

**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 16, 2021**

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

On September 16, 2021, Michael Amoroso, President and Chief Executive Officer of Abeona Therapeutics Inc. (the "Company"), and a member of the Board of Directors (the "Board"), notified the Company of his resignation as President and Chief Executive Officer effective October 14, 2021. Mr. Amoroso will remain a member of the Board. On September 17, 2021, Steven Rouhandeh, Chairman of the Board, notified the Company of his retirement and resignation as a member of the Board effective October 14. Also on September 17, the Board voted unanimously to appoint Mr. Amoroso Chairman of the Board effective October 15.

On September 17, 2021, the Board appointed Vishwas Seshadri, Ph.D., M.B.A., as President and Chief Executive Officer and director effective October 15, 2021. As President and Chief Executive Officer, Dr. Seshadri, 46, will serve as the Company's principal executive officer and principal operating officer. Dr. Seshadri will serve as a Class 2 director and is not expected to serve on any committees of the Board. Dr. Seshadri has served as the Company's Senior Vice President, Head of Research & Clinical Development since June 1, 2021. Prior to joining the Company, Dr. Seshadri served as executive director at Bristol Myers Squibb from January 2020 to June 2021. Dr. Seshadri also served in various capacities at Celgene Corporation between October 2010 and January 2020, having most recently served as senior director, global marketing. The Company is not aware of any transaction or relationship involving Dr. Seshadri requiring disclosure under Item 404(a) of Regulation S-K.

In connection with his appointment as Chief Executive Officer, Dr. Seshadri and the Company entered into a letter agreement (the "Agreement"), pursuant to which Dr. Seshadri will receive an annual base salary of \$500,000, payable in accordance with regular payroll practices of the Company. Dr. Seshadri will also be entitled to an annual bonus opportunity, with a target range equal to 50% of his base salary and prorated for any partial year of service. Any such bonus will be contingent on Dr. Seshadri's satisfaction of objective and subjective performance goals established by the Company's Board of Directors (the "Board"). Additionally, Dr. Seshadri will receive 50,000 shares of restricted stock and options to purchase 300,000 shares of common stock of the Company. The options have a 10-year term and will vest 25% on the one-year anniversary of the grant date and the remaining 75% will vest in equal monthly installments over the following 36 months. The restricted stock will vest 25% on the one-year anniversary of the grant

date and the remaining 75% will vest in equal annual installments over the following 36 months. Dr. Seshadri will also be entitled to receive stock option grants and other long-term compensation grants under the Abeona Therapeutics Inc. 2015 Equity Incentive Plan subject to the Board's discretion and approval. The foregoing summary of the Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Agreement, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending September 30, 2021.

Item 7.01 Regulation FD.

The Company has issued a press release, dated September 21, 2021, announcing the foregoing leadership changes. 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.

Exhibit No. Description

99.1 [Press release dated September 21, 2021, entitled "Abeona Announces New Chairman, Executive Leadership Promotions and Key Talent Additions for Final Push Towards Two Biologics License Application \(BLA\) Filings"](#)

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

Date: September 21, 2021



**Abeona Announces New Chairman, Executive Leadership Promotions and
Key Talent Additions for Final Push Towards Two Biologics License
Application (BLA) Filings**

Steven H. Rouhandeh to retire as Chairman of the Board; Michael Amoroso appointed Chairman of the Board

Vishwas Seshadri, Ph.D., M.B.A. to become Chief Executive Officer

*Brendan M. O'Malley, J.D., Ph.D. promoted to General Counsel, Brian Kevany, Ph.D. promoted to
Chief Technical Officer, Scott Nogi, M.B.A., Head of Business Operations to expand role and
lead operations at Abeona's Cleveland facility*

*Regulatory veterans in AAV-based gene therapy, Carl Denny and Kate Imhoff, added to team in
preparation for two upcoming Biologics License Application submissions*

NEW YORK and CLEVELAND, Sept 21, 2021 – Abeona Therapeutics Inc. (Nasdaq: ABEO), a fully-integrated leader in gene and cell therapy, today announced Board appointments, executive leadership promotions, and additions of senior regulatory veterans to prepare for the potential of two Biologics License Application (BLA) submissions for EB-101 and ABO-102 currently in pivotal studies.

Steven Rouhandeh will retire from his position as Chairman of the Board and Board member of Abeona, effective October 14, 2021. Mr. Rouhandeh has served as a Director on Abeona's Board since the Company's public debut in 2015. The Board has appointed Michael Amoroso Chairman of the Board, effective October 15, 2021.

Dr. Vishwas (Vish) Seshadri, Ph.D., M.B.A., has been appointed President and Chief Executive Officer (CEO), and member of the Company's Board of Directors, effective October 15, 2021. Until then, Dr. Seshadri will remain in his current role as Head of Research & Clinical Development and will lead the Company's search for a new R&D leader with late-stage clinical and regulatory experience in preparation for two pivotal data readouts beginning in 2022.

