UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

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

Date of report (Date of earliest event reported): **May 15, 2024**

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

Delaware	**001-15771**	**83-0221517**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

6555 Carnegie Ave, 4th Floor
Cleveland, OH 44103
(Address of principal executive offices) (Zip Code)

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

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of Each Class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	**ABEO**	**Nasdaq Capital Markets**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company □

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

Item 2.02. Results of Operations and Financial Condition.

On May 15, 2024, Abeona Therapeutics Inc. issued a press release entitled "Abeona Therapeutics Reports First Quarter 2024 Financial Results and Recent Corporate Progress" regarding its financial results for the quarter ended March 31, 2024. The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein.

The information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated May 15, 2024, entitled "Abeona Therapeutics Reports First Quarter 2024 Financial Results and Recent Corporate Progress"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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 hereunto duly authorized.

Abeona Therapeutics Inc.
(Registrant)

By: */s/ Joseph Vazzano*
Name: Joseph Vazzano
Title: Chief Financial Officer

Date: May 15, 2024

Exhibit 99.1

Abeona Therapeutics Reports First Quarter 2024 Financial Results and Recent Corporate Progress

BLA resubmission anticipated in second half of 2024

Closed $75 million underwritten offering in May, extending expected cash runway into 2026

CLEVELAND, May 15, 2024 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today reported financial results for the first quarter of 2024 and recent corporate progress.

"We are grateful to our existing as well as new investors who have demonstrated their support through the recent financing, which has extended our cash runway into 2026, well beyond anticipated regulatory milestones," said Vish Seshadri, Chief Executive Officer of Abeona. "We now remain focused on working with the FDA to address the CMC deficiencies noted in the CRL and making the BLA resubmission to bring pz-cel to RDEB patients as soon as possible."

First Quarter and Recent Progress

Corporate highlights

- On May 7, 2024, Abeona closed a $75 million underwritten securities offering with participation from both new and existing investors.
- In January 2024, Abeona entered into a $50 million credit facility and received the first tranche of $20 million.

Pz-cel for RDEB

- In April 2024, Abeona received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the Company's Biologics License Application (BLA) for prademagene zamikeracel (pz-cel) for recessive dystrophic epidermolysis bullosa (RDEB), based on the need for additional Chemistry Manufacturing and Controls (CMC) information. In the CRL, the FDA noted that certain additional information needed to satisfy CMC requirements must be resolved before the application can be approved. The information needed to satisfy the CMC requests in the CRL pertains to validation requirements for certain manufacturing and release testing methods. The CRL did not identify any deficiencies related to the clinical efficacy or clinical safety data in the BLA, and the FDA did not request any new clinical trials or clinical data to support the approval of pz-cel. The Company anticipates completing the BLA resubmission in the second half of 2024.
- New pz-cel data will be presented at upcoming medical meetings. At the Society for Investigative Dermatology (SID) Annual Meeting, being held on May 15-18, 2024, new long-term safety data with up to 11 years of follow-up has been accepted as a late-breaking presentation.

U.S. commercial launch preparations for pz-cel

- Abeona continues to advance key commercial activities in preparation for a potential U.S. launch for pz-cel, including onboarding discussions with epidermolysis bullosa treatment sites, conducting medical and payer engagement, as well as building supply chain and enterprise capabilities to support the Company's transition to a commercial stage company.

First Quarter Financial Results and Cash Runway Guidance

Cash, cash equivalents, restricted cash and short-term investments totaled $62.7 million as of March 31, 2024, compared to $52.6 million as of December 31, 2023. Net cash used in operating activities was $14.5 million for the three months ended March 31, 2024.

Abeona estimates that its current cash and cash equivalents, restricted cash and short-term investments, as well as the credit facility, combined with the net proceeds from the underwritten securities offering, are sufficient resources to fund operations into 2026, before accounting for any potential revenue from commercial sales of pz-cel, if approved, or proceeds from the sale of a Priority Review Voucher or PRV, if awarded by the FDA.

Research and development expenses for the three months ended March 31, 2024 were $7.2 million, compared to $8.0 million for the same period of 2023. General and administrative expenses were $7.1 million for the three months ended March 31, 2024, compared to $4.0 million for the same period of 2023. Net loss was $31.6 million for the first quarter of 2024, or $1.16 loss per common share, including a change in the fair value of warrant liabilities due to remeasurement of the Company's issued stock purchase warrants. Net loss in the first quarter of 2023 was $9.1 million, or $0.54 loss per common share.

