# 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): **August 8, 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 August 8, 2023, Abeona Therapeutics Inc. issued a press release regarding its results of operations and financial condition for the second 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 August 8, 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: August 8, 2023

**Exhibit 99.1**

**Abeona Therapeutics Reports Second Quarter 2023 Financial Results**

*On track for Biologics License Application (BLA) submission in third quarter of 2023*

*Proceeds from $25 million registered direct offering in July allow initiation of pre-commercial launch activities for EB-101*

*Cash on hand plus proceeds from registered direct offering projected to fund operations into the fourth quarter of 2024*

CLEVELAND, August 8, 2023 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today reported financial results for the second quarter of 2023 and provided an update on progress toward achieving key corporate objectives.

"Abeona is at a pivotal moment in our history as we are busy finalizing and planning to soon submit the BLA for EB-101 for the treatment of recessive dystrophic epidermolysis bullosa," said Vish Seshadri, Chief Executive Officer of Abeona. "The recent capital raise allows us to initiate preparations for the commercial launch of EB-101 in the U.S., while also extending our cash runway well beyond the anticipated regulatory approval time for EB-101."

**Second Quarter and Recent Progress**

*Strengthened balance sheet, preparing for commercialization of EB-101 in the U.S.*

- In July, Abeona raised $25 million in a registered direct offering priced at-the-market with select existing investors to primarily fund initiation of the Company's launch preparations in anticipation of the EB-101 BLA submission and potential approval.

*EB-101 for recessive dystrophic epidermolysis bullosa (RDEB)*

- Completed the Process Performance Qualification manufacturing runs for both retroviral vector (RVV) and EB-101 drug product manufacturing to demonstrate Abeona's validated process and readiness for commercial production. This data will be included in the chemistry, manufacturing, and control (CMC) module for the EB-101 BLA submission.
- Generated the additional data requested by the U.S. Food and Drug Administration (FDA) that supports comparability between two RVV sources used in EB-101 clinical studies. This data will be included in the CMC module for the EB-101 BLA submission.
- Abeona submitted the briefing package for the pre-BLA meeting with the FDA in August 2023 for its anticipated BLA submission of EB-101 in the treatment of RDEB. Abeona anticipates submitting the BLA in the third quarter of 2023.
- Additional efficacy and safety data from the pivotal Phase 3 VIITAL study of investigational EB-101 in RDEB were presented at the International Societies for Investigative Dermatology (ISID) and Society for Pediatric Dermatology (SPD) meetings. The positive top-line data from the VIITAL study were reported in November 2022.

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*Preclinical programs*

- Completed pre-Investigational New Drug Application (IND) meetings with the FDA regarding the preclinical development plans and regulatory requirements to support first-in-human trials for two preclinical gene therapy product candidates from its adeno-associated virus (AAV) ophthalmology program. The Company intends to initiate IND-enabling studies in the second half of 2023.
- Abeona presented new preclinical data at the 26th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT), including data on three internally developed preclinical gene therapy product candidates from its AAV ophthalmology program.

**Second Quarter Financial Results**

Cash, cash equivalents, restricted cash and short-term investments totaled $37.1 million as of June 30, 2023, prior to the $25 million registered direct offering in July 2023, as compared to $40.7 million as of March 31, 2023. Abeona estimates that its cash and cash equivalents, restricted cash and short-term investments as of June 30, 2023, in addition to the proceeds from the $25 million registered direct offering in July 2023, are sufficient resources to fund operations into the fourth quarter of 2024.

License and other revenues in the second quarter of 2023 were $3.5 million, compared to $1.0 million in the second quarter of 2022. Research and development expenses for the three months ended June 30, 2023 were $8.5 million, compared to $6.7 million for the same period of 2022. General and administrative expenses were $5.0 million for the three months ended June 30, 2023, compared to $3.5 million for the same period of 2022. Net loss attributable to common shareholders was $16.7 million for the second quarter of 2023, or $0.92 loss per common share as compared to a net loss attributable to common shareholders of $7.9 million, or $1.36 loss per common share, in the second quarter of 2022.