Prior to joining Abeona, Dr. Seshadri served in roles of increasing responsibility at Celgene Corporation, now a subsidiary of Bristol-Myers Squibb Company (BMS), where he focused on development and commercialization of novel therapies in hematology and oncology. Most recently, he led the team responsible for the launch of Breyanzi[®] (lisocabtagene maraleucel; liso-cel), an autologous CD19-directed chimeric antigen receptor (CAR) T cell therapy for relapsed or refractory large B-cell lymphoma. Dr. Seshadri has more than 20 years of experience including academia and various senior and executive leadership roles in the life sciences industry overseeing product development, regulatory submissions, and commercialization for novel therapies including personalized, autologous cell and gene therapies.

Dr. Seshadri commented, "I am grateful to the Board and Michael for this opportunity to serve Abeona's patients, shareholders, and employees. I have been fortunate to work directly with Michael for many years and look forward to continuing to learn from him in his new role as Chairman. Abeona has recently enhanced its BLA-ready talent with key additions across regulatory, clinical, quality and technical operations, and I look forward to leading our organization towards delivering top-line data for two pivotal clinical studies in RDEB and MPS IIIA. Our operational roadmap is clear, including alignment with the FDA for our two pivotal programs, and the Abeona team is motivated and laser-focused on delivering against the milestones that will enable us to bring both EB-101 and AAV-based gene therapy ABO-102 to patients as safely, effectively and quickly, as possible."

As Chairman, Mr. Amoroso, along with the Board, will continue to play an important leadership role focusing on the longer-term strategic direction of the Company in its pursuit of bringing important therapies to patients and creating shareholder value. Mr. Amoroso will continue in his role as President and CEO through mid-October 2021, working seamlessly with Dr. Seshadri to ensure a thorough transition and business continuity across all Abeona stakeholders.

Mr. Amoroso said, "We are very appreciative of Steve's dedicated service over the years and have benefitted from his leadership and contributions to Abeona. I am personally grateful that Steve delayed his retirement this past year to ensure a seamless transition for me as the President and CEO, while also preparing me to now take the reigns as Chairman of the Board. Additionally, I have known Vish personally and professionally over the past 10 years and have great confidence in his ability to lead Abeona in its critical final stages toward BLA submissions. Vish will continue to be surrounded by a highly talented and committed management team, as well as a purpose-driven and exceptional employee base. I look forward to working closely with Vish as he transitions into his new role."

Executive Team Promotions and Key Appointments

Brendan O'Malley, J.D., Ph.D. has been promoted to Senior Vice President, General Counsel. Dr. O'Malley joined Abeona in May 2019 as Chief IP Counsel and was promoted to Head of Legal & IP in April 2020. In his role as General Counsel, Dr. O'Malley will leverage his significant legal and technical expertise in the biotechnology industry to oversee legal, corporate, IP, compliance, and other related matters for Abeona.

Brian Kevany, Ph.D. has been promoted to Vice President, Chief Technical Officer. Dr. Kevany joined the Company in January 2018 and has been instrumental in advancing Abeona's preclinical ophthalmology programs. Dr. Kevany was promoted to Vice President, Manufacturing and Interim Head of Technical Operations in June 2021. As Chief Technical Officer, Dr. Kevany will oversee and direct all manufacturing, assay development, process development, and supply chain operations for Abeona.

Effective immediately, Scott Nogi, M.B.A., Vice President, Head of Business Operations will expand his role to include leading day-to-day operations as site head at Abeona's Cleveland facility. Mr. Nogi, who joined the Company in March 2018, has been instrumental in the design and execution of the plans to expand Abeona's manufacturing capabilities with the construction of a new 10,000+ square foot AAV manufacturing facility as the Company approaches commercialization of its AAV-based gene therapies.

Abeona has recently added gene and biopharmaceutical industry veterans with deep operational expertise across the areas of clinical development, regulatory, and quality, including the recent additions of proven regulatory leaders Carl Denny as Vice President, Regulatory Affairs and Kate Imhoff as Senior Director, Regulatory Affairs.

Mr. Denny joins the Company from Sarepta Therapeutics, Inc., and has over 20 years of experience in Chemistry Manufacturing and Controls (CMC) and regulatory affairs in the registration of gene therapies and mRNA products including AMONDYS 45 (casimersen) and AAV-based gene therapy Zolgensma[®] (onasemnogene abeparvovec-xioi). Carl has also served in multiple roles of increasing responsibility at AveXis, Inc., GE Healthcare, Takeda Pharmaceuticals, Catalent Pharma Services, Abbott Laboratories and Eli Lilly.

Ms. Imhoff joins the Company from Sarepta Therapeutics, Inc., and has over 15 years of experience in the pharmaceutical industry, including supporting AAV-based gene

therapy submissions at AveXis, Inc. She has experience across various functions including regulatory affairs, quality systems, quality control, manufacturing/product support, and R&D.

These additions bolster the Company's strong regulatory team that includes Advyzom, LLC, a leading consulting company led by Dr. Cindy Dinella, R.Ph. Pharm. D, formerly the Vice President of Drug Regulatory Affairs, Nutley Site Head for Global Development and Member of the CEO's North American Operating Committee at Hoffman La Roche Inc.

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 investigational autologous, gene-corrected cell therapy for recessive dystrophic epidermolysis bullosa in Phase 3 development, as well as ABO-102 and ABO-101, novel investigational 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 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 gene and cell therapy cGMP manufacturing facility produces EB-101 for the pivotal Phase 3 VIITAL™ study and is capable of clinical and planned 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 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 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 developments or otherwise, except as required by the federal securities laws.

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