entered into a sublicense agreement with Taysha Gene Therapies ("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 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 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 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 September 30, 2023 and 2022, and $3.5 million and $1.0 million in revenue during the nine months ended September 30, 2023 and 2022, respectively. Revenue recognized was based on payments related to clinical milestones achieved by our sublicensor as per the sublicense agreement noted above. As of September 30, 2023 and December 31, 2022, the Company had no contract assets included in accounts receivable on the Company's condensed consolidated balance sheet, respectively. As of September 30, 2023 and December 31, 2022, the Company had no contract liabilities included in accounts payable on the Company's condensed consolidated balance sheet, respectively, 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. There were no amounts due to the Company from Ultragenyx under the License Agreement as of September 30, 2023 and December 31, 2022, respectively.

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, 2022 (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 EB-101, a genetically engineered, autologous cell therapy, 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 EB-101. 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 EB-101 to the U.S. Food and Drug Administration ("FDA"). As part of the submission, we requested Priority Review, which, if granted, would shorten the FDA's review period to six months from the filing acceptance of the BLA, instead of 10 months under standard review.

We have continued to prepare our current Good Manufacturing Practices ("cGMP") commercial facility in Cleveland, Ohio for manufacturing EB-101 drug product to support our planned commercial launch of EB-101, if approved. EB-101 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 EB-101. We have also begun discussions with high volume treatment centers of excellence to onboard them for EB-101 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™ capsid platform 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.

Recent Developments

On July 6, 2023, we closed on a $25.0 million registered direct offering priced at-the market under Nasdaq rules to certain existing institutional investors. After offering costs, net proceeds consisted of $23.0 million. We sold 3,284,407 shares of our common stock (and, in lieu of common stock for certain investors, pre-funded warrants to purchase 2,919,140 shares of our common stock) at an offering price of $4.03 per share (or $4.0299 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 are immediately exercisable at a nominal exercise price of $0.0001 per share and may be exercised at any time.

On September 12, 2023, we announced the appointment of Madhav Vasanthavada, Ph.D., M.B.A. to the role of Chief Commercial Officer and Head of Business Development. In this capacity, in addition to his current business development responsibilities, Dr. Vasanthavada will oversee all aspects of commercial strategy, planning and operations as we prepare for a potential launch of EB-101.

On September 25, 2023, we submitted a BLA for EB-101 to the FDA. As part of the submission, we requested Priority Review, which, if granted, would shorten the FDA's review period to six months from the filing acceptance of the BLA, instead of 10 months under standard review.

RESULTS OF OPERATIONS

Comparison of Three Months Ended September 30, 2023 and September 30, 2022

($ in thousands)	For the three months ended		Change	
	September 30, 2023	**September 30, 2022**	**$**	**%**
Expenses:				
Royalties	30	—	30	N/A
Research and development	7,148	5,490	1,658	30%
General and administrative	4,156	3,890	266	7%
Total expenses	11,334	9,380	1,954	21%
Loss from operations	(11,334)	(9,380)	(1,954)	21%
Interest income	593	72	521	724%
Interest expense	(105)	(157)	52	(33)%
Change in fair value of warrant liabilities	(1,101)	3,050	(4,151)	(136)%
Other income (expense)	111	(19)	130	(684)%
Net loss	$ (11,836)	$ (6,434)	$ (5,402)	84%

N/A – not applicable or not meaningful

Royalties

Total royalties were $30,000 for the three months ended September 30, 2023, as compared to nil for the same period of 2022, an increase of $30,000. The increase in expense was due to milestones owed to our licensors.

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 September 30, 2023 was $7.1 million, as compared to $5.5 million for the same period of 2022, an increase of $1.6 million. The increase in expenses was primarily due to:

- increased clinical and development work and related costs of $0.8 million associated with our BLA filing for EB-101;
- increased salary and related costs of $0.9 million; and partially offset by
- decrease other costs of $0.1 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 $4.2 million for the three months ended September 30, 2023, as compared to $3.9 million for the same period of 2022, an increase of $0.3 million. The increase in expenses was primarily due to:

- increased non-cash stock-based compensation of $0.8 million; partially offset by
- decreased professional fees of $0.3 million; and
- decreased rent and utilities of $0.2 million.

