

**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 June 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

(State or other jurisdiction of incorporation or organization)

83-0221517

(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 August 1, 2023 was 24,755,873 shares.

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

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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: our plans to submit 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: our ability to successfully submit a Biologics License Application for EB-101 and the outcome thereof; our ability to find a potential commercialization partner for EB-101; 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)

	June 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,225	\$ 14,217
Short-term investments	30,547	37,932
Restricted cash	338	338
Accounts receivable	3,500	—
Other receivables	2,227	188
Prepaid expenses and other current assets	1,201	424
Total current assets	<u>44,038</u>	<u>53,099</u>
Property and equipment, net	4,489	5,741
Right-of-use lease assets	4,915	5,331
Other assets	108	43
Total assets	<u>\$ 53,550</u>	<u>\$ 64,214</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,477	\$ 1,811
Accrued expenses	4,161	3,991
Current portion of lease liability	1,597	1,773
Other current liabilities	205	204
Total current liabilities	<u>9,440</u>	<u>7,779</u>
Payable to licensor	4,367	4,163
Long-term lease liabilities	4,377	5,854
Warrant liabilities	26,021	19,657
Total liabilities	<u>44,205</u>	<u>37,453</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock - \$0.01 par value; authorized 2,000,000 shares; No shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	—	—
Common stock - \$0.01 par value; authorized 200,000,000 shares; 21,478,157 and 17,719,720 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	215	177
Additional paid-in capital	730,322	722,049
Accumulated deficit	(721,097)	(695,336)
Accumulated other comprehensive loss	(95)	(129)
Total stockholders' equity	<u>9,345</u>	<u>26,761</u>
Total liabilities and stockholders' equity	<u>\$ 53,550</u>	<u>\$ 64,214</u>

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

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

	For the three months ended June 30,		For the six months ended June 30,	
	2023	2022	2023	2022
Revenues:				
License and other revenues	\$ 3,500	\$ 1,000	\$ 3,500	\$ 1,346
Expenses:				
Royalties	1,575	350	1,575	350
Research and development	8,523	6,658	16,564	17,203
General and administrative	5,021	3,460	9,018	7,684
Impairment of licensed technology	—	—	—	1,355
Loss/(gain) on right-of-use lease assets	(1,065)	—	(1,065)	1,561
Impairment of construction-in-progress	—	(1,460)	—	1,792
Total expenses	<u>14,054</u>	<u>9,008</u>	<u>26,092</u>	<u>29,945</u>
Loss from operations	(10,554)	(8,008)	(22,592)	(28,599)
Interest income	417	31	781	38
Interest expense	(103)	(200)	(204)	(401)
Change in fair value of warrant liabilities	(8,629)	4,198	(6,364)	2,945
Other income (expense)	2,215	(118)	2,618	(124)
Net loss	<u>\$ (16,654)</u>	<u>\$ (4,097)</u>	<u>\$ (25,761)</u>	<u>\$ (26,141)</u>
Deemed dividends related to Series A and Series B Convertible Redeemable Preferred Stock	—	(3,782)	—	(3,782)
Net loss attributable to Common Shareholders	<u>\$ (16,654)</u>	<u>\$ (7,879)</u>	<u>\$ (25,761)</u>	<u>\$ (29,923)</u>
Basic and diluted loss per common share	<u>\$ (0.92)</u>	<u>\$ (1.36)</u>	<u>\$ (1.48)</u>	<u>\$ (5.16)</u>
Weighted average number of common shares outstanding – basic and diluted	<u>18,017,874</u>	<u>5,806,473</u>	<u>17,464,026</u>	<u>5,800,822</u>
Other comprehensive income (loss):				
Change in unrealized gains (losses) related to available-for-sale debt securities	(30)	(4)	34	(7)
Comprehensive loss	<u>\$ (16,684)</u>	<u>\$ (7,883)</u>	<u>\$ (25,727)</u>	<u>\$ (29,930)</u>

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

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

Three months ended June 30, 2023

	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-in	Deficit	Other	Stockholders'
			Capital		Comprehensive	Equity
					Loss	
Balance at March 31, 2023	17,929,344	\$ 179	\$ 723,069	\$ (704,443)	\$ (65)	\$ 18,740
Stock-based compensation expense	—	—	927	—	—	927
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement	1,657,052	17	(22)	—	—	(5)
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	1,891,761	19	6,348	—	—	6,367
Net loss	—	—	—	(16,654)	—	(16,654)
Other comprehensive loss	—	—	—	—	(30)	(30)
Balance at June 30, 2023	<u>21,478,157</u>	<u>\$ 215</u>	<u>\$ 730,322</u>	<u>\$ (721,097)</u>	<u>\$ (95)</u>	<u>\$ 9,345</u>

Six months ended June 30, 2023

	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-in	Deficit	Other	Stockholders'
			Capital		Comprehensive	Equity
					Loss	
Balance at December 31, 2022	17,719,720	\$ 177	\$ 722,049	\$ (695,336)	\$ (129)	\$ 26,761
Stock-based compensation expense	—	—	1,697	—	—	1,697
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax withholding settlement	1,768,116	18	(27)	—	—	(9)
Issuance of common stock, net of offering costs under open market sale agreement (ATM)	1,990,321	20	6,603	—	—	6,623
Net loss	—	—	—	(25,761)	—	(25,761)
Other comprehensive income	—	—	—	—	34	34
Balance at June 30, 2023	<u>21,478,157</u>	<u>\$ 215</u>	<u>\$ 730,322</u>	<u>\$ (721,097)</u>	<u>\$ (95)</u>	<u>\$ 9,345</u>

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

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

Three months ended June 30, 2022

	Convertible Redeemable Preferred Stock				Common Stock		Additional	Accumulated	Accumulated Other Comprehensive	Total
	Series A		Series B				Paid-in	Deficit	Loss	Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital			Equity
Balance at March 31, 2022	—	\$ —	—	\$ —	5,883,196	\$ 1,471	\$ 697,426	\$ (677,684)	\$ (30)	\$ 21,183
Stock-based compensation expense	—	—	—	—	—	—	724	—	—	724
Issuance of common stock in connection with restricted share awards, net of cancellations	—	—	—	—	(12,821)	(4)	4	—	—	—
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)	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(4,097)	—	(4,097)
Other comprehensive loss	—	—	—	—	—	—	—	—	(4)	(4)
Balance at June 30, 2022	—	\$ —	—	\$ —	<u>5,870,375</u>	<u>\$ 1,467</u>	<u>\$ 694,372</u>	<u>\$ (681,781)</u>	<u>\$ (34)</u>	<u>\$ 14,024</u>

Six months ended June 30, 2022

	Convertible Redeemable Preferred Stock				Common Stock		Additional	Accumulated	Accumulated Other Comprehensive	Total
	Series A		Series B				Paid-in	Deficit	Loss	Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital			Equity
Balance at December 31, 2021	—	\$ —	—	\$ —	5,888,217	\$ 1,472	\$ 696,563	\$ (655,640)	\$ (27)	\$ 42,368
Stock-based compensation expense	—	—	—	—	—	—	1,586	—	—	1,586
Issuance of common stock in connection with restricted share awards, net of cancellations	—	—	—	—	(17,842)	(5)	5	—	—	—
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)	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(26,141)	—	(26,141)
Other comprehensive loss	—	—	—	—	—	—	—	—	(7)	(7)
Balance at June 30, 2022	—	\$ —	—	\$ —	<u>5,870,375</u>	<u>\$ 1,467</u>	<u>\$ 694,372</u>	<u>\$ (681,781)</u>	<u>\$ (34)</u>	<u>\$ 14,024</u>

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

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

	For the six months ended June 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (25,761)	\$ (26,141)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,276	1,584
Stock-based compensation expense	1,697	1,586
Change in fair value of warrant liabilities	6,364	(2,945)
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	(74)	(177)
Amortization of right-of-use lease assets	450	899
Non-cash interest	204	402
Loss on disposal of property and equipment	47	106
Change in operating assets and liabilities:		
Accounts receivable	(3,500)	2,000
Other receivables	(2,039)	(1,827)
Prepaid expenses and other current assets	(777)	937
Other assets	(65)	148
Accounts payable, accrued expenses and lease liabilities	1,214	(3,684)
Other current liabilities	1	—
Change in payable to licensor	—	(296)
Net cash used in operating activities	(22,028)	(22,700)
Cash flows from investing activities:		
Capital expenditures	(250)	(103)
Proceeds from disposal of property and equipment	179	1,487
Purchases of short-term investments	(14,156)	(34,442)
Proceeds from maturities of short-term investments	21,649	32,735
Net cash provided by (used in) investing activities	7,422	(323)
Cash flows from financing activities:		
Proceeds from ATM sales of common stock, net of issuance costs	6,623	—
Proceeds from net settlement of restricted share awards	(9)	—
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 (used in) financing activities	6,614	(3,782)
Net decrease in cash, cash equivalents and restricted cash	(7,992)	(26,805)
Cash, cash equivalents and restricted cash at beginning of period	14,555	38,829
Cash, cash equivalents and restricted cash at end of period	\$ 6,563	\$ 12,024
Supplemental cash flow information:		
Cash and cash equivalents	\$ 6,225	\$ 6,133
Restricted cash	338	5,891
Total cash, cash equivalents and restricted cash	\$ 6,563	\$ 12,024
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.

