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