Interest income

Interest income was $0.6 million for the three months ended September 30, 2023, as compared to $0.1 million in the same period of 2022. The increase resulted from higher earnings on short-term investments driven by higher interest rates and increased short-term investment balances.

Interest expense

Interest expense was $0.1 million for the three months ended September 30, 2023, as compared to $0.2 million in the same period of 2022. The decrease results primarily from the $5.0 million settlement payment made in November 2022 of a disputed liability owed to our prior licensor, REGENXBIO, Inc.

Change in fair value of warrant liabilities

The change in fair value of warrant liabilities was a loss of $1.1 million for the three months ended September 30, 2023, as compared to a gain of $3.0 million for the same period in 2022.

We issued stock purchase warrants that are required to be classified as a liability and valued at fair market value at each reporting period. The change in the fair value of warrant liabilities was primarily due to the fluctuation in our stock price year over year and a shorter term.

Other income (expense)

Other income was $0.1 million for the three months ended September 30, 2023, as compared to other expense of $19,000 in the same period of 2022. The change was primarily a result of the Company subletting certain office space during 2023.

Comparison of Nine Months Ended September 30, 2023 and September 30, 2022

	For the nine months ended		Change	
($ in thousands)	**September 30, 2023**	**September 30, 2022**	**$**	**%**
Revenues:				
License and other revenues	$ 3,500	$ 1,346	$ 2,154	160%
Expenses:				
Royalties	1,605	350	1,255	359%
Research and development	23,712	22,693	1,019	4%
General and administrative	13,174	11,574	1,600	14%
Impairment of licensed technology	—	1,355	(1,355)	N/A
Loss/(gain) on right-of-use lease assets	(1,065)	1,561	(2,626)	(168)%
Impairment of construction-in-progress	—	1,792	(1,792)	N/A
Total expenses	37,426	39,325	(1,899)	(5)%
Loss from operations	(33,926)	(37,979)	4,053	(11)%
Interest income	1,374	103	1,271	1,234%
Interest expense	(309)	(558)	249	(45)%
Change in fair value of warrant liabilities	(7,465)	5,995	(13,460)	(225)%
Other income (expense)	2,729	(136)	2,865	(2,107)%
Net loss	$ (37,597)	$ (32,575)	$ (5,022)	15%

N/A – not applicable or not meaningful

License and other revenues

License and other revenues for the nine months ended September 30, 2023 was $3.5 million, as compared to $1.3 million for the same period of 2022. The revenues in both periods mainly result from clinical milestones achieved under a sublicense agreement we entered into with Taysha Gene Therapies in October 2020 relating to an investigational AAV-based gene therapy for Rett syndrome. In 2022, there was also revenue consisting of the recognition of deferred revenue related to grants for the ABO-102 and ABO-101 development programs.

Royalties

Total royalties were $1.6 million for the nine months ended September 30, 2023, as compared to $0.4 million for the same period of 2022, an increase of $1.2 million. The increase in expense was due to royalties owed to our licensors resulting from the milestones due from Taysha related to Rett syndrome.

Research and development

Total research and development spending for the nine months ended September 30, 2023 was $23.7 million, as compared to $22.7 million for the same period of 2022, an increase of $1.0 million. The increase in expenses was primarily due to an increase of $1.0 million in salaries and related costs due to increased headcount related to the filing of our BLA.

General and administrative

Total general and administrative expenses were $13.2 million for the nine months ended September 30, 2023, as compared to $11.6 million for the same period of 2022, an increase of $1.6 million. The increase in expenses was primarily due to:

- increased salary and related costs of $1.5 million;
- increased non-cash stock-based compensation of $1.0 million; partially offset by
- decreased other costs of $0.9 million.

Impairment of licensed technology

Impairment of licensed technology was nil for the nine months ended September 30, 2023, as compared to $1.4 million in the same period of 2022. The licensed technology was for the ABO-102 and ABO-101 development programs and as a result of our shift in priorities in 2022, we determined the remaining value of the licensed technology had no future value and thus recorded an impairment charge of $1.4 million for the nine months ended September 30, 2022.

