

**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 17, 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 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

As previously disclosed on a Current Report on Form 8-K filed November 19, 2021, on November 16, 2021, Abeona Therapeutics Inc. (the "Company") received a deficiency letter from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market ("Nasdaq") informing the Company that its common stock was below the minimum \$1.00 per share requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement") based on the closing bid price of the common stock for the 30 consecutive business days prior to the date of notice from Nasdaq.

On May 17, 2022, the Company received notice from Nasdaq indicating that, while the Company has not regained compliance with the Bid Price Requirement, Nasdaq has determined that the Company is eligible for an additional 180-day period, or until November 14, 2022, to regain compliance. According to the notification from Nasdaq, the Staff's determination was based on (i) the Company meeting the continued listing requirement for market value of its publicly held shares and all other Nasdaq initial listing standards, with the exception of the minimum bid price requirement, and (ii) the Company's written notice to Nasdaq of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If at any time during this second 180-day compliance period, the closing bid price of the common stock is at least \$1 per share for a minimum of 10 consecutive business days, Nasdaq will provide the Company with written confirmation of compliance. If compliance cannot be demonstrated by November 14, 2022, Nasdaq will provide written notification that the common stock will be delisted. At that time, the Company may appeal Nasdaq's determination to a Hearings Panel.

Item 7.01 Regulation FD Disclosure.

The Company has issued a press release, dated May 19, 2022, announcing the notice received from the Staff. The press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein. The information furnished in Exhibit 99.1 hereto shall not be considered "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 incorporated by reference into future filings by the Company under the Securities Act of 1933, as amended, or under the Exchange Act, unless the Company expressly sets forth in such future filings that such information is to be considered "filed" or incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

See the Exhibit Index below, which is incorporated by reference herein.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated May 19, 2022, entitled "Abeona Therapeutics Granted Second 180-Day Period by Nasdaq to Regain Compliance with Minimum Bid Price Rule"
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 19, 2022



Abeona Therapeutics Granted Second 180-Day Period by Nasdaq to Regain Compliance with Minimum Bid Price Rule

NEW YORK, NY and CLEVELAND, OH, May 19, 2022 – Abeona Therapeutics Inc. (Nasdaq: ABEO), a fully-integrated leader in cell and gene therapy, today announced that the Company has been granted an additional 180-day period from Nasdaq’s Listing Qualification Department, through November 14, 2022, to regain compliance with the \$1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market. The Company’s common stock continues to trade on the Nasdaq Capital Market under the symbol “ABEO.”

If at any time until November 14, 2022, the closing bid price of the Company’s common stock is at or above \$1.00 per share for a minimum of 10 consecutive trading days, Nasdaq will provide the Company with written confirmation of compliance. If compliance cannot be demonstrated during the additional 180-day grace period, Nasdaq will provide written notification that the common stock will be subject to delisting. At such time, the Company may appeal the determination to a Nasdaq Hearings Panel. The Company’s common stock would remain listed pending the completion of the appeal process.

As part of the Company’s strategy to regain compliance with Nasdaq’s minimum bid price requirement, 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.

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, our ability to regain compliance with the \$1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market; 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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