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 30, 2020

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 | e) |
| | (Registrant's telephone number, including area cod | de) |
| Check the appropriate box below if the Form 8-K filing is General Instruction A.2. below): | intended to simultaneously satisfy the filing obligat | ion of the registrant under any of the following provisions (see |
| ☐ Written communications pursuant to Rule 425 under the | e Securities Act (17 CFR 230.425) | |
| ☐ Soliciting material pursuant to Rule 14a-12 under the E | xchange Act (17 CFR 240.14a-12) | |
| ☐ Pre-commencement communications pursuant to Rule 1 | 4d-2(b) under the Exchange Act (17 CFR 240.14d-2 | 2(b)) |
| ☐ Pre-commencement communications pursuant to Rule 1 | 3e-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 Market |
| Indicate by check mark whether the registrant is an emergin the Securities Exchange Act of 1934 (§240.12b-2 of this cha | | curities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of |
| Emerging growth company □ | | |
| If an emerging growth company, indicate by check mark if accounting standards provided pursuant to Section 13(a) of t | | ansition period for complying with any new or revised financial |
| | | |

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On September 17, 2020, Abeona Therapeutics Inc. (the "Company") had filed a Current Report on Form 8-K reporting that Steven H. Rouhandeh had notified the Company of his resignation from the Board of Directors (the "Board"), effective September 30, 2020. On September 30, 2020, Mr. Rouhandeh rescinded his resignation from the Board, and the Board accepted his rescission of resignation. Also on September 30, 2020, the Board voted unanimously to elect Mr. Rouhandeh as Chairman of the Board. Mr. Rouhandeh will not be taking on any additional compensation as Chairman other than what he was already receiving as a non-employee director, which such compensation is disclosed in the Company's proxy statement filed on April 10, 2020.

Item 7.01 Regulation FD.

On October 6, 2020, the Company issued a press release announcing Mr. Rouhandeh's appointment as Chairman, the creation of a special committee of the Board to oversee and advise the executive leadership team on the operations of the Company, and the retention of Jefferies LLC as financial advisor to assist with the review of strategic options. 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 Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Press release, dated October 6, 2020

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.

October 6, 2020 Abeona Therapeutics Inc.

(Registrant)

By: /s/ Brendan M. O'Malley

Name: Brendan M. O'Malley
Title: Corporate Secretary



Abeona Therapeutics' Board of Directors Forms Special Committee to Oversee Operations, Develop Strategic Direction and Leadership Plan

Steven H. Rouhandeh Appointed as Chairman of the Board of Directors

Jefferies LLC Retained as Financial Advisor to Assist with the Review of Strategic Options

NEW YORK and CLEVELAND, Oct. 6, 2020 – Abeona Therapeutics Inc. (Nasdaq: ABEO), a fully-integrated leader in gene and cell therapy, today announced that its Board of Directors has formed a Special Committee to oversee and advise the executive leadership team on the operations of the Company, leveraging the respective medical, business development and financial expertise of its members. The Special Committee, which consists of current board members, is also working closely with the executive leadership team to develop the Company's strategic direction and leadership plan as it continues to advance its clinical programs toward providing novel gene and cell therapies to patients who currently have no approved treatment options. The Company also announced the appointment of Steven H. Rouhandeh as Chairman of its Board of Directors.

Strategic Review

Abeona 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. 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.

About Abeona Therapeutics

Abeona Therapeutics Inc. is a clinical-stage biopharmaceutical company developing gene and cell therapies for serious diseases. Abeona's clinical programs include EB-101, its autologous, gene-corrected cell therapy for recessive dystrophic epidermolysis bullosa in Phase 3 development, as well as ABO-102 and ABO-101, novel AAV-based gene therapies for Sanfilippo syndrome types A and B (MPS IIIA and MPS IIIB), respectively, in Phase 1/2 development. The Company's portfolio of AAV-based gene therapies also features ABO-201 for CLN3 disease. Abeona's novel, next-generation AIMTM capsids have shown potential to improve tropism profiles for a variety of devastating diseases. Abeona's fully functional, gene and cell therapy GMP manufacturing facility produces EB-101 for the pivotal Phase 3 VIITALTM study and is capable of clinical and 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. These statements include statements about the Company exploring all strategic options, including the sale of some or all of its assets or sale of the Company. 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, the outcome of the strategic review, continued interest in our rare disease portfolio, 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 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 disclosed in the Company's most recent Annual Report on Form 10-K and subsequent quarterly reports on Form 10-Q 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 deve

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