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Notes to Unaudited Condensed Consolidated Financial 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.

Reverse Stock Split

As described in Note 1 to the consolidated financial statements included in the Company's 2022 Annual Report on Form 10-K/A, on June 30, 2022, the Company filed a Certificate of Amendment to the Company's Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Certificate of Amendment"), to effectuate a reverse stock split of the Company's outstanding common stock, par value \$0.01 per share ("Common Stock"), at an exchange ratio of 25-to-1 (the "Reverse Stock Split"). The Reverse Stock Split was effective on July 1, 2022. The number of authorized shares of Common Stock immediately after the Reverse Stock Split ("New Common Stock") remained at 200,000,000 shares. All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated.

Uses and Sources of Liquidity

The unaudited interim condensed consolidated financial statements have been prepared on the going concern basis, which assumes the Company will have sufficient cash to pay its operating expenses, as and when they become payable, for a period of at least 12 months from the date the financial report is issued.

As of June 30, 2023, the Company had cash, cash equivalents, restricted cash and short-term investments of \$37.1 million. For the six months ended June 30, 2023, the Company had cash outflows from operations of \$22.0 million. The Company has not generated significant revenues and has not achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and nonclinical testing, and commercialization of the Company's product candidates will require significant additional financing.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery and development of product candidates, obtaining the necessary regulatory approval to market the Company's product candidates, raising additional capital to continue to fund the Company's operations, development of competing drugs and therapies and protection of proprietary technology. As a result of these and other risks and the related uncertainties, there can be no assurance of the Company's future success.

Subsequent to June 30, 2023, as described in Note 12, the Company raised \$25.0 million, with net proceeds of \$23.0 million, after offering costs through the issuance of common stock and warrants.

The Company believes that its current cash and cash equivalents, restricted cash and short-term investments are sufficient resources to fund operations through at least the next 12 months from the date of this quarterly report on Form 10-Q. The Company may need to secure additional funding to carry out all of its planned research and development and commercialization activities. If the Company is 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 its future prospects.

Use of Estimates

The preparation of unaudited interim condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amount of assets and disclosure of contingent assets and liabilities at the date of the unaudited interim condensed consolidated financial statements and the reported amounts of revenue and expenses during the reported period. Actual results could differ from these estimates and assumptions.

Other receivables

Other receivables include employee retention credits ("ERC"), sublease rent receivables and other miscellaneous receivables. As of June 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.

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 six months ended June 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):

Condensed Consolidated Statement of Operations and Comprehensive Loss	For the three months ended June 30, 2022		
	As Reported	Adjustment	As Revised
Change in fair value of warrant liabilities	\$ —	\$ 4,198	\$ 4,198
Net loss	\$ (8,295)	\$ 4,198	\$ (4,097)
Net loss attributable to Common Shareholders	\$ (12,077)	\$ 4,198	\$ (7,879)
Basic and diluted loss per common share	\$ (2.08)	\$ 0.72	\$ (1.36)
Comprehensive loss	\$ (12,081)	\$ 4,198	\$ (7,883)

Condensed Consolidated Statement of Operations and Comprehensive Loss	For the six months ended June 30, 2022		
	As Reported	Adjustment	As Revised
Change in fair value of warrant liabilities	\$ —	\$ 2,945	\$ 2,945
Net loss	\$ (29,086)	\$ 2,945	\$ (26,141)
Net loss attributable to Common Shareholders	\$ (32,868)	\$ 2,945	\$ (29,923)
Basic and diluted loss per common share	\$ (5.67)	\$ 0.51	\$ (5.16)
Comprehensive loss	\$ (32,875)	\$ 2,945	\$ (29,930)

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 six months ended June 30, 2022		
	As Reported	Adjustment	As Revised
Net loss	\$ (29,086)	\$ 2,945	\$ (26,141)
Adjustments to reconcile net loss to cash used in operating activities:			
Change in fair value of warrant liabilities	\$ —	\$ (2,945)	\$ (2,945)
Net cash provided by operating activities	\$ (22,700)	\$ —	\$ (22,700)

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

Condensed Consolidated Statement of Stockholders' Equity	As of June 30, 2022		
	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, March 31, 2022	\$ 706,433	\$ (9,007)	\$ 697,426
Additional paid-in capital, March 31, 2022	\$ 31,443	\$ (10,260)	\$ 21,183
Net loss	\$ (29,086)	\$ 2,945	\$ (26,141)
Additional paid-in capital, June 30, 2022	\$ 703,379	\$ (9,007)	\$ 694,372
Total stockholders' equity, June 30, 2022	\$ 20,086	\$ (6,062)	\$ 14,024

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 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 income/(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 six months ended June 30,	
	2023	2022
Stock options	230,723	265,411
Restricted stock	2,566,303	61,108
Warrants	9,397,879	1,788,000
Total	12,194,905	2,114,519

New Accounting Pronouncements

No new accounting pronouncement issued or effective had, or is expected to have, a material impact on the Company's condensed consolidated financial statements.

NOTE 2 – SHORT-TERM INVESTMENTS

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

June 30, 2023				
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments:				
U.S. treasury and federal agency securities	\$ 30,613	—	(66)	\$ 30,547
Total available-for-sale, short-term investments	<u>\$ 30,613</u>	<u>—</u>	<u>(66)</u>	<u>\$ 30,547</u>

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	<u>\$ 38,032</u>	<u>—</u>	<u>(100)</u>	<u>\$ 37,932</u>

As of June 30, 2023, the available-for-sale securities classified as short-term investments mature in one year or less. Unrealized losses on available-for-sale securities as of June 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 six months ended June 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 six months ended June 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)	June 30, 2023	December 31, 2022
Laboratory equipment	5	\$ 7,276	\$ 7,636
Furniture, software and office equipment	3 to 5	991	1,379
Leasehold improvements	Shorter of remaining lease term or useful life	8,603	8,605
Subtotal		16,870	17,620
Less: accumulated depreciation		(12,381)	(11,879)
Total property and equipment, net		<u>\$ 4,489</u>	<u>\$ 5,741</u>

Depreciation expense was \$0.6 million and \$0.8 million for the three months ended June 30, 2023 and 2022, respectively, and \$1.3 million and \$1.6 million for the six months ended June 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 six months ended June 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 A and Type B. The license is 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 six months ended June 30, 2022. There is no remaining net value of licensed technology as of June 30, 2023 and December 31, 2022.

Amortization expense on licensed technology was nil and \$29,000 for the six months ended June 30, 2023 and 2022, respectively. There was no amortization expense for the three months ended June 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 June 30, 2023 and December 31, 2022 (in thousands):

Description	Fair Value at June 30, 2023	Level 1	Level 2	Level 3
Recurring Assets				
Cash equivalents				
Money market fund	\$ 5,678	\$ 5,678	\$ —	\$ —
Short-term investments				
U.S. treasury and federal agency securities	30,547	—	30,547	—
Total assets measured at fair value	<u>\$ 36,225</u>	<u>\$ 5,678</u>	<u>\$ 30,547</u>	<u>\$ —</u>
Liabilities				
Warrant liabilities	\$ 26,021	—	—	\$ 26,021
Total liabilities measured at fair value	<u>\$ 26,021</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 26,021</u>

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 and federal agency securities	37,932	—	37,932	—
Total assets measured at fair value	<u>\$ 50,855</u>	<u>\$ 12,923</u>	<u>\$ 37,932</u>	<u>\$ —</u>
Liabilities				
Warrant liabilities	\$ 19,657	—	—	\$ 19,657
Total liabilities measured at fair value	<u>\$ 19,657</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 19,657</u>

Warrant Liabilities

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:

	June 30, 2023	December 31, 2022
Common share price	\$4.03	\$3.08
Expected term (years)	3.47 – 4.35	3.96 – 4.84
Risk-free interest rate (%)	4.13% – 4.28%	3.91% – 4.01%
Volatility (%)	100.00% – 105.04%	102.40% – 107.55%

As of June 30, 2023, 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 June 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 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	6,364
Warrant liabilities as of June 30, 2023	<u>\$ 26,021</u>

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 June 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 interest rate of 9.6%. The long-term portion due in November 2024 was \$4.4 million and \$4.2 million as of June 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):

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
Accrued employee compensation	\$ 1,434	\$ 2,593
Accrued contracted services and other	2,727	1,398
Total accrued expenses	<u>\$ 4,161</u>	<u>\$ 3,991</u>

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 from the difference of the right-of-use assets and lease liabilities in the three and six months ended June 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 six months ended June 30, 2022.

