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 25, 2019**

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.)

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 8.01. Other Events.

Abeona Therapeutics Inc. ("Abeona" or the "Company") recently held a meeting with the U.S. Food and Drug Administration (the "FDA" or "Agency") to discuss preparations for Abeona's upcoming VITAL™ Phase 3 clinical trial for EB-101 for the treatment of recessive dystrophic epidermolysis bullosa. EB-101 is an autologous, collagen 7 gene-corrected cell therapy manufactured by Abeona. The FDA addressed information previously submitted by the Company on its chemistry, manufacturing and controls ("CMC") and the Phase 3 clinical protocol. The Company received valuable feedback and is currently working through outstanding items with the Agency, including the clinical measurement for certain patient reported outcomes, the clarification of CMC information related to product transport, and the protocol to assess comparability of certain clinical materials to be conducted during the Phase 3 trial. The Company will utilize the increased clarity it obtained from these recent interactions with the FDA to promptly address the few remaining items and now expects to initiate the VITAL™ Phase 3 trial for its EB-101 program in the fourth quarter of 2019.

Forward Looking Statements

This communication 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. These statements include but are not limited to statements related to the expected timing of the initiation of the Phase 3 clinical trial for the Company's EB-101 program. We have attempted to identify forward looking statements by such terminology as "may," "will," "anticipate," "believe," "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 outcome of future interactions with the Food and Drug Administration including but not limited to those relating to the EB-101 program; receipt of additional requests or questions from the FDA that could affect trial commencement, including the timing thereof; any other continued interest in our rare disease portfolio; our ability to submit protocols and protocol amendments to regulatory agencies; our ability to initiate and enroll patients in clinical trials; the adequacy of manufacturing capabilities; the impact of competition; the ability to secure licenses or establish intellectual property rights for any technology that may be necessary to continue to develop and commercialize our products; 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; and other risks as may be detailed from time to time in the Company's annual reports on Form 10-K and quarterly reports on Form 10-Q and other reports filed by the Company with the Securities and Exchange Commission. The Company undertakes no obligation to revise the forward-looking statements or update them to reflect events or circumstances occurring after the date of this communication, except as required by the federal securities laws.

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/ Neena M. Patil
Name: Neena M. Patil
Title: General Counsel and Secretary

Date: July 25, 2019