# 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): July 7, 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** | **The Nasdaq Capital Market** |

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 8.01 Other Events.**

On July 7, 2023, Abeona Therapeutics Inc. issued a press release entitled "Abeona Therapeutics Announces Closing of $25 Million Registered Direct Offering Priced At-the-Market Under Nasdaq Rules." A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release dated July 7, 2023, entitled "Abeona Therapeutics Announces Closing of $25 Million Registered Direct Offering Priced At-the-Market Under Nasdaq Rules." |
| 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: July 7, 2023

**Abeona Therapeutics Announces Closing of $25 Million Registered Direct Offering Priced At-the-Market Under Nasdaq Rules**

CLEVELAND, July 7, 2023 – Abeona Therapeutics Inc. (Nasdaq: ABEO) announced the closing of its previously announced registered direct offering for total gross proceeds of $25 million, before deducting the placement agents' fees and other offering expenses.

"Our existing institutional investors have shown their confidence in Abeona by participating in this registered direct offering without discounts or warrant coverage," said Vish Seshadri, Chief Executive Officer of Abeona. "We have been very encouraged by the favorable feedback and insights from healthcare professionals, patient communities, payors and hospital administrators based on the results of EB-101 in clinical trials, and we are positioned to launch EB-101 in the U.S. without depending on a partner. The $25 million offering allows us to now start preparing for the commercialization of EB-101 and aim for a timely launch upon potential BLA approval in the first half of 2024, while also extending our cash runway well into the fourth quarter of 2024."

Abeona will use the net proceeds from the offering primarily to fund preparations for commercialization of its product candidate EB-101, as well as for working capital and general corporate purposes. Based on EB-101's Rare Pediatric Disease designation, Abeona expects to qualify to receive a priority review voucher (PRV) upon Biologics License Application (BLA) approval and subject to final determination by the FDA. The PRV can be used to receive an expedited review process of a subsequent marketing application for a different product or sold to another company to create additional capital.

The Company sold 3,284,407 shares of its common stock (and, in lieu of common stock for certain investors, pre-funded warrants to purchase 2,919,140 shares of its common stock) at an offering price of $4.03 per share (or $4.0299 per pre-funded warrant, which represents the per share offering price for the common stock less the $0.0001 per share exercise price for each pre-funded warrant). The pre-funded warrants are immediately exercisable at a nominal exercise price of $0.0001 per share and may be exercised at any time until the pre-funded warrants are exercised in full.

The offering was led by Nantahala Capital Management, LLC and included participation by Adage Capital Partners LP and two other existing investors.

Cantor Fitzgerald & Co. acted as the sole lead-placement agent for the offering. A.G.P./Alliance Global Partners acted as the co-placement agent for the offering.

The securities described above were offered pursuant to a shelf registration statement on Form S-3 (File No. 333-256850) that was filed with the Securities and Exchange Commission (the "SEC") on June 7, 2021 and amended on August 27, 2021 and October 19, 2021, and was declared effective by the SEC on October 22, 2021. The prospectus supplement and the accompanying prospectus that form a part of the registration statement have been filed with the SEC and are available on the SEC's website at www.sec.gov. Copies of the prospectus supplement and the accompanying prospectus may also be obtained by contacting Cantor Fitzgerald & Co., Attention: Equity Capital Markets, 499 Park Avenue, 4th Floor, New York, NY 10022, or by e-mail at prospectus@cantor.com.



*The securities described above have not been qualified under any state blue sky laws. This press release does not constitute an offer to sell or the solicitation of offers to buy any securities of Abeona being offered, and shall not constitute an offer, solicitation or sale of any security in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.*

**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 produces EB-101 for the pivotal Phase 3 VIITAL™ study and is capable of clinical and potential commercial production of AAV-based gene therapies.

**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:**

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