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

	<u>For the three months ended June 30,</u>		<u>For the six months ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Operating lease cost	\$ 353	\$ 461	\$ 708	\$ 933
Variable lease cost	116	116	215	212
Short-term lease cost	13	20	31	41
Total operating lease costs	<u>\$ 482</u>	<u>\$ 597</u>	<u>\$ 954</u>	<u>\$ 1,186</u>

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

Future minimum lease payments and obligations	Operating Leases
2023, remainder	\$ 799
2024	993
2025	1,552
2026	791
2027	807
Thereafter	2,516
Total undiscounted operating lease payments	7,458
Less: imputed interest	1,484
Present value of operating lease liabilities	<u>\$ 5,974</u>

The weighted-average remaining term of the Company's operating leases was 68 months and the weighted-average discount rate used to measure the present value of the Company's operating lease liabilities was 7.5% as of June 30, 2023.

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

Future cash receipts	Operating Subleases
2023, remainder	\$ 270
2024	634
2025	485
Total future cash receipts	<u>\$ 1,389</u>

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 June 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 six months ended June 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 six months ended June 30, 2023. There were no sales under the ATM Agreement during the three and six months ended June 30, 2022.

Private Placement Offerings

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

In the event of certain fundamental transactions involving the Company, the holders of the stock purchase warrants may require the Company to make a payment based on a Black-Scholes valuation, using specific inputs that are not considered indexed to the Company’s stock in accordance with ASC 815. Therefore, the Company accounted for the stock purchase warrants as liabilities. 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 June 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.

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 June 30, 2023, there were 149,291 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 to be granted to six new hires as inducement grants (“Inducement Grants”).

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

	For the three months ended June 30,		For the six months ended June 30,	
	2023	2022	2023	2022
Research and development	\$ 218	\$ 184	\$ 404	\$ 556
General and administrative	709	540	1,293	1,030
Total stock-based compensation expense	<u>\$ 927</u>	<u>\$ 724</u>	<u>\$ 1,697</u>	<u>\$ 1,586</u>

Stock Options

The Company estimates the fair value of each option award on the date of grant using the Black-Scholes option valuation 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-valuation model utilizing the following assumptions:

	For the six months ended June 30,	
	2023*	2022
Expected volatility	n/a	95.1% - 96.0%
Expected term	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 six months ended June 30, 2023.

The following table summarizes stock option activity for the 2015 Incentive Plan and the 2005 Incentive Plan during the six months ended June 30, 2023 (there were no stock options granted under the 2023 Incentive Plan during the six months ended June 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	(10,047)	\$ 36.19	—	\$ —
Exercised	—	\$ —	—	\$ —
Outstanding at June 30, 2023	230,723	\$ 37.08	5.82	\$ —
Exercisable	169,637	\$ 36.33	5.09	\$ —
Unvested	61,086	\$ 39.17	7.87	\$ —

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 June 30, 2023, the total compensation cost related to non-vested option awards not yet recognized was approximately \$2.0 million with a weighted average remaining vesting period of 1.7 years.

Restricted Stock

The following table summarizes restricted stock award activity for the 2023 Incentive Plan, 2015 Incentive Plan and Inducement Grants during the six months ended June 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	(46,394)	\$ 4.40
Vested	(21,820)	\$ 28.34
Outstanding at June 30, 2023	<u>2,566,303</u>	<u>\$ 4.18</u>

As of June 30, 2023, there was approximately \$9.7 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 2.5 years. The total fair value of restricted stock awards that vested during the six months ended June 30, 2023 was \$0.6 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 and 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 of 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 \$3.5 million and \$1.0 million in revenue during the three and six months ended June 30, 2023 and 2022, respectively based on event-based-milestone payments. As of June 30, 2023 and December 31, 2022, the Company had \$3.5 million and nil in contract assets included in accounts receivable on the Company’s condensed consolidated balance sheet, respectively. As of June 30, 2023 and December 31, 2022, the Company had \$1.6 million and nil in 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 June 30, 2023 and December 31, 2022, respectively.

NOTE 12 – SUBSEQUENT EVENTS

On July 3, 2023, the Company entered into a securities purchase agreement (the “Purchase Agreement”) with certain existing institutional investors relating to the issuance and sale of an aggregate of (a) 3,284,407 shares of the Company’s common stock (the “Shares”), and (b) pre-funded warrants to purchase 2,919,140 shares of the Company’s common stock (the “2023 Pre-Funded Warrants”) to certain of such investors (the “Offering”). On July 6, 2023, the Shares were sold to the investors at an offering price of \$4.03 per share for \$25.0 million with net proceeds of \$23.0 million after offering costs. The 2023 Pre-Funded Warrants were sold to certain of the investors at an offering price of \$4.0299 per 2023 Pre-Funded Warrant, 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 until the 2023 Pre-Funded Warrants are exercised in full.

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 its two co-primary efficacy endpoints demonstrating statistically significant, clinically meaningful improvements in wound healing and pain reduction in large chronic RDEB wounds. Based on the positive results, we intend to submit a Biologics License Application ("BLA") for EB-101 to the U.S. Food and Drug Administration ("FDA") in the third quarter of 2023.

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.

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.

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 ("IND") meetings with the FDA regarding the preclinical development plans and regulatory requirements to support first-in-human trials. We plan to initiate IND-enabling preclinical studies in the second half of 2023.

Recent Developments

On July 6, 2023, we closed on a \$25.0 million, with net proceeds of \$23.0 million after offering costs, registered direct offering priced at-the market under Nasdaq rules to certain existing institutional investors. 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 until the pre-funded warrants are exercised in full.

In July 2023, we submitted the briefing package for the pre-BLA meeting with the FDA for our anticipated submission of EB-101 in the treatment of RDEB. The briefing package contains information regarding Chemistry, Manufacturing, and Controls ("CMC") and clinical data. The pre-BLA meeting is scheduled for late-August 2023 and Abeona anticipates filing its EB-101 BLA in the third quarter of 2023 following a successful pre-BLA meeting with the FDA.

RESULTS OF OPERATIONS

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

(\$ in thousands)	For the three months ended		Change	
	June 30, 2023	June 30, 2022	\$	%
Revenues:				
License and other revenues	\$ 3,500	\$ 1,000	\$ 2,500	250%
Expenses:				
Royalties	1,575	350	1,225	350%
Research and development	8,523	6,658	1,865	28%
General and administrative	5,021	3,460	1,561	45%
Loss/(gain) on right-of-use lease assets	(1,065)	—	(1,065)	N/A
Impairment of construction-in-progress	—	(1,460)	1,460	N/A
Total expenses	14,054	9,008	5,046	56%
Loss from operations	(10,554)	(8,008)	(2,546)	32%
Interest income	417	31	386	1,245%
Interest expense	(103)	(200)	97	(49)%
Change in fair value of warrant liabilities	(8,629)	4,198	(12,827)	(306)%
Other income (expense)	2,215	(118)	2,333	(1,977)%
Net loss	\$ (16,654)	\$ (4,097)	\$ (12,557)	306%

N/A – not applicable or not meaningful

License and other revenues

License and other revenues for the three months ended June 30, 2023 was \$3.5 million as compared to \$1.0 million for the same period of 2022. The revenues in both periods result from clinical milestones achieved under a sublicense agreement we entered into with Taysha Gene Therapies (“Taysha”) in October 2020 relating to an investigational AAV-based gene therapy for Rett syndrome (“Rett”).

Royalties

Total royalties were \$1.6 million for the three months ended June 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.

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 June 30, 2023 was \$8.5 million, as compared to \$6.7 million for the same period of 2022, an increase of \$1.9 million. The increase in expenses was primarily due to:

- increased clinical and development work and related costs of \$0.7 million associated with our planned BLA filing for EB-101;
- increased salary and related costs of \$0.8 million; and
- increased other costs of \$0.4 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) and other general operating expenses not otherwise included in research and development expenses.

Total general and administrative expenses were \$5.0 million for the three months ended June 30, 2023, as compared to \$3.4 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 \$1.1 million;
- increased non-cash stock-based compensation of \$0.2 million;
- increased professional fees of \$0.2 million; and
- increased other costs of \$0.1 million.

