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): **March 18, 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 March 18, 2024, Abeona Therapeutics Inc. issued a press release regarding its financial results for the year ended December 31, 2023. 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 March 18, 2024
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: March 18, 2024

Exhibit 99.1

Abeona Therapeutics Reports Full Year 2023 Financial Results and Announces Completion of FDA Inspections

- FDA completed Pre-License Inspection of Abeona's Cleveland manufacturing facility, as well as inspection of clinical trial sites for pz-cel pivotal Phase 3 VIITAL™ study -

CLEVELAND, March 18, 2024 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today reported financial results for the full year of 2023 and provided an update on progress toward achieving key corporate objectives.

Abeona also announced today that the U.S. Food and Drug Administration (FDA) has completed a Pre-License Inspection (PLI) of its Cleveland, Ohio manufacturing facility related to the Company's Biologics License Application (BLA) for pz-cel (prademagene zamikeracel) for recessive dystrophic epidermolysis bullosa (RDEB). During the inspection, the FDA reviewed the facilities, systems, and processes at the Cleveland site. The FDA also observed the manufacturing process for pz-cel, as well as performance of in-process and release assays. The two-week PLI, which was conducted by five FDA inspectors, concluded on March 1, 2024. Upon completion of the inspection, a Form 483 was issued with observations related to process controls. On March 15, 2024, the Company submitted a response to the FDA, outlining already implemented and ongoing steps toward resolution that follow FDA guidance provided during the audit. In addition, the FDA has completed the clinical study site inspections of Stanford University School of Medicine in Palo Alto, CA and University of Massachusetts Medical School in Worcester, MA, both which enrolled subjects in the pivotal Phase 3 VIITAL™ study supporting the pz-cel BLA, with no Form 483 observations noted. The FDA's review of Abeona's pz-cel BLA is ongoing, with a target Prescription Drug User Fee Act (PDUFA) date of May 25, 2024, and the FDA does not currently plan to conduct an Advisory Committee.

"We appreciate the FDA's collaborative conduct of the PLI, and look forward to working with them through the remainder of the BLA review." said Vish Seshadri, Chief Executive Officer of Abeona.

Fourth Quarter and Recent Progress

Pz-cel for RDEB

- In November 2023, the FDA accepted and granted Priority Review for the Company's BLA for pz-cel for RDEB with a target PDUFA date of May 25, 2024. The FDA also advised that it does not plan to convene an Advisory Committee meeting to discuss the pz-cel application.
- In January 2024, the FDA completed both a Bioresearch Monitoring (BIMO) inspection of Abeona and the Mid-Cycle Meeting regarding the pz-cel BLA. Following completion of the BIMO inspection, the FDA inspector did not issue any observations or FDA Form 483s. At the BLA Mid-Cycle Review meeting, the FDA reaffirmed that it does not currently plan to convene an Advisory Committee for pz-cel. In addition, the FDA advised that Risk Evaluation and Mitigation Strategies (REMS) are not anticipated for the pz-cel BLA at this time, though review is ongoing, and reconfirmed the target PDUFA date of May 25, 2024.
- In March 2024, Abeona received a written Establishment Inspection Report (EIR), the formal report from the FDA regarding the BIMO inspection. The results of the inspection determined there were no deficiencies with the monitoring or management of study sites, IP accountability, retention of study site documents, or safety oversight.

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 EB treatment sites, payer engagement, hiring key commercial roles, and conducting market research.
- The Company recently completed payer market research that supports reimbursement coverage of pz-cel at a price commensurate with the value of approved gene therapies that offer years of durable benefit following a one-time application.

Corporate highlights

- In January 2024, Abeona entered a $50 million credit facility with the Avenue Venture Opportunities Fund, L.P. The credit agreement includes a first tranche of $20 million, which was funded in January 2024, a second tranche of $10 million of committed capital, and an option for an additional $20 million upon satisfaction of certain terms and conditions. Proceeds from the facility are intended to support the Company's ongoing preparations for launch and commercialization in anticipation of a potential FDA approval of pz-cel.

Full Year 2023 Financial Results and Cash Runway Guidance

Cash, cash equivalents, restricted cash and short-term investments totaled $52.6 million as of December 31, 2023, compared to $52.5 million as of December 31, 2022. Net cash used in operating activities was $37.0 million for the full year of 2023, compared to $43.5 million in the full year of 2022.

