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 14, 2022**

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.)

1330 Avenue of the Americas, 33rd Floor,
New York, NY 10019
(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 14, 2022, Abeona Therapeutics Inc. issued a press release regarding its results of operations and financial condition for the third quarter of 2022. 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 14, 2022
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 14, 2022

Exhibit 99.1

Abeona Therapeutics Reports Third Quarter 2022 Financial Results

Following positive topline data from Phase 3 VIITAL™ study of EB-101 with both co-primary endpoints met, Abeona plans to submit BLA to U.S. FDA in 2Q 2023

Company well-funded with expected cash runway into 3Q 2024

NEW YORK and CLEVELAND, November 14, 2022 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today announced financial results for the third quarter of 2022.

"The positive topline data from the Phase 3 VIITAL study provides strong support for EB-101's potential and validation of the Abeona team's extensive efforts," said Vish Seshadri, Chief Executive Officer of Abeona. "This is an exciting time for Abeona as we are sharply focused on submitting a Biologics License Application for EB-101 to the U.S. FDA. With the additional capital raised after quarter-end, we are now well-funded into the third quarter of 2024, beyond the anticipated timing for potential BLA approval."

Third Quarter and Recent Operating Highlights

EB-101 for the treatment of recessive dystrophic epidermolysis bullosa (RDEB)

- On November 3, 2022, Abeona announced positive topline data from the pivotal Phase 3 VIITAL study of investigational EB-101 in RDEB. 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. The Company intends to present more detailed results from this study at future medical meetings and in a peer-reviewed journal.
- Based on the positive VIITAL topline results, the Company plans to submit a Biologics License Application (BLA) for EB-101 to the U.S. Food and Drug Administration (FDA) in the second quarter of 2023. If the BLA is approved, Abeona may be eligible for a Priority Review Voucher (PRV), which can be used to receive expedited review by the FDA of a subsequent marketing application for a different product or sold to another company.
- Long-term follow up data up to eight years and quality of life data from a completed Phase 1/2a study of EB-101 in RDEB were published in *Orphanet Journal of Rare Diseases*. The data showed that large chronic RDEB wounds treated with EB-101 had sustained wound healing with mean 5.9 years of follow-up, and long-term symptomatic relief, including reduction in pain and itch.

Preclinical programs

- Abeona's preclinical programs are investigating the use of novel adeno-associated virus (AAV) capsids in AAV-based therapies for five undisclosed ophthalmic conditions. The Company has generated appropriate mouse models, produced research grade vectors, and started dosing mice in proof-of-concept studies to support possible pre-Investigational New Drug Application (IND) meetings with the FDA in early 2023.

Corporate highlights

- On November 3, 2022, the Company announced a private placement financing with gross proceeds of $35.0 million. The private placement included participation from new and existing institutional investors.

Third Quarter Financial Results

Cash, cash equivalents, restricted cash and short-term investments totaled $23.5 million as of September 30, 2022. Net cash used in operating activities was $6.8 million for the third quarter of 2022, compared to $9.0 million in the second quarter of 2022. Abeona estimates that its current cash and cash equivalents, restricted cash and short-term investments plus the net proceeds from the private placement financing on November 3, 2022 are sufficient resources to fund operations into the third quarter of 2024.

Research and development (R&D) expenses for the three months ended September 30, 2022 were $5.5 million, compared to $9.1 million for the same period of 2021. General and administrative (G&A) expenses were $3.9 million for the three months ended September 30, 2022, compared to $5.8 million for the same period of 2021.

Net loss attributable to common shareholders for the third quarter of 2022 was $9.5 million, or $1.48 loss per common share as compared to $7.0 million, or $1.80 loss per common share, in the third quarter of 2021.

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 EB-101, its investigational autologous, engineered cell therapy 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 EB-101 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," "plans," "intend," and similar 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 EB-101; our ability to fund operations with current cash and cash equivalents, restricted cash and short-term investments plus the net proceeds from our November 2022 private placement; continued interest in our rare disease portfolio; our ability to enroll patients in clinical trials; the outcome of any future meetings with the FDA or other regulatory agencies; the ability to achieve or obtain necessary regulatory approvals; the impact of 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 other 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
(Unaudited)
(In thousands, except share and per share amounts)

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
Revenues:				
License and other revenues	$ -	$ -	$ 1,346	$ -
Expenses:				
Royalties	-	-	350	-
Research and development	5,490	9,056	22,693	25,923
General and administrative	3,890	5,816	11,574	17,261
Impairment of licensed technology	-	-	1,355	-
Impairment of right-of-use lease asset	-	-	1,561	-
Impairment of construction-in-progress	-	-	1,792	-
Total expenses	9,380	14,872	39,325	43,184
Loss from operations	(9,380)	(14,872)	(37,979)	(43,184)
Gain on settlement with licensor	-	6,743	-	6,743
PPP loan payable forgiveness income	-	1,758	-	1,758
Interest income	72	7	103	35
Interest expense	(157)	(683)	(558)	(3,603)
Other income (expense)	(19)	3	(136)	(2)
Net loss	$ (9,484)	$ (7,044)	$ (38,570)	$ (38,253)
Deemed dividends related to Series A and Series B Convertible Redeemable Preferred Stock	-	-	(3,782)	-
Net loss attributable to Common Shareholders	$ (9,484)	$ (7,044)	$ (42,352)	$ (38,253)
Basic and diluted loss per common share	$ (1.48)	$ (1.80)	$ (7.05)	$ (9.93)
Weighted average number of common shares outstanding – basic and diluted	6,421,245	3,924,024	6,009,902	3,853,318
Other comprehensive income (loss):				
Change in unrealized gains (losses) related to available-for-sale debt securities	(4)	1	(11)	10
Foreign currency translation adjustments	(6)	(9)	(6)	(9)
Comprehensive loss	$ (9,494)	$ (7,052)	$ (42,369)	$ (38,252)

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

	September 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,733	$ 32,938
Short-term investments	12,434	12,086
Restricted cash	5,338	5,891
Accounts receivable	-	3,000
Other receivables	1,047	-
Prepaid expenses and other current assets	945	2,377
Total current assets	25,497	56,292
Property and equipment, net	6,606	12,339
Right-of-use lease assets	6,638	9,403
Licensed technology, net	-	1,384
Other assets	20	168

Total assets	$ 38,761	$ 79,586
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,748	$ 4,325
Accrued expenses	4,121	5,585
Current portion of lease liability	1,810	1,818
Current portion of payable to licensor	4,921	4,599
Deferred revenue	-	296
Total current liabilities	12,600	16,623
Payable to licensor	4,064	3,828
Other long-term liabilities	200	200
Long-term lease liabilities	6,484	7,560
Total liabilities	23,348	28,211
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, 2022 and December 31, 2021, respectively	-	-
Common stock - $0.01 par value; authorized 200,000,000 shares; 7,671,351 and 5,888,217 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively*	77	1,472
Additional paid-in capital	709,590	705,570
Accumulated deficit	(694,210)	(655,640)
Accumulated other comprehensive loss	(44)	(27)
Total stockholders' equity	15,413	51,375
Total liabilities and stockholders' equity	$ 38,761	$ 79,586

* As of November 7, 2022, Abeona had 17,175,799 shares of common stock outstanding.