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

The gain on right-of-use lease assets was \$1.1 million for the three months ended June 30, 2023, as compared to nil in the same period of 2022. At the end of June 2023, we terminated an operating lease for office space that we no longer use, resulting in a gain from the difference of the right-of-use lease assets and the lease liabilities.

Impairment of construction-in-progress

Construction-in-progress impairment charge was nil for the three months ended June 30, 2023, as compared to a reduction in the impairment charge of \$1.5 million in the same period of 2022. The construction-in-progress was for a facility for the MPS IIIA and MPS IIIB 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 \$3.3 million for the three months ended March 31, 2022. We subsequently received certain refunds pertaining to the planned facility build-out, which reduced the overall impairment charge by \$1.5 million for the three months ended June 30, 2022.

Interest income

Interest income was \$0.4 million for the three months ended June 30, 2023, as compared to \$31,000 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 June 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 \$8.6 million for the three months ended June 30, 2023, as compared to a gain of \$4.2 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 \$2.2 million for the three months ended June 30, 2023, as compared to other expense of \$118,000 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.

Comparison of Six Months Ended June 30, 2023 and June 30, 2022

(\$ in thousands)	For the six months ended		Change	
	June 30, 2023	June 30, 2022	\$	%
Revenues:				
License and other revenues	\$ 3,500	\$ 1,346	\$ 2,154	160%
Expenses:				
Royalties	1,575	350	1,225	350%
Research and development	16,564	17,203	(639)	(4)%
General and administrative	9,018	7,684	1,334	17%
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	26,092	29,945	(3,853)	(13)%
Loss from operations	(22,592)	(28,599)	6,007	(21)%
Interest income	781	38	743	1,955%
Interest expense	(204)	(401)	197	(49)%
Change in fair value of warrant liabilities	(6,364)	2,945	(9,309)	(316)%
Other income (expense)	2,618	(124)	2,742	(2,211)%
Net loss	\$ (25,761)	\$ (26,141)	\$ 380	(1)%

N/A – not applicable or not meaningful

License and other revenues

License and other revenues for the six months ended June 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 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 six months ended June 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.

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 six months ended June 30, 2023 was \$16.6 million, as compared to \$17.2 million for the same period of 2022, a decrease of \$0.6 million. The decrease in expenses was primarily due to:

- decreased clinical and development work for our cell and gene therapy product candidates and other related costs of \$1.0 million which was due to the discontinuation of the ABO-102 and ABO-101 programs partially offset by increased costs related to our planned BLA filing;
- decreased stock compensation expenses of \$0.2 million; partially offset by
- increased other costs of \$0.6 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) and other general operating expenses not otherwise included in research and development expenses.

Total general and administrative expenses were \$9.0 million for the six months ended June 30, 2023, as compared to \$7.7 million for the same period of 2022, an increase of \$1.3 million. The increase in expenses was primarily due to:

- increased salary and related costs of \$1.4 million;
- increased non-cash stock-based compensation of \$0.3 million; partially offset by
- decreased other costs of \$0.4 million.

Impairment of licensed technology

Impairment of licensed technology was nil for the six months ended June 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, 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 six months ended June 30, 2022.

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

The gain on right-of-use lease assets was \$1.1 for the six months ended June 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 of the right-of-use lease assets and the 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, 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 six months ended June 30, 2022.

Impairment of construction-in-progress

Construction-in-progress impairment charge was nil for the six months ended June 30, 2023, as compared to \$1.8 million in the same period of 2022. The construction-in-progress was for a facility for the MPS IIIA and MPS IIIB development programs. 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 six months ended June 30, 2022.

Interest income

Interest income was \$0.8 million for the six months ended June 30, 2023, as compared to \$38,000 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 \$0.2 million for the six months ended June 30, 2023, as compared to \$0.4 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 \$6.4 million for the six months ended June 30, 2023, as compared to a gain of \$2.9 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 \$2.6 million for the six months ended June 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 Six Months Ended June 30, 2023 and 2022

(\$ in thousands)	For the six months ended	
	June 30, 2023	June 30, 2022
Total cash, cash equivalents and restricted cash (used in) provided by:		
Operating activities	\$ (22,028)	\$ (22,700)
Investing activities	7,422	(323)
Financing activities	6,614	(3,782)
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (7,992)</u>	<u>\$ (26,805)</u>

Operating activities

Net cash used in operating activities was \$22.0 million for the six months ended June 30, 2023, primarily comprised of our net loss of \$25.8 million, increases in operating assets and liabilities of \$5.1 million and net non-cash charges of \$8.9 million.

Net cash used in operating activities was \$22.7 million for the six months ended June 30, 2022, primarily comprised of our net loss of \$29.1 million and a decrease in operating assets and liabilities of \$2.7 million, partially offset by net non-cash charges of \$9.1 million.

Investing activities

Net cash provided by investing activities was \$7.4 million for the six months ended June 30, 2023, primarily comprised of proceeds from maturities of short-term investments of \$21.6 million, partially offset by purchases of short-term investments of \$14.2 million.

Net cash used in investing activities was \$0.3 million for the six months ended June 30, 2022, primarily comprised of proceeds from maturities of short-term investments of \$32.7 million and proceeds from disposal of property and equipment of \$1.5 million, partially offset by purchases of short-term investments of \$34.4 million and capital expenditures of \$0.1 million.

Financing activities

Net cash provided by financing activities was \$6.6 million for the six months ended June 30, 2023, primarily comprised of \$6.6 million in net proceeds from ATM sales of common stock.

Net cash used in financing activities was \$3.8 million for the six months ended June 30, 2022, primarily comprised of 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 June 30, 2023, our cash resources were \$37.1 million. On July 6, 2023, we raised a further \$23.0 million net proceeds in cash via a registered direct offering priced at-the market under Nasdaq rules to existing investors. As a result, 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 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 six months ended June 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 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 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;
- any continuing impact to our business, operations, and clinical programs from the COVID-19 pandemic and government actions related thereto;
- 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 June 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 June 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 June 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 June 30, 2023:

	Total number of shares (or units) purchased ^(a)	Average price paid per share (or unit)
<i>Shares delivered or withheld pursuant to restricted stock awards</i>		
April 1, 2023 – April 30, 2023	—	\$ —
May 1, 2023 – May 31, 2023	—	\$ —
June 1, 2023 – June 30, 2023	1,125	\$ 3.42
	<u>1,125</u>	<u>\$ 3.42</u>

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

ITEM 5. OTHER INFORMATION

On June 15, 2023, the Company awarded retention bonuses (the “Retention Bonus Agreements”) to Vishwas Seshadri, Ph.D., Joseph Vazzano, and Brendan O’Malley, Ph.D. (collectively, the “NEOs”). Under the Retention Bonus Agreements, the Company has awarded the NEOs bonus payments in addition to their base salaries in three installments conditioned upon their continued employment at the Company through the second anniversary of the effective date of the applicable Retention Bonus Agreement. Such bonuses are to be disbursed at the Company’s sole discretion, including upon the determination that the Company’s financial performance permits such payment. In the event the Company undergoes a change of control transaction, then any outstanding payment shall immediately become due and payable to the employee upon the closing of such change of control transaction.

The foregoing description of the Retention Bonus Agreements is qualified in its entirety by reference to the full text of the Retention Bonus Agreements, which are filed herewith as Exhibits 10.3, 10.4, and 10.5 and incorporated by reference herein in their entirety.

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 \(incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K filed with the Securities and Exchange Commission on July 3, 2023\)](#)
- 10.1 [Securities Purchase Agreement Warrant, dated as of July 3, 2023, between the Company and the purchasers thereto \(incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K filed with the Securities and Exchange Commission on July 3, 2023\)](#)
- 10.2 [2023 Equity Incentive Plan \(incorporated by reference to Exhibit 99.1 of our Registration Statement on Form S-8 filed with the Securities and Exchange Commission on May 19, 2023\)](#)
- 10.3 [Retention Bonus Letter, dated June 15, 2023, to Vishwas Seschadri, Ph.D.](#)
- 10.4 [Retention Bonus Letter, dated June 15, 2023, to Joseph Vazzano.](#)
- 10.5 [Retention Bonus Letter, dated June 15, 2023, to Brendon O'Malley, Ph.D.](#)
- 31.1 [Principal Executive Officer Certification Pursuant to Rule 13a-14\(a\) of the Securities Exchange Act of 1934.](#)
- 31.2 [Principal Financial Officer Certification Pursuant to Rule 13a-14\(a\) of the Securities Exchange Act of 1934.](#)
- 32* [Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 101.1 The following materials from Abeona's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, formatted in Inline XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at June 30, 2023 and December 31, 2022 (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2023 and 2022 (unaudited), (iii) Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2023 and 2022 (unaudited), (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 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: August 8, 2023

By: /s/ Vishwas Seshadri

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

Date: August 8, 2023

By: /s/ Joseph Vazzano

Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)



June 15, 2023

Vishwas Seshadri
[REDACTED]
[REDACTED]

Re: Retention Bonus

Dear Vishwas,

We consider your continued service and dedication to Abeona Therapeutics Inc. ("Abeona" or the "Company") essential to our business and future success. To incentivize you to remain employed with Abeona, we are pleased to inform you of Abeona's retention bonus, as described herein.