**Conference Call Details**

Abeona Therapeutics will host a conference call and webcast today, August 8, 2023, at 8:30 a.m. ET, to discuss its financial results and business update. To access the call, dial 888-506-0062 (U.S. toll-free) or 973-528-0011 (international) and Entry Code: 446072 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, 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.

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**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," 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; 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

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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 June 30, | | For the six months ended June 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Revenues: | | | | |
| License and other revenues | $ 3,500 | $ 1,000 | $ 3,500 | $ 1,346 |
| Expenses: | | | | |
| Royalties | 1,575 | 350 | 1,575 | 350 |
| Research and development | 8,523 | 6,658 | 16,564 | 17,203 |
| General and administrative | 5,021 | 3,460 | 9,018 | 7,684 |
| Impairment of licensed technology | — | — | — | 1,355 |
| Loss/(gain) on right-of-use lease assets | (1,065) | — | (1,065) | 1,561 |
| Impairment of construction-in-progress | — | (1,460) | — | 1,792 |
| Total expenses | 14,054 | 9,008 | 26,092 | 29,945 |
| Loss from operations | (10,554) | (8,008) | (22,592) | (28,599) |
| Interest income | 417 | 31 | 781 | 38 |
| Interest expense | (103) | (200) | (204) | (401) |
| Change in fair value of warrant liabilities | (8,629) | 4,198 | (6,364) | 2,945 |
| Other income (expense) | 2,215 | (118) | 2,618 | (124) |
| Net loss | $ (16,654) | $ (4,097) | $ (25,761) | $ (26,141) |
| Deemed dividends related to Series A and Series B Convertible Redeemable Preferred Stock | — | (3,782) | — | (3,782) |
| Net loss attributable to Common Shareholders | $ (16,654) | $ (7,879) | $ (25,761) | $ (29,923) |
| Basic and diluted loss per common share | $ (0.92) | $ (1.36) | $ (1.48) | $ (5.16) |
| Weighted average number of common shares outstanding – basic and diluted | 18,017,874 | 5,806,473 | 17,464,026 | 5,800,822 |
| Other comprehensive income (loss): | | | | |
| Change in unrealized gains (losses) related to available-for-sale debt securities | (30) | (4) | 34 | (7) |
| Comprehensive loss | $ (16,684) | $ (7,883) | $ (25,727) | $ (29,930) |

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

| | June 30, 2023 (Unaudited) | December 31, 2022 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 6,225 | $ 14,217 |

| | | |
|---|---|---|
| Short-term investments | 30,547 | 37,932 |
| Restricted cash | 338 | 338 |
| Accounts receivable | 3,500 | — |
| Other receivables | 2,227 | 188 |
| Prepaid expenses and other current assets | 1,201 | 424 |
| Total current assets | 44,038 | 53,099 |
| Property and equipment, net | 4,489 | 5,741 |
| Right-of-use lease assets | 4,915 | 5,331 |
| Other assets | 108 | 43 |
| Total assets | $ 53,550 | $ 64,214 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,477 | $ 1,811 |
| Accrued expenses | 4,161 | 3,991 |
| Current portion of lease liability | 1,597 | 1,773 |
| Other current liabilities | 205 | 204 |
| Total current liabilities | 9,440 | 7,779 |
| Payable to licensor | 4,367 | 4,163 |
| Long-term lease liabilities | 4,377 | 5,854 |
| Warrant liabilities | 26,021 | 19,657 |
| Total liabilities | 44,205 | 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 June 30, 2023 and December 31, 2022, respectively | — | — |
| Common stock - $0.01 par value; authorized 200,000,000 shares; 21,478,157 and 17,719,720 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively | 215 | 177 |
| Additional paid-in capital | 730,322 | 722,049 |
| Accumulated deficit | (721,097) | (695,336) |
| Accumulated other comprehensive loss | (95) | (129) |
| Total stockholders' equity | 9,345 | 26,761 |
| Total liabilities and stockholders' equity | $ 53,550 | $ 64,214 |