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 16, 2018**

ABEONA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**0-9314**	**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) 813-4712
(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))

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. 7.01. Other Events

Abeona Therapeutics Inc. (NASDAQ:ABEO), a leading clinical-stage biopharmaceutical company focused on developing novel cell and gene therapies for life-threatening rare genetic diseases, today announced that it is working closely with the U.S. Food and Drug Administration (FDA) to confirm the final protocol guidance for the EB-101 Phase 3 pivotal trial in recessive dystrophic epidermolysis bullosa (RDEB). The Company noted that a draft version of the protocol for the trial had been prematurely posted by its collaborator on the FDA clinical trial online portal (www.clinicaltrials.gov) and the collaborator has agreed to either retract or withdraw the posting. Based on FDA input, the planned Phase 3 clinical trial will be a single-center, randomized, controlled study conducted at Stanford University School of Medicine.

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/Carsten Thiel
Carsten Thiel
Chief Executive Officer

Dated: August 16, 2018