

**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 13, 2022**

ABEONA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-15771
(Commission
File Number)

83-0221517
(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 May 13, 2022, Abeona Therapeutics Inc. issued a press release regarding its results of operations and financial condition for the first quarter 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 May 13, 2022, entitled "Abeona Therapeutics Reports First Quarter 2022 Financial Results"](#)
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 13, 2022



Abeona Therapeutics Reports First Quarter 2022 Financial Results

Disposition of MPS programs to reduce operating expenses and extend projected cash runway into 2Q 2023

Focus R&D resources on EB-101 pivotal phase 3 VIITAL™ topline data expected in 3Q 2022

NEW YORK and CLEVELAND, May 13, 2022 – Abeona Therapeutics Inc. (Nasdaq: ABEO), a fully-integrated leader in cell and gene therapy, today announced financial results for the first quarter of 2022. The Company will host a conference call and webcast on Tuesday, May 17, 2022, at 8:30 a.m. ET, to discuss its financial results and business update.

“During the quarter, we took significant steps to preserve our capital with the goal to fund operations over the next 12 months with existing cash resources,” said Vish Seshadri, Chief Executive Officer of Abeona. “First, we began off-loading our MPS assets to reduce cash burn. Second, having completed accrual for the EB-101 pivotal Phase 3 VIITAL™ study, we are now focusing R&D resources on generating topline results in the third quarter of 2022, while aggressively exploring partnerships for commercialization of EB-101. Furthermore, we have initiated steps toward regaining compliance with Nasdaq listing requirements.”

First Quarter and Recent Highlights

- Completed patient enrollment in pivotal Phase 3 VIITAL™ study evaluating EB-101 for recessive dystrophic epidermolysis bullosa (RDEB), and anticipate topline data readout in the third quarter of 2022.
- Additional long-term follow up data up to eight years and quality of life data from a completed Phase 1/2 study evaluating EB-101 for RDEB will be presented at the Society of Investigative Dermatology (SID) Annual Meeting, which will be held on May 18-21, 2022 in Portland, OR. The data will be featured in an oral presentation entitled “Long-term efficacy and safety of investigational autologous gene-corrected skin sheets (EB-101) for recessive dystrophic epidermolysis bullosa (RDEB).”
- Reported non-human primate data for AAV204, a novel adeno-associated virus (AAV) capsid from Abeona’s AIM™ capsid library, highlighting its ability to produce more robust transduction in the macula area of the eye following para-retinal administration, which unlike subretinal administration does not create a retinal detachment. The data was featured at the Association for Research and Vision in Ophthalmology (ARVO) 2022 Annual Meeting.
- Appointed Joseph Vazzano as Chief Financial Officer, who brings valuable experience while serving as the Chief Financial Officer at Avenue Therapeutics, Inc. where he secured multiple equity financings.

Nasdaq Compliance Plan

- Requested a 180-calendar day extension to regain compliance with the Nasdaq Capital Market’s minimum closing bid price requirement of \$1.00 per share.
- As part of the Company’s strategy to regain compliance, Abeona intends to seek approval of a reverse stock split of the outstanding shares of common stock at a Special Meeting of stockholders at 10:00 am ET on June 14, 2022. Stockholders as of May 3, 2022, the record date, are entitled to attend the online Special Meeting, view the proxy statement and vote at: www.virtualshareholdermeeting.com/ABEO2022SM.
- On May 2, 2022, Abeona completed a \$25 million private placement offering of convertible redeemable preferred stock. Holders of the preferred stock will vote together with the Company’s common stockholders on a proposal to effect a reverse stock split of the Company’s common stock at the Special Meeting.

First Quarter Financial Results

The unaudited interim condensed consolidated financial statements for the quarter ended March 31, 2022, which were filed on Form 10-Q on May 13, 2022, 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.

Cash, cash equivalents, restricted cash and short-term investments totaled \$37.2 million as of March 31, 2022. Net cash used in operating activities was \$13.7 million for the three months ended March 31, 2022.

License and other revenues in the first quarter of 2022 were \$0.3 million, compared to nil in the first quarter of 2021. The revenue in the first quarter of 2022 consisted mainly of the recognition of deferred revenue related to grants for the ABO-102 and ABO-101 development programs.

Research and development (R&D) expenses for the three months ended March 31, 2022 were \$10.5 million, compared to \$8.3 million for the same period of 2021. General and administrative (G&A) expenses were \$4.2 million for the three months ended March 31, 2022, compared to \$6.3 million for the same period of 2021.