In recognition of your continued service with Abeona, we are offering you a retention bonus in the total gross amount of \$1,600,000, less all applicable withholdings and deductions (the "Retention Bonus"), payable in three annual payments (each a "Payment," and separately the "First Payment," "Second Payment," and "Third Payment"). Each Payment is subject to a "Retention Period" beginning on the date of that Payment, through and until the date that is one year from that date. By way of example, if the First Payment is made on June 30, 2023, the First Payment Retention Period would expire at the end of the workday on June 30, 2024. The Retention Bonus is in addition to the compensation already provided to you in your role for the Company.

You will be eligible to receive this Retention Bonus if all the following eligibility criteria are satisfied and the Company determines in its sole discretion that the financial performance of the Company permits each Payment:

1. You remain a full-time, active employee of Abeona through the end of the Retention Period.
2. Your performance has been satisfactory and meets expectations, as determined in Abeona's sole discretion, from the date of this letter through the end of the Retention Period.
3. You do not receive a disciplinary action, such as a written warning, during the Retention Period.
4. You are actively and continuously employed by Abeona through each of the bonus payments dates described herein, including the last day of the Retention Period.
5. You have not given notice of your intent to resign from employment on or before the last day of the Retention Period.
6. Abeona Therapeutics has not given you notice of its intent to terminate your employment on or before the last day of the Retention Period.

For the avoidance of doubt, the Retention Bonus payment is within the sole discretion of Abeona based on a variety of factors, including, but not limited to, overall financial performance of the Company. There will be no pro-rata apportionment of the bonus and you must meet all of the eligibility criteria to be considered for this discretionary bonus. For the sake of clarity, an approved leave of absence in compliance with Abeona's Time Off policy during the Retention Period will be treated as active and continuous employment for the purpose of the bonus eligibility criteria.

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If you remain eligible to receive the Retention Bonus pursuant to the requirements above, and the Company in its discretion determines to pay you a Retention Bonus, it will be paid in three lump sum cash Payments (with each Payment subject to the Company's discretion):

- The First Payment will be in the gross amount of \$533,333, less applicable withholdings, payable on the Effective Date of the Agreement.
- The Second Payment will be in the gross amount of \$533,333, less applicable withholdings, payable on the date of the first anniversary of the Effective Date of the Agreement.
- The Third Payment will be in the gross amount of \$533,333, less applicable withholdings, payable on the date of the second anniversary of the Effective Date of the Agreement.

In the event that there is a change in ownership or control of the Company effected through any of the following transactions:

(A) a merger, consolidation or other reorganization approved by the Company's stockholders, unless securities representing at least fifty percent (50%) of the total combined voting power of the voting securities of the successor corporation are immediately thereafter beneficially owned, directly or indirectly and in substantially the same proportion, by the persons who beneficially owned the Company's outstanding voting securities immediately prior to such transaction,

(B) a sale, transfer or other disposition of all or substantially all of the Company's assets, or

(C) the closing of any transaction or series of related transactions pursuant to which any person or any group of persons comprising a "group" within the meaning of Rule 13d-5(b)(1) of the Securities Exchange Act of 1934 ("1934 Act") (other than the Company or a person that, prior to such transaction or series of related transactions, directly or indirectly controls, is controlled by or is under common control with, the Company) becomes directly or indirectly (whether as a result of a single acquisition or by reasons of one or more acquisitions within the twelve (12)-month period ending with the most recent acquisition) the beneficial owner (within the meaning of Rule 13d-3 of the 1934 Act) of securities possessing (or convertible into or exercisable for securities possessing) more than fifty percent (50%) of the total combined voting power of the Company's securities (as measured in terms of the power to vote with respect to the election of Board members) outstanding immediately after the consummation of such transaction or series of related transactions, whether such transaction involves a direct issuance from the Company or the acquisition of outstanding securities held by one or more of the Company's existing stockholders.

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(D) a change in the composition of the Board over a period of twelve (12) consecutive months or less such that a majority of the Board members ceases to be comprised of individuals who either (A) have been Board members continuously since the beginning of such period ("Incumbent Directors") or (B) have been elected or nominated for election as Board members during such period by at least a majority of the Incumbent Directors who were still in office at the time the Board approved such election or nomination; provided that any individual who becomes a Board member subsequent to the beginning of such period and whose election or nomination was approved by two-thirds of the Board members then comprising the Incumbent Directors will be considered an Incumbent Director.

(Each of A through D shall collectively be defined as a "Triggering Event"), then any outstanding Retention Bonus payments shall immediately become due to you upon the closing of the Triggering Event (the "Accelerated Bonus Payment"), provided that such Triggering Event constitutes a change in ownership or control event within the meaning of Treasury Regulations Section 1.409A-3(i)(5)(v) or (vii). The Accelerated Bonus Payment shall be made in a single lump sum to you at or within ten days after the closing date of the Triggering Event.

The Retention Bonus described herein does not alter the at-will nature of your employment. Your employment remains at-will, meaning that you and Abeona may terminate the employment relationship at any time, with or without cause, and with or without notice, subject to the terms and conditions contained within your employment agreement, if any.

In the event that (1) you are terminated for Cause (as defined below) or (2) voluntarily resign and/or leave your employment with Abeona prior to the end of the Retention Period, you are required to pay Abeona an amount equal to the total amount of the Payment paid to you at the beginning of the then-current Retention Period, prior to your separation of employment. By way of example, if the Second Payment is made to you on June 30, 2024, and you are terminated for Cause or voluntarily resign before the end of the workday on June 30, 2025, you will be required to pay back the Second Payment; whereas, if you are terminated for Cause or voluntarily resign after the end of the workday on June 30, 2025, you will not be required to return the Second Payment. Under the scenarios in the preceding sentence, you would not be required to pay back the First Payment in either case.

For the purpose of this Retention Bonus only, "Cause" shall mean: (A) your substantial failure to perform your duties and job responsibilities (other than any such failure resulting from incapacity due to physical or mental disability) that continues for fifteen (15) calendar days after written notice from the Company; (B) your failure to comply with any valid and legal directive of the CEO or the Board (as applicable) that continues for fifteen (15) calendar days after written notice from the Company; (C) your engagement in dishonesty, illegal conduct, or misconduct (or the discovery of your having engaged in such conduct in the past), which, in each case, materially harms or is reasonably likely to materially harm, reputationally, financially or otherwise, the Company or its subsidiaries; (D) your engagement in embezzlement, misappropriation, or fraud, whether or not related to your employment with the Company; (E) your conviction of or plea of guilty or nolo contendere to a crime that constitutes a felony; (F) your willful violation of a material policy of the Company; (G) your willful or grossly negligent unauthorized disclosure of Confidential Information as defined in your Employee Confidentiality, Non-Competition, and Proprietary Information Agreement; (H) your material breach of any material obligation under any written agreement between you and the Company that continues for fifteen (15) calendar days after written notice from the Company (if such breach is reasonably curable); (I) any willful material failure by you to comply with the Company's written policies or written rules, as they may be in effect from time to time; (J) you perform your duties for the Company under the influence of illegal drugs or substantial intoxication; or (K) you fail, in the Company's sole judgment, to perform your duties and responsibilities in a satisfactory manner.

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This Retention Bonus shall not renew automatically or extend beyond the Third Payment Retention Period unless set forth otherwise in a written instrument signed by a duly authorized officer of Abeona.

This Retention Bonus is intended to comply with, or be exempt from, Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A") and shall be construed and administered in accordance with Section 409A, including, but not limited to, a scenario where there is a change of control within the meaning of the regulations under Section 409A.

