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): **November 13, 2023**

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 November 13, 2023, Abeona Therapeutics Inc. issued a press release regarding its results of operations and financial condition for the third quarter of 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 November 13, 2023
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: November 13, 2023

Exhibit 99.1

Abeona Therapeutics Reports Third Quarter 2023 Financial Results and Corporate Developments

Abeona's first-ever U.S. Biologics License Application (BLA) submission completed in September 2023

FDA decision on priority review and acceptance of BLA for pz-cel (prademagene zamikeracel, formerly known as EB-101) in recessive dystrophic epidermolysis bullosa (RDEB) expected by late-November 2023

Initiated commercial readiness activities for potential U.S. launch of pz-cel

CLEVELAND, November 13, 2023 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today reported financial results for the third quarter of 2023 and provided corporate updates.

"In the third quarter, we made substantial progress in our evolution from a late-stage clinical development company to one with significant commercial opportunity," said Vish Seshadri, Chief Executive Officer of Abeona. "With the completion of Abeona's first-ever U.S. BLA submission, we moved a step closer toward the potential approval of pz-cel as the first therapy that delivered instantaneous wound coverage and multi-year healing in RDEB wounds with a one-time application in clinical trials. In addition, we are also establishing Abeona's capabilities in late-stage development and manufacturing of autologous engineered cell therapies. Lastly, we have initiated commercial readiness activities for our potential launch of pz-cel."

Third Quarter and Recent Progress

Pz-cel for RDEB

- The proposed non-proprietary (generic) name prademagene zamikeracel (referred to as "pz-cel" going forward) was approved by the World Health Organization as the International Nonproprietary Name for Abeona's investigational autologous, COL7A1 gene-corrected epidermal sheets formerly known as EB-101.
- In August, Abeona completed a positive pre-BLA meeting in which it reached alignment with the U.S. Food and Drug Administration (FDA) that the pz-cel clinical efficacy and safety data appear adequate to support a BLA submission. The FDA also agreed that retroviral vector manufactured at Abeona and Indiana University appear comparable based on the data that Abeona provided in its briefing book.
- In September, Abeona submitted a BLA to FDA seeking approval with priority review of pz-cel for RDEB. The FDA's decision on BLA acceptance is typically made during the 60-day window following submission. If accepted with Priority Review, Abeona expects potential BLA approval in the second quarter of 2024.

Strengthened balance sheet, initiated U.S. commercial launch preparations for pz-cel

- Abeona raised $25 million in a registered direct offering priced at-the-market with select existing institutional investors to primarily fund the Company's initial commercial preparations in support of the potential U.S. launch of pz-cel.
- Appointed Madhav Vasanthavada, Ph.D., M.B.A. as Chief Commercial Officer and Head of Business Development. Dr. Vasanthavada brings over 20 years of diverse leadership experience in the life sciences industry with recent experience in launching autologous cell therapies at Bristol Myers Squibb (BMS) and Celgene.
- Started U.S. commercial launch planning activities for pz-cel, including initiating onboarding discussions with EB treatment sites, payer engagement, and hiring key commercial roles.

Third Quarter Financial Results

Cash, cash equivalents, restricted cash and short-term investments totaled $54.1 million as of September 30, 2023, including the net proceeds from the $25 million registered direct offering in July 2023, as compared to $37.1 million as of June 30, 2023. Abeona estimates that its cash and cash equivalents, restricted cash and short-term investments as of September 30, 2023 are sufficient resources to fund operations into the fourth quarter of 2024.

Research and development expenses for the three months ended September 30, 2023 were $7.1 million, compared to $5.5 million for the same period of 2022. General and administrative expenses were $4.2 million for the three months ended September 30, 2023, compared to $3.9 million for the same period of 2022. Net loss attributable to common shareholders was $11.8 million for the third quarter of 2023, or $0.48 loss per common share as compared to a net loss attributable to common shareholders of $6.4 million, or $1.00 loss per common share, in the third quarter of 2022.

Conference Call Details

Abeona Therapeutics will host a conference call and webcast today, November 13, 2023, at 8:30 a.m. ET, to discuss its financial results and developments. To access the call, dial 888-506-0062 (U.S. toll-free) or 973-528-0011 (international) and Entry Code: 963663 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 www.abeonatherapeutics.com. 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. Abeona's lead clinical program is pz-cel (prademagene zamikeracel, formerly known as EB-101), its investigational autologous, COL7A1 gene-corrected epidermal sheets currently in development for recessive dystrophic epidermolysis bullosa. 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. Abeona's fully integrated cell and gene therapy cGMP manufacturing facility produced pz-cel for the pivotal Phase 3 VIITAL™ study and is capable of clinical and potential commercial production of AAV-based gene therapies. 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; 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
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ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

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

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

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,712	$ 14,217
Short-term investments	49,042	37,932
Restricted cash	338	338
Other receivables	2,209	188
Prepaid expenses and other current assets	963	424
Total current assets	57,264	53,099
Property and equipment, net	3,999	5,741
Right-of-use lease assets	4,685	5,331

Other assets	139	43
Total assets	$ 66,087	$ 64,214
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,592	$ 1,811
Accrued expenses	3,972	3,991
Current portion of lease liability	1,649	1,773
Other current liabilities	199	204
Total current liabilities	8,412	7,779
Payable to licensor	4,472	4,163
Long-term lease liabilities	4,043	5,854
Warrant liabilities	27,122	19,657
Total liabilities	44,049	37,453
Commitments and contingencies		
Stockholders' equity:		
Preferred stock - $0.01 par value; authorized 2,000,000 shares; No shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	—	—
Common stock - $0.01 par value; authorized 200,000,000 shares; 24,713,908 and 17,719,720 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	247	177
Additional paid-in capital	754,823	722,049
Accumulated deficit	(732,933)	(695,336)
Accumulated other comprehensive loss	(99)	(129)
Total stockholders' equity	22,038	26,761
Total liabilities and stockholders' equity	$ 66,087	$ 64,214