Net loss was \$20.8 million for the first quarter of 2022, or \$0.14 loss per common share as compared to a net loss of \$16.0 million, or \$0.17 loss per common share, in the first quarter of 2021. The net loss in the first quarter of 2022 includes \$6.2 million in non-cash impairment charges resulting from the disposition of the ABO-102 and ABO-101 development programs as the Company focuses resources on its EB-101 pivotal program and preclinical eye gene therapy programs. The impairment charges have no impact on the Company’s cash position or cash flow from operating activities and do not have an impact on future operations.

Conference Call Details

Abeona Therapeutics will host a conference call and webcast on Tuesday, May 17, 2022, at 8:30 a.m. ET, to discuss its financial results and business update. To access the call, dial 877-545-0320 (U.S. toll-free) or 973-528-0002 (international) and Entry Code: 221025 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 EB-101, its investigational autologous, gene-corrected cell therapy for recessive dystrophic epidermolysis bullosa in Phase 3 development. 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 produces 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,” “estimate,” “expect,” 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 potential impacts of the COVID-19 pandemic on our business, operations, and financial condition; continued interest in our rare disease portfolio; our ability to potentially commercialize our EB-101 product candidate; obtaining a strategic partnership to take over development activities for ABO-102 and the successful discontinuation of development activities for our ABO-101 program; the outcome of any future meetings with the U.S. Food and Drug Administration or other regulatory agencies; the impact of competition; the ability to secure licenses for any technology that may be necessary to potentially commercialize our product candidates; 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; reducing our operating expenses and extending our cash runway; our ability to execute our operating plan and achieve important anticipated milestones; and other risks disclosed in the Company’s most recent Annual Report on Form 10-K and other periodic reports subsequently 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 March 31,	
	2022	2021
Revenues:		
License and other revenues	\$ 346	\$ -
Expenses:		
Research and development	10,545	8,317
General and administrative	4,224	6,280
Licensed technology impairment charge	1,355	-
Lease impairment charge	1,561	-
Construction-in-progress impairment charge	3,252	-
Total expenses	<u>20,937</u>	<u>14,597</u>
Loss from operations	(20,591)	(14,597)
Interest and miscellaneous income	1	15
Interest expense	(201)	(1,420)
Net loss	<u>\$ (20,791)</u>	<u>\$ (16,002)</u>
Basic and diluted loss per common share	<u>\$ (0.14)</u>	<u>\$ (0.17)</u>
Weighted average number of common shares outstanding – basic and diluted	<u>144,877,693</u>	<u>94,234,653</u>
Other comprehensive income:		
Change in unrealized gains related to available-for-sale debt securities	3	13
Comprehensive loss	<u>\$ (20,788)</u>	<u>\$ (15,989)</u>

Abeona Therapeutics Inc. and Subsidiaries Condensed Consolidated Balance Sheets

(\$ in thousands, except share and per share amounts)
(unaudited)

	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 20,326	\$ 32,938
Short-term investments	10,989	12,086
Restricted cash	5,891	5,891

Accounts receivable	-	3,000
Prepaid expenses and other current assets	1,998	2,377
Total current assets	39,204	56,292
Property and equipment, net	8,408	12,339
Right-of-use lease assets	7,540	9,403
Licensed technology, net	-	1,384
Other assets	20	168
Total assets	\$ 55,172	\$ 79,586

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$ 1,601	\$ 4,325
Accrued expenses	4,206	5,585
Current portion of lease liability	1,822	1,818
Current portion of payable to licensor	4,708	4,599
Deferred revenue	-	296
Total current liabilities	12,337	16,623

Payable to licensor	3,919	3,828
Other long-term liabilities	200	200
Long-term lease liabilities	7,273	7,560
Total liabilities	23,729	28,211

Commitments and contingencies

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Stockholders' equity:

Preferred stock - \$0.01 par value; authorized 2,000,000 shares; No shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	-	-
Common stock - \$0.01 par value; authorized 200,000,000 shares; 147,079,899 and 147,205,422 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	1,471	1,472
Additional paid-in capital	706,433	705,570
Accumulated deficit	(676,431)	(655,640)
Accumulated other comprehensive loss	(30)	(27)
Total stockholders' equity	31,443	51,375
Total liabilities and stockholders' equity	\$ 55,172	\$ 79,586