In the event of a change in ownership or control of the Company under Section 280G of the Code, if it shall be determined that any payment or distribution in the nature of compensation (within the meaning of Section 280G(b)(2) of the Code) to or for your benefit, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise ("Compensation"), would constitute an "excess parachute payment" within the meaning of Section 280G of the Code, the aggregate present value of the total such Compensation under this Agreement or other agreement shall be reduced (but not below zero) to the Reduced Amount (defined below) if and only if the Accounting Firm (described below) determines that the reduction will provide you with a greater net after-tax benefit than would no reduction. No reduction shall be made unless the reduction would provide you with a greater net after-tax benefit. The determinations under this Section shall be made as follows:

(i) The "Reduced Amount" shall be an amount expressed in present value which maximizes the aggregate present value of Compensation under this Agreement and other agreements without causing any Compensation under this Agreement or other agreements to be subject to the Excise Tax (defined below), determined in accordance with Section 280G(d)(4) of the Code. The term "Excise Tax" means the excise tax imposed under Section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax.

(ii) Compensation under this Agreement and other agreements shall be reduced on a nondiscretionary basis in such a way as to minimize the reduction in the economic value deliverable to you. Where more than one payment of Compensation has the same value for this purpose and they are payable at different times, they will be reduced in reverse order as to when paid, with the furthest out reduced first, provided no violation of Section 409A Code would result. If a violation of Section 409A of the Code would result, then such Compensation shall be reduced on a pro-rata basis.

(iii) All determinations to be made under this Section shall be made by an independent certified public accounting firm selected by the Company and agreed to by you immediately prior to the change in ownership or control transaction (the "Accounting Firm"). The Accounting Firm shall provide its determinations and any supporting calculations both to the Company and you within ten (10) days of the transaction. Any such determination by the Accounting Firm shall be binding upon the Company and you. All of the fees and expenses of the Accounting Firm in performing the determinations referred to in this Section shall be borne solely by the Company.

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In the event there is a provision regarding the impact of Section 280G on Compensation, within the meaning above, in any other agreement between the Company and you, to the extent there is a conflict with the provisions regarding 280G in this Agreement, the provisions in this Agreement shall control and supersede such other provision, provided there is not a violation of Section 409A of the Code.

This letter contains all of the understandings and representations between Abeona and you relating to the Retention Bonus and supersedes all prior and contemporaneous understandings, discussions, agreements, representations and warranties, both written and oral, with respect to any retention bonus. This letter shall not supersede any other agreements between Abeona and you, including, without limitation, your offer letter, employment agreement, and any non-compete and/or confidentiality agreement between you and Abeona, which shall remain in full force and effect. This letter may not be amended or modified unless in a writing signed by both the VP, Human Resources of Abeona and you.

By signing this letter, you acknowledge that you have read it in its entirety, understand all of its terms and conditions, that you have had the opportunity to consult with counsel, that you are entering this Agreement knowingly and voluntarily, and that you agree to abide by all of the terms and conditions set forth herein.

This letter and all related documents are governed by, and construed in accordance with, the laws of Ohio without regard to conflicts-of-law principles.

If you agree to these terms, please sign and date this letter and return the signed copy to Alison Hardgrove, VP, Human Resources June 20, 2023. We look forward to your continued employment with us and sincerely appreciate your commitment to Abeona's future success.

Best Regards,

Agreed to and accepted:

Joseph Vazzano
Chief Financial Officer

Employee Signature
Date _____

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June 15, 2023

Joseph Vazzano
[REDACTED]
[REDACTED]

Re: Retention Bonus

Dear Joseph,

We consider your continued service and dedication to Abeona Therapeutics Inc. ("Abeona" or the "Company") essential to our business and future success. To incentivize you to remain employed with Abeona, we are pleased to inform you of Abeona's retention bonus, as described herein.

In recognition of your continued service with Abeona, we are offering you a retention bonus in the total gross amount of \$706,000, less all applicable withholdings and deductions (the "Retention Bonus"), payable in three annual payments (each a "Payment," and separately the "First Payment," "Second Payment," and "Third Payment"). Each Payment is subject to a "Retention Period" beginning on the date of that Payment, through and until the date that is one year from that date. By way of example, if the First Payment is made on June 30, 2023, the First Payment Retention Period would expire at the end of the workday on June 30, 2024. The Retention Bonus is in addition to the compensation already provided to you in your role for the Company.

You will be eligible to receive this Retention Bonus if all the following eligibility criteria are satisfied and the Company determines in its sole discretion that the financial performance of the Company permits each Payment:

1. You remain a full-time, active employee of Abeona through the end of the Retention Period.
2. Your performance has been satisfactory and meets expectations, as determined in Abeona's sole discretion, from the date of this letter through the end of the Retention Period.
3. You do not receive a disciplinary action, such as a written warning, during the Retention Period.
4. You are actively and continuously employed by Abeona through each of the bonus payments dates described herein, including the last day of the Retention Period.
5. You have not given notice of your intent to resign from employment on or before the last day of the Retention Period.
6. Abeona Therapeutics has not given you notice of its intent to terminate your employment on or before the last day of the Retention Period.

For the avoidance of doubt, the Retention Bonus payment is within the sole discretion of Abeona based on a variety of factors, including, but not limited to, overall financial performance of the Company. There will be no pro-rata apportionment of the bonus and you must meet all of the eligibility criteria to be considered for this discretionary bonus. For the sake of clarity, an approved leave of absence in compliance with Abeona's Time Off policy during the Retention Period will be treated as active and continuous employment for the purpose of the bonus eligibility criteria.

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If you remain eligible to receive the Retention Bonus pursuant to the requirements above, and the Company in its discretion determines to pay you a Retention Bonus, it will be paid in three lump sum cash Payments (with each Payment subject to the Company's discretion):

- The First Payment will be in the gross amount of \$235,333, less applicable withholdings, payable on the Effective Date of the Agreement.
- The Second Payment will be in the gross amount of \$235,333, less applicable withholdings, payable on the date of the first anniversary of the Effective Date of the Agreement.
- The Third Payment will be in the gross amount of \$235,333, less applicable withholdings, payable on the date of the second anniversary of the Effective Date of the Agreement.

In the event that there is a change in ownership or control of the Company effected through any of the following transactions:

(A) a merger, consolidation or other reorganization approved by the Company's stockholders, unless securities representing at least fifty percent (50%) of the total combined voting power of the voting securities of the successor corporation are immediately thereafter beneficially owned, directly or indirectly and in substantially the same proportion, by the persons who beneficially owned the Company's outstanding voting securities immediately prior to such transaction,

(B) a sale, transfer or other disposition of all or substantially all of the Company's assets, or

(C) the closing of any transaction or series of related transactions pursuant to which any person or any group of persons comprising a "group" within the meaning of Rule 13d-5(b)(1) of the Securities Exchange Act of 1934 ("1934 Act") (other than the Company or a person that, prior to such transaction or series of related transactions, directly or indirectly controls, is controlled by or is under common control with, the Company) becomes directly or indirectly (whether as a result of a single acquisition or by reasons of one or more acquisitions within the twelve (12)-month period ending with the most recent acquisition) the beneficial owner (within the meaning of Rule 13d-3 of the 1934 Act) of securities possessing (or convertible into or exercisable for securities possessing) more than fifty percent (50%) of the total combined voting power of the Company's securities (as measured in terms of the power to vote with respect to the election of Board members) outstanding immediately after the consummation of such transaction or series of related transactions, whether such transaction involves a direct issuance from the Company or the acquisition of outstanding securities held by one or more of the Company's existing stockholders.

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(D) a change in the composition of the Board over a period of twelve (12) consecutive months or less such that a majority of the Board members ceases to be comprised of individuals who either (A) have been Board members continuously since the beginning of such period ("Incumbent Directors") or (B) have been elected or nominated for election as Board members during such period by at least a majority of the Incumbent Directors who were still in office at the time the Board approved such election or nomination; provided that any individual who becomes a Board member subsequent to the beginning of such period and whose election or nomination was approved by two-thirds of the Board members then comprising the Incumbent Directors will be considered an Incumbent Director.

(Each of A through D shall collectively be defined as a "Triggering Event"), then any outstanding Retention Bonus payments shall immediately become due to you upon the closing of the Triggering Event (the "Accelerated Bonus Payment"), provided that such Triggering Event constitutes a change in ownership or control event within the meaning of Treasury Regulations Section 1.409A-3(i)(5)(v) or (vii). The Accelerated Bonus Payment shall be made in a single lump sum to you at or within ten days after the closing date of the Triggering Event.

The Retention Bonus described herein does not alter the at-will nature of your employment. Your employment remains at-will, meaning that you and Abeona may terminate the employment relationship at any time, with or without cause, and with or without notice, subject to the terms and conditions contained within your employment agreement, if any.

