

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): **September 3, 2019**

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) 813-4712
(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))

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 September 3, 2019, Abeona Therapeutics Inc. (the “Company”) issued a press release entitled “Abeona Therapeutics Announces Strategic Review.” The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press release dated September 3, 2019, entitled “Abeona Therapeutics Announces Strategic Review.”</u>

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/ Edward A. Sturchio
Name: Edward A. Sturchio
Title: Senior Vice President and General Counsel

Date: September 4, 2019

CONFIDENTIAL



Abeona Therapeutics Announces Strategic Review

Company engages Jefferies LLC in response to strategic inbound interest

NEW YORK and CLEVELAND, Sept. 03, 2019 (GLOBE NEWSWIRE) -- Abeona Therapeutics Inc. (Nasdaq: ABEO), a fully-integrated leader in gene and cell therapy, today announced that it has retained Jefferies LLC as its financial advisor to assist with the review of strategic options focused on advancing the Company's mission and maximizing stakeholder value. In response to interest, Abeona has initiated a process to explore a broad range of strategic alternatives, including, but not limited to the partnering of its various clinical and preclinical programs, or a sale or merger of the Company, in an effort to unlock the potential of those assets.

"With four clinical stage programs, a broad pre-clinical pipeline, GMP manufacturing facilities, and a talented team, Abeona remains committed to advancing the promise of genetic medicine," said João Siffert, M.D., Chief Executive Officer. "Given our expertise in gene and cell therapy, we believe we are well positioned to explore a variety of opportunities, pursue strategic partnerships and alliances, improve our capital structure, and accelerate development of candidates towards commercialization."

There can be no assurance this strategic review will result in the completion of any particular course of action. There is no defined timeline for completion of the review process and the Company does not intend to comment further unless a specific initiative is approved by the Board of Directors, the review process is concluded, or it is otherwise determined that other disclosure is appropriate.

Steven H. Rouhandeh, Chairman of the Board commented, "Our management team and employees have developed multiple programs that are innovative and transformative for patients. We look to translate our assets and capabilities into value for stakeholders and are confident that the strategic review process will facilitate our efforts to achieve that goal."

About Abeona Therapeutics

Abeona Therapeutics Inc. is a clinical-stage biopharmaceutical company developing gene and cell therapies for serious diseases. The Company's clinical programs include EB-101, its autologous, gene-corrected cell therapy for recessive dystrophic epidermolysis bullosa, as well as ABO-102 and ABO-101, novel AAV9-based gene therapies for Sanfilippo syndrome types A and B (MPS IIIA and MPS IIIB), respectively. The Company's portfolio of AAV9-based gene therapies also features ABO-202 and ABO-201 for CLN1 disease and CLN3 disease, respectively. Its preclinical assets include ABO-401, which uses a novel vector from Abeona's AIM™ AAV capsid platform to address all mutations of cystic fibrosis. Abeona has received numerous regulatory designations from the FDA and EMA for its pipeline candidates, including Regenerative Medicine Advanced Therapy designation for two candidates (EB-101 and ABO-102). For more information, visit www.abeonatherapeutics.com.

Forward Looking Statement

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. These statements include statements about the ability of its management team to lead the Company and deliver on key strategies, the market opportunities for the Company's products and product candidates, and the Company's goals and objectives. We have attempted to identify forward looking statements by such terminology as "may," "will," "anticipate," "believe," "estimate," "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 continued interest in our rare disease portfolio, our ability to enroll patients in clinical trials, the impact of competition, the ability to secure licenses for any technology that may be necessary to 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 to update them to reflect events or circumstances occurring after the date of this presentation, whether as a result of new information, future developments or otherwise, except as required by the federal securities laws.

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