Loss/(gain) of right-of-use lease assets

The gain on right-of-use lease assets was $1.1 for the nine months ended September 30, 2023, as compared to a loss on right-of-use assets of $1.6 million in the same period of 2022. The gain on right-of-use assets for 2023 was related to the termination of our operating leases for office space that we no longer use, resulting in a gain from the difference between the carrying value of the right-of-use lease assets and the related lease liabilities.

The loss on right-of-use assets for 2022 was related to a lease for a future manufacturing facility for the ABO-102 and ABO-101 development programs, which, as a result of our shift in priorities in 2022, we determined the remaining value of the portion of this lease had no future value and thus recorded an impairment charge of $1.6 million for the nine months ended September 30, 2022.

Impairment of construction-in-progress

Construction-in-progress impairment charge was nil for the nine months ended September 30, 2023, as compared to $1.8 million in the same period of 2022. The construction-in-progress was for a facility for the ABO-102 and ABO-101 development programs. As a result of our shift in priorities, we determined the remaining value of the construction-in-progress facility had no future value and thus, we recorded impairment of $1.8 million for the nine months ended September 30, 2022.

Interest income

Interest income was $1.4 million for the nine months ended September 30, 2023, as compared to $0.1 million in the same period of 2022. The increase resulted from higher earnings on short-term investments driven by higher interest rates and increased short-term investment balances.

Interest expense

Interest expense was $0.3 million for the nine months ended September 30, 2023, as compared to $0.6 million in the same period of 2022. The decrease results primarily from the $5.0 million settlement payment made in November 2022 of a disputed liability owed to our prior licensor, REGENXBIO, Inc.

Change in fair value of warrant liabilities

The change in fair value of warrant liabilities was a loss of $7.5 million for the nine months ended September 30, 2023, as compared to a gain of $6.0 million for the same period in 2022.

We issued stock purchase warrants that are required to be classified as a liability and valued at fair market value at each reporting period. The change in the fair value of warrant liabilities is primarily due to the fluctuation in our stock price year over year and a shorter term.

Other income (expense)

Other income was $2.7 million for the nine months ended September 30, 2023, as compared to other expense of $0.1 million in the same period of 2022. The change was primarily a result of $2.1 million in other income related to the impact of the employee retention credit that we have submitted for 2020 and 2021.

LIQUIDITY AND CAPITAL RESOURCES

Cash Flows for the Nine Months Ended September 30, 2023 and 2022

	For the nine months ended	
($ in thousands)	**September 30, 2023**	**September 30, 2022**
Total cash, cash equivalents and restricted cash (used in) provided by:		
Operating activities	$ (27,774)	$ (29,491)
Investing activities	(11,321)	1,326
Financing activities	29,590	407
Net decrease in cash, cash equivalents and restricted cash	$ (9,505)	$ (27,758)

Operating activities

Net cash used in operating activities was $27.8 million for the nine months ended September 30, 2023, primarily comprised of our net loss of $37.6 million, increases in operating assets and liabilities of $2.8 million and net non-cash charges of $12.6 million.

Net cash used in operating activities was $29.5 million for the nine months ended September 30, 2022, primarily comprised of our net loss of $32.6 million and a decrease in operating assets and liabilities of $1.9 million, partially offset by net non-cash charges of $5.0 million.

Investing activities

Net cash used in investing activities was $11.3 million for the nine months ended September 30, 2023, primarily comprised of purchases of short-term investments of $48.2 million, partially offset by proceeds from maturities of short-term investments of $37.0 million.

Net cash provided by investing activities was $1.3 million for the nine months ended September 30, 2022, primarily comprised of proceeds from maturities of short-term investments of $43.7 million and proceeds from disposal of property and equipment of $1.6 million, partially offset by purchases of short-term investments of $43.9 million and capital expenditures of $0.1 million.

Financing activities

Net cash provided by financing activities was $29.6 million for the nine months ended September 30, 2023, primarily comprised of $23.0 million in net proceeds from our direct placement sale of common stock and $6.6 million in net proceeds from ATM sales of common stock pursuant to our ATM Agreement (as defined below).