In the event that (1) you are terminated for Cause (as defined below) or (2) voluntarily resign and/or leave your employment with Abeona prior to the end of the Retention Period, you are required to pay Abeona an amount equal to the total amount of the Payment paid to you at the beginning of the then-current Retention Period, prior to your separation of employment. By way of example, if the Second Payment is made to you on June 30, 2024, and you are terminated for Cause or voluntarily resign before the end of the workday on June 30, 2025, you will be required to pay back the Second Payment; whereas, if you are terminated for Cause or voluntarily resign after the end of the workday on June 30, 2025, you will not be required to return the Second Payment. Under the scenarios in the preceding sentence, you would not be required to pay back the First Payment in either case.

For the purpose of this Retention Bonus only, "Cause" shall mean: (A) your substantial failure to perform your duties and job responsibilities (other than any such failure resulting from incapacity due to physical or mental disability) that continues for fifteen (15) calendar days after written notice from the Company; (B) your failure to comply with any valid and legal directive of the CEO or the Board (as applicable) that continues for fifteen (15) calendar days after written notice from the Company; (C) your engagement in dishonesty, illegal conduct, or misconduct (or the discovery of your having engaged in such conduct in the past), which, in each case, materially harms or is reasonably likely to materially harm, reputationally, financially or otherwise, the Company or its subsidiaries; (D) your engagement in embezzlement, misappropriation, or fraud, whether or not related to your employment with the Company; (E) your conviction of or plea of guilty or nolo contendere to a crime that constitutes a felony; (F) your willful violation of a material policy of the Company; (G) your willful or grossly negligent unauthorized disclosure of Confidential Information as defined in your Employee Confidentiality, Non-Competition, and Proprietary Information Agreement; (H) your material breach of any material obligation under any written agreement between you and the Company that continues for fifteen (15) calendar days after written notice from the Company (if such breach is reasonably curable); (I) any willful material failure by you to comply with the Company's written policies or written rules, as they may be in effect from time to time; (J) you perform your duties for the Company under the influence of illegal drugs or substantial intoxication; or (K) you fail, in the Company's sole judgment, to perform your duties and responsibilities in a satisfactory manner.

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This Retention Bonus shall not renew automatically or extend beyond the Third Payment Retention Period unless set forth otherwise in a written instrument signed by a duly authorized officer of Abeona.

This Retention Bonus is intended to comply with, or be exempt from, Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A") and shall be construed and administered in accordance with Section 409A, including, but not limited to, a scenario where there is a change of control within the meaning of the regulations under Section 409A.

In the event of a change in ownership or control of the Company under Section 280G of the Code, if it shall be determined that any payment or distribution in the nature of compensation (within the meaning of Section 280G(b)(2) of the Code) to or for your benefit, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise ("Compensation"), would constitute an "excess parachute payment" within the meaning of Section 280G of the Code, the aggregate present value of the total such Compensation under this Agreement or other agreement shall be reduced (but not below zero) to the Reduced Amount (defined below) if and only if the Accounting Firm (described below) determines that the reduction will provide you with a greater net after-tax benefit than would no reduction. No reduction shall be made unless the reduction would provide you with a greater net after-tax benefit. The determinations under this Section shall be made as follows:

(i) The "Reduced Amount" shall be an amount expressed in present value which maximizes the aggregate present value of Compensation under this Agreement and other agreements without causing any Compensation under this Agreement or other agreements to be subject to the Excise Tax (defined below), determined in accordance with Section 280G(d)(4) of the Code. The term "Excise Tax" means the excise tax imposed under Section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax.

(ii) Compensation under this Agreement and other agreements shall be reduced on a nondiscretionary basis in such a way as to minimize the reduction in the economic value deliverable to you. Where more than one payment of Compensation has the same value for this purpose and they are payable at different times, they will be reduced in reverse order as to when paid, with the furthest out reduced first, provided no violation of Section 409A Code would result. If a violation of Section 409A of the Code would result, then such Compensation shall be reduced on a pro-rata basis.

(iii) All determinations to be made under this Section shall be made by an independent certified public accounting firm selected by the Company and agreed to by you immediately prior to the change in ownership or control transaction (the "Accounting Firm"). The Accounting Firm shall provide its determinations and any supporting calculations both to the Company and you within ten (10) days of the transaction. Any such determination by the Accounting Firm shall be binding upon the Company and you. All of the fees and expenses of the Accounting Firm in performing the determinations referred to in this Section shall be borne solely by the Company.

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In the event there is a provision regarding the impact of Section 280G on Compensation, within the meaning above, in any other agreement between the Company and you, to the extent there is a conflict with the provisions regarding 280G in this Agreement, the provisions in this Agreement shall control and supersede such other provision, provided there is not a violation of Section 409A of the Code.

This letter contains all of the understandings and representations between Abeona and you relating to the Retention Bonus and supersedes all prior and contemporaneous understandings, discussions, agreements, representations and warranties, both written and oral, with respect to any retention bonus. This letter shall not supersede any other agreements between Abeona and you, including, without limitation, your offer letter, employment agreement, and any non-compete and/or confidentiality agreement between you and Abeona, which shall remain in full force and effect. This letter may not be amended or modified unless in a writing signed by both the VP, Human Resources of Abeona and you.

By signing this letter, you acknowledge that you have read it in its entirety, understand all of its terms and conditions, that you have had the opportunity to consult with counsel, that you are entering this Agreement knowingly and voluntarily, and that you agree to abide by all of the terms and conditions set forth herein.

This letter and all related documents are governed by, and construed in accordance with, the laws of Ohio without regard to conflicts-of-law principles.

If you agree to these terms, please sign and date this letter and return the signed copy to Alison Hardgrove, VP, Human Resources June 20, 2023. We look forward to your continued employment with us and sincerely appreciate your commitment to Abeona's future success.

Best Regards,

Agreed to and accepted:

Vishwas Seshadri
Chief Executive Officer

Employee Signature
Date _____

6555 Carnegie Avenue, Suite 400, Cleveland, OH 44103
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June 15, 2023

Brendan O'Malley
[REDACTED]
[REDACTED]

Re: Retention Bonus

Dear Brendan,

We consider your continued service and dedication to Abeona Therapeutics Inc. ("Abeona" or the "Company") essential to our business and future success. To incentivize you to remain employed with Abeona, we are pleased to inform you of Abeona's retention bonus, as described herein.

In recognition of your continued service with Abeona, we are offering you a retention bonus in the total gross amount of \$450,000, less all applicable withholdings and deductions (the "Retention Bonus"), payable in three annual payments (each a "Payment," and separately the "First Payment," "Second Payment," and "Third Payment"). Each Payment is subject to a "Retention Period" beginning on the date of that Payment, through and until the date that is one year from that date. By way of example, if the First Payment is made on June 30, 2023, the First Payment Retention Period would expire at the end of the workday on June 30, 2024. The Retention Bonus is in addition to the compensation already provided to you in your role for the Company.

You will be eligible to receive this Retention Bonus if all the following eligibility criteria are satisfied and the Company determines in its sole discretion that the financial performance of the Company permits each Payment:

1. You remain a full-time, active employee of Abeona through the end of the Retention Period.
2. Your performance has been satisfactory and meets expectations, as determined in Abeona's sole discretion, from the date of this letter through the end of the Retention Period.
3. You do not receive a disciplinary action, such as a written warning, during the Retention Period.
4. You are actively and continuously employed by Abeona through each of the bonus payments dates described herein, including the last day of the Retention Period.
5. You have not given notice of your intent to resign from employment on or before the last day of the Retention Period.
6. Abeona Therapeutics has not given you notice of its intent to terminate your employment on or before the last day of the Retention Period.

For the avoidance of doubt, the Retention Bonus payment is within the sole discretion of Abeona based on a variety of factors, including, but not limited to, overall financial performance of the Company. There will be no pro-rata apportionment of the bonus and you must meet all of the eligibility criteria to be considered for this discretionary bonus. For the sake of clarity, an approved leave of absence in compliance with Abeona's Time Off policy during the Retention Period will be treated as active and continuous employment for the purpose of the bonus eligibility criteria.

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If you remain eligible to receive the Retention Bonus pursuant to the requirements above, and the Company in its discretion determines to pay you a Retention Bonus, it will be paid in three lump sum cash Payments (with each Payment subject to the Company's discretion):

- The First Payment will be in the gross amount of \$150,000, less applicable withholdings, payable on the Effective Date of the Agreement.
- The Second Payment will be in the gross amount of \$150,000, less applicable withholdings, payable on the date of the first anniversary of the Effective Date of the Agreement.
- The Third Payment will be in the gross amount of \$150,000, less applicable withholdings, payable on the date of the second anniversary of the Effective Date of the Agreement.