In January 2024, Abeona received a first tranche of $20 million as part of the credit facility with Avenue Venture Opportunities Fund, L.P. Abeona estimates that its current cash and cash equivalents, restricted cash and short-term investments, as well as the credit facility with Avenue Venture Opportunities Fund, L.P, are sufficient resources to fund operations into the first quarter of 2025 before accounting for any revenue from commercial sales of pz-cel, if approved, or proceeds from the sale of a Priority Review Voucher, if awarded by the FDA.

License and other revenues for the year ended December 31, 2023 were $3.5 million, as compared to $1.4 million for the same period of 2022. The revenues in both years primarily represent clinical milestone payments under a licensing agreement with Taysha Gene Therapies for investigational AAV-based gene therapy for Rett syndrome.

Research and development expenses for the full year ended December 31, 2023 were $31.1 million, compared to $29.0 million for the full year ended December 31, 2022, primarily a result of increased headcount related to BLA activities. General and administrative expenses were $19.0 million for the full year ended December 31, 2023, compared to $17.3 million for the year ended December 31, 2022, primarily a result of increased headcount for the potential launch of pz-cel. Net loss attributable to common shareholders for the full year ended December 31, 2023 was $54.2 million, or $2.53 loss per common share as compared to $43.5 million, or $5.53 loss per common share, for the full year of 2022.

Conference Call Details

Abeona Therapeutics will host a conference call and webcast today, March 18, 2024, at 8:30 a.m. ET. To access the call, dial 888-506-0062 (U.S. toll-free) or 973-528-0011 (international) and Entry Code: 428606 five minutes prior to the start of the call. A live, listen-only webcast and archived replay of the call can be accessed 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. The U.S. FDA has accepted and granted Priority Review with a PDUFA target action date of May 25, 2024 for the Biologics License Application for pz-cel (prademagene zamikeracel), 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 outcome of our Biologics License Application submission to the FDA for pz-cel; the FDA's grant of a Priority Review Voucher; continued interest in our rare disease portfolio; our ability to enroll patients in clinical trials; the outcome of future meetings with and inspections from 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
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	For the years ended December 31,	
	2023	**2022**
Revenues:		
License and other revenues	$ 3,500	$ 1,414
Expenses:		
Royalties	1,605	450
Research and development	31,091	28,965
General and administrative	19,004	17,256
Impairment of licensed technology	—	1,355
Loss/(gain) on operating lease right-of-use assets	(1,065)	2,511
Impairment of construction-in-progress	—	1,792
Total expenses	50,635	52,329
Loss from operations	(47,135)	(50,915)
Interest income	2,117	431
Interest expense	(418)	(736)
Change in fair value of warrant liabilities	(11,695)	11,383
Other income	2,943	141
Net loss	$ (54,188)	$ (39,696)
Deemed dividends related to Series A and Series B Convertible Redeemable Preferred Stock	—	(3,782)
Net loss attributable to Common Shareholders	$ (54,188)	$ (43,478)
Basic and diluted loss per common share	$ (2.53)	$ (5.53)
Weighted average number of common shares outstanding – basic and diluted	21,380,476	7,861,515
Other comprehensive income (loss):		
Change in unrealized gains (losses) related to available-for-sale debt securities	34	(99)
Foreign currency translation adjustments	29	(3)
Comprehensive loss	$ (54,125)	$ (43,580)

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES

Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,473	$ 14,217
Short-term investments	37,753	37,932
Restricted cash	338	338
Other receivables	2,444	188
Prepaid expenses and other current assets	729	424
Total current assets	55,737	53,099
Property and equipment, net	3,533	5,741
Operating lease right-of-use assets	4,455	5,331
Other assets	277	43
Total assets	$ 64,002	$ 64,214
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,858	$ 1,811
Accrued expenses	5,985	3,991
Current portion of operating lease liability	998	1,773
Current portion of payable to licensor	4,580	—
Other current liabilities	1	204
Total current liabilities	13,422	7,779
Payable to licensor	—	4,163
Long-term operating lease liabilities	4,402	5,854
Warrant liabilities	31,352	19,657
Total liabilities	49,176	37,453
Commitments and contingencies		
Stockholders' equity:		
Preferred stock - $0.01 par value; authorized 2,000,000 shares; No shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	—	—
Common stock - $0.01 par value; authorized 200,000,000 shares; 26,523,878 and 17,719,720 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	265	177
Additional paid-in capital	764,151	722,049
Accumulated deficit	(749,524)	(695,336)
Accumulated other comprehensive loss	(66)	(129)
Total stockholders' equity	14,826	26,761
Total liabilities and stockholders' equity	$ 64,002	$ 64,214