Net cash provided by financing activities was $0.4 million for the nine months ended September 30, 2022, primarily comprised of proceeds of $4.2 million from open market sales of common stock pursuant to the ATM Agreement (as defined below), partially offset by the proceeds and redemption of our convertible redeemable preferred stock.

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 September 30, 2023, our cash resources were $54.1 million. We believe that our current cash and cash equivalents, restricted cash and short-term investments are sufficient to fund operations through at least the next 12 months from the date of this report on Form 10-Q. We may need to secure additional funding to carry out all of our planned research and development and potential commercialization activities. If we are unable to obtain additional financing or generate license or product revenue, the lack of liquidity and sufficient capital resources could have a material adverse effect on our future prospects.

We have an open market sale agreement with Jefferies LLC (as amended, the "ATM Agreement") pursuant to which, we may sell from time to time, through Jefferies LLC, shares of our common stock for an aggregate sales price of up to $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 1,990,321 shares of our common stock under the ATM Agreement resulting in net proceeds of $6.6 million for the nine months ended September 30, 2023.

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 material impact in our results of operations or financial condition.

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

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

Recently Issued Accounting Standards Not Yet Effective or Adopted

See Note 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 September 30, 2023, 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 September 30, 2023 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 September 30, 2023 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/A for the year ended December 31, 2022 should be carefully considered. There have been no material changes in the assessment of our risk factors from those set forth in our Annual Report on Form 10-K/A for the year ended December 31, 2022.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

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 September 30, 2023:

	Total number of shares (or units) purchased [(a)]		Average price paid per share (or unit)
Shares delivered or withheld pursuant to restricted stock awards			
July 1, 2023 – July 31, 2023	1,187	$	3.73
August 1, 2023 – August 31, 2023	7	$	4.43
September 1, 2023 – September 30, 2023	37,458	$	3.93
	38,652	$	3.92

(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 6. EXHIBITS

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

Exhibit Index

Exhibits:

3.1	Restated Certificate of Incorporation of Abeona Therapeutics Inc. (incorporated by reference to Exhibit 3.1 of our Form 10-Q for the quarter ended March 31, 2019)
3.2	Amended and Restated Bylaws of Abeona Therapeutics Inc. (incorporated by reference to Exhibit 3.3 of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2023).
4.1	Pre-Funded Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K filed with the Securities and Exchange Commission on July 3, 2023).
23.1	Consent of Independent Registered Public Accounting Firm, dated October 9, 2023 (incorporated by reference to Exhibit 23.1 of Form S-8 filed with the Securities and Exchange Commission on October 10, 2023).
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.
99.1	Abeona Therapeutics Inc. 2023 Employment Inducement Equity Incentive Plan (incorporated by reference to Exhibit 99.1 of Form S-8 filed with the Securities and Exchange Commission on October 10, 2023).
99.2	2023 Employment Inducement Equity Incentive Plan Restricted Stock Award Agreement (incorporated by reference to Exhibit 99.2 of Form S-8 filed with the Securities and Exchange Commission on October 10, 2023).
101.1	The following materials from Abeona's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, formatted in Inline XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at September 30, 2023 and December 31, 2022 (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2023 and 2022 (unaudited), (iii) Condensed Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2023 and 2022 (unaudited), (iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2023 and 2022 (unaudited), and (v) Notes to Condensed Consolidated Financial Statements (unaudited).

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ABEONA THERAPEUTICS INC.

Date: November 13, 2023

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

Date: November 13, 2023

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

EXHIBIT 31.1

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

I, Vishwas Seshadri, certify that:

1. I have reviewed this report on Form 10-Q for the quarterly period ended September 30, 2023, of Abeona Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2023

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

EXHIBIT 31.2

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

I, Joseph Vazzano, certify that:

1. I have reviewed this report on Form 10-Q for the quarterly period ended September 30, 2023, of Abeona Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2023

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

EXHIBIT 32

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

In connection with the Quarterly Report of Abeona Therapeutics Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Vishwas Seshadri, President and Chief Executive Officer of the Company, and Joseph Vazzano, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2023

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

Date: November 13, 2023

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