In the event that there is a change in ownership or control of the Company effected through any of the following transactions:

(A) a merger, consolidation or other reorganization approved by the Company's stockholders, unless securities representing at least fifty percent (50%) of the total combined voting power of the voting securities of the successor corporation are immediately thereafter beneficially owned, directly or indirectly and in substantially the same proportion, by the persons who beneficially owned the Company's outstanding voting securities immediately prior to such transaction,

(B) a sale, transfer or other disposition of all or substantially all of the Company's assets, or

(C) the closing of any transaction or series of related transactions pursuant to which any person or any group of persons comprising a "group" within the meaning of Rule 13d-5(b)(1) of the Securities Exchange Act of 1934 ("1934 Act") (other than the Company or a person that, prior to such transaction or series of related transactions, directly or indirectly controls, is controlled by or is under common control with, the Company) becomes directly or indirectly (whether as a result of a single acquisition or by reasons of one or more acquisitions within the twelve (12)-month period ending with the most recent acquisition) the beneficial owner (within the meaning of Rule 13d-3 of the 1934 Act) of securities possessing (or convertible into or exercisable for securities possessing) more than fifty percent (50%) of the total combined voting power of the Company's securities (as measured in terms of the power to vote with respect to the election of Board members) outstanding immediately after the consummation of such transaction or series of related transactions, whether such transaction involves a direct issuance from the Company or the acquisition of outstanding securities held by one or more of the Company's existing stockholders.

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(D) a change in the composition of the Board over a period of twelve (12) consecutive months or less such that a majority of the Board members ceases to be comprised of individuals who either (A) have been Board members continuously since the beginning of such period ("Incumbent Directors") or (B) have been elected or nominated for election as Board members during such period by at least a majority of the Incumbent Directors who were still in office at the time the Board approved such election or nomination; provided that any individual who becomes a Board member subsequent to the beginning of such period and whose election or nomination was approved by two-thirds of the Board members then comprising the Incumbent Directors will be considered an Incumbent Director.

(Each of A through D shall collectively be defined as a "Triggering Event"), then any outstanding Retention Bonus payments shall immediately become due to you upon the closing of the Triggering Event (the "Accelerated Bonus Payment"), provided that such Triggering Event constitutes a change in ownership or control event within the meaning of Treasury Regulations Section 1.409A-3(i)(5)(v) or (vii). The Accelerated Bonus Payment shall be made in a single lump sum to you at or within ten days after the closing date of the Triggering Event.

The Retention Bonus described herein does not alter the at-will nature of your employment. Your employment remains at-will, meaning that you and Abeona may terminate the employment relationship at any time, with or without cause, and with or without notice, subject to the terms and conditions contained within your employment agreement, if any.

In the event that (1) you are terminated for Cause (as defined below) or (2) voluntarily resign and/or leave your employment with Abeona prior to the end of the Retention Period, you are required to pay Abeona an amount equal to the total amount of the Payment paid to you at the beginning of the then-current Retention Period, prior to your separation of employment. By way of example, if the Second Payment is made to you on June 30, 2024, and you are terminated for Cause or voluntarily resign before the end of the workday on June 30, 2025, you will be required to pay back the Second Payment; whereas, if you are terminated for Cause or voluntarily resign after the end of the workday on June 30, 2025, you will not be required to return the Second Payment. Under the scenarios in the preceding sentence, you would not be required to pay back the First Payment in either case.

For the purpose of this Retention Bonus only, "Cause" shall mean: (A) your substantial failure to perform your duties and job responsibilities (other than any such failure resulting from incapacity due to physical or mental disability) that continues for fifteen (15) calendar days after written notice from the Company; (B) your failure to comply with any valid and legal directive of the CEO or the Board (as applicable) that continues for fifteen (15) calendar days after written notice from the Company; (C) your engagement in dishonesty, illegal conduct, or misconduct (or the discovery of your having engaged in such conduct in the past), which, in each case, materially harms or is reasonably likely to materially harm, reputationally, financially or otherwise, the Company or its subsidiaries; (D) your engagement in embezzlement, misappropriation, or fraud, whether or not related to your employment with the Company; (E) your conviction of or plea of guilty or nolo contendere to a crime that constitutes a felony; (F) your willful violation of a material policy of the Company; (G) your willful or grossly negligent unauthorized disclosure of Confidential Information as defined in your Employee Confidentiality, Non-Competition, and Proprietary Information Agreement; (H) your material breach of any material obligation under any written agreement between you and the Company that continues for fifteen (15) calendar days after written notice from the Company (if such breach is reasonably curable); (I) any willful material failure by you to comply with the Company's written policies or written rules, as they may be in effect from time to time; (J) you perform your duties for the Company under the influence of illegal drugs or substantial intoxication; or (K) you fail, in the Company's sole judgment, to perform your duties and responsibilities in a satisfactory manner.

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This Retention Bonus shall not renew automatically or extend beyond the Third Payment Retention Period unless set forth otherwise in a written instrument signed by a duly authorized officer of Abeona.

This Retention Bonus is intended to comply with, or be exempt from, Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A") and shall be construed and administered in accordance with Section 409A, including, but not limited to, a scenario where there is a change of control within the meaning of the regulations under Section 409A.

In the event of a change in ownership or control of the Company under Section 280G of the Code, if it shall be determined that any payment or distribution in the nature of compensation (within the meaning of Section 280G(b)(2) of the Code) to or for your benefit, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise ("Compensation"), would constitute an "excess parachute payment" within the meaning of Section 280G of the Code, the aggregate present value of the total such Compensation under this Agreement or other agreement shall be reduced (but not below zero) to the Reduced Amount (defined below) if and only if the Accounting Firm (described below) determines that the reduction will provide you with a greater net after-tax benefit than would no reduction. No reduction shall be made unless the reduction would provide you with a greater net after-tax benefit. The determinations under this Section shall be made as follows:

(i) The "Reduced Amount" shall be an amount expressed in present value which maximizes the aggregate present value of Compensation under this Agreement and other agreements without causing any Compensation under this Agreement or other agreements to be subject to the Excise Tax (defined below), determined in accordance with Section 280G(d)(4) of the Code. The term "Excise Tax" means the excise tax imposed under Section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax.

(ii) Compensation under this Agreement and other agreements shall be reduced on a nondiscretionary basis in such a way as to minimize the reduction in the economic value deliverable to you. Where more than one payment of Compensation has the same value for this purpose and they are payable at different times, they will be reduced in reverse order as to when paid, with the furthest out reduced first, provided no violation of Section 409A Code would result. If a violation of Section 409A of the Code would result, then such Compensation shall be reduced on a pro-rata basis.

(iii) All determinations to be made under this Section shall be made by an independent certified public accounting firm selected by the Company and agreed to by you immediately prior to the change in ownership or control transaction (the "Accounting Firm"). The Accounting Firm shall provide its determinations and any supporting calculations both to the Company and you within ten (10) days of the transaction. Any such determination by the Accounting Firm shall be binding upon the Company and you. All of the fees and expenses of the Accounting Firm in performing the determinations referred to in this Section shall be borne solely by the Company.

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In the event there is a provision regarding the impact of Section 280G on Compensation, within the meaning above, in any other agreement between the Company and you, to the extent there is a conflict with the provisions regarding 280G in this Agreement, the provisions in this Agreement shall control and supersede such other provision, provided there is not a violation of Section 409A of the Code.

This letter contains all of the understandings and representations between Abeona and you relating to the Retention Bonus and supersedes all prior and contemporaneous understandings, discussions, agreements, representations and warranties, both written and oral, with respect to any retention bonus. This letter shall not supersede any other agreements between Abeona and you, including, without limitation, your offer letter, employment agreement, and any non-compete and/or confidentiality agreement between you and Abeona, which shall remain in full force and effect. This letter may not be amended or modified unless in a writing signed by both the VP, Human Resources of Abeona and you.

By signing this letter, you acknowledge that you have read it in its entirety, understand all of its terms and conditions, that you have had the opportunity to consult with counsel, that you are entering this Agreement knowingly and voluntarily, and that you agree to abide by all of the terms and conditions set forth herein.

This letter and all related documents are governed by, and construed in accordance with, the laws of Ohio without regard to conflicts-of-law principles.

If you agree to these terms, please sign and date this letter and return the signed copy to Alison Hardgrove, VP, Human Resources June 20, 2023. We look forward to your continued employment with us and sincerely appreciate your commitment to Abeona's future success.

Best Regards,

Agreed to and accepted:

Vishwas Seshadri
Chief Executive Officer

Employee Signature
Date _____

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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 June 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: August 8, 2023

By: /s/ Vishwas Seshadri

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

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 June 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: August 8, 2023

By: /s/ Joseph Vazzano

Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)

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 June 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: August 8, 2023

By: /s/ Vishwas Seshadri

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

Date: August 8, 2023

By: /s/ Joseph Vazzano

Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)
