

**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 19, 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:

| <u>Title of Each Class</u> | <u>Trading Symbol</u> | <u>Name of each exchange on which registered</u> |
|---------------------------------------|-----------------------|--|
| 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 8.01. Other Events.

On July 19, 2022, Abeona Therapeutics Inc. (the "Company") received formal notification (the "Notification") from the Nasdaq Stock Market LLC ("Nasdaq") confirming that the Company has regained compliance with Nasdaq Listing Rule 5550(a)(2), which requires that the Company's common stock maintain a minimum bid price of at least \$1.00 per share, and that the matter is now closed. A Press release issued by the Company on July 20, 2022 regarding the Notification is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Press release dated July 20, 2022, entitled "Abeona Therapeutics Regains Compliance with Nasdaq Listing Requirements" |
| 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 20, 2022



Abeona Therapeutics Regains Compliance with Nasdaq Listing Requirements

NEW YORK and CLEVELAND, July 20, 2022 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today announced that it received notice from The Nasdaq Stock Market LLC (Nasdaq) on July 19, 2022 informing Abeona that it has regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) (the “Rule”) for continued listing on The Nasdaq Capital Market. In order to regain compliance with the Rule, the Company’s common stock was required to maintain a minimum closing bid price of \$1.00 or more for at least 10 consecutive trading days. That requirement was met on July 18, 2022.

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; our ability to enroll patients in clinical trials; 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 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 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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