Conference Call Details

The Company will host a conference call and webcast on Wednesday, May 15, 2024, at 8:30 a.m. ET, to discuss the first quarter results. To access the call, dial 888-506-0062 (U.S. toll-free) or 973-528-0011 (international) and Entry Code: 496484 five minutes prior to the start of the call. A live, listen-only webcast and archived replay of the call can be accessed on the Investors & Media section of Abeona's website at https://investors.abeonatherapeutics.com/events. The archived webcast replay will be available for 30 days following the call.

About Abeona Therapeutics

Abeona Therapeutics Inc. is a clinical-stage biopharmaceutical company developing cell and gene therapies for serious diseases. Prademagene zamikeracel (pz-cel) is Abeona's investigational autologous, COL7A1 gene-corrected epidermal sheets currently in development for recessive dystrophic epidermolysis bullosa. The Company's fully integrated cell and gene therapy cGMP manufacturing facility served as the manufacturing site for pz-cel used in its Phase 3 VIITAL™ trial, and is capable of supporting commercial production of pz-cel upon FDA approval. The Company's development portfolio also features AAV-based gene therapies for ophthalmic diseases with high unmet medical need. Abeona's novel, next-generation AAV capsids are being evaluated to improve tropism profiles for a variety of devastating diseases. For more information, visit www.abeonatherapeutics.com.

Forward-Looking Statements

This press release contains certain statements that are forward-looking 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, and that involve risks and uncertainties. We have attempted to identify forward-looking statements by such terminology as "may," "will," "believe," "anticipate," "expect," "intend," "potential," and similar words and expressions (as well as other words or expressions referencing future events, conditions or circumstances), which constitute and are intended to identify forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, numerous risks and uncertainties, including but not limited to, the timing and results of ongoing testing and other corrective actions being performed in response to the FDA's identified deficiencies, which could delay the Company's BLA resubmission; the timing and outcome of the FDA's review of our resubmission; the FDA's grant of a Priority Review Voucher upon approval; continued interest in our rare disease portfolio; our ability to enroll patients in clinical trials; the outcome of future meetings with the FDA or other regulatory agencies, including those relating to preclinical programs; the ability to achieve or obtain necessary regulatory approvals; the impact of any changes in the financial markets and global economic conditions; risks associated with data analysis and reporting; and other risks disclosed in the Company's most recent Annual Report on Form 10-K and subsequent periodic reports filed with the Securities and Exchange Commission. The Company undertakes no obligation to revise the forward-looking statements or to update them to reflect events or circumstances occurring after the date of this press release, whether as a result of new information, future developments or otherwise, except as required by the federal securities laws.

Investor and Media Contact:

Greg Gin
VP, Investor Relations and Corporate Communications
Abeona Therapeutics
ir@abeonatherapeutics.com

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

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

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,558	$ 14,473
Short-term investments	44,786	37,753
Restricted cash	338	338
Other receivables	2,232	2,444
Prepaid expenses and other current assets	1,811	729
Total current assets	66,725	55,737
Property and equipment, net	3,767	3,533
Operating lease right-of-use assets	4,222	4,455
Other assets	114	277
Total assets	$ 74,828	$ 64,002
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 3,362	$ 1,858
Accrued expenses	2,791	5,985
Current portion of operating lease liability	1,044	998
Current portion payable to licensor	4,691	4,580
Other current liabilities	1	1
Total current liabilities	11,889	13,422
Long-term operating lease liabilities	4,046	4,402
Long-term debt	18,079	—
Derivative liabilities	1,005	—
Warrant liabilities	48,690	31,352
Total liabilities	83,709	49,176
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock - $0.01 par value; authorized 2,000,000 shares; No shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	—	—
Common stock - $0.01 par value; authorized 200,000,000 shares; 27,550,693 and 26,523,878 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	276	265
Additional paid-in capital	772,129	764,151
Accumulated deficit	(781,102)	(749,524)
Accumulated other comprehensive loss	(184)	(66)
Total stockholders' (deficit) equity	(8,881)	14,826
Total liabilities and stockholders' equity	$ 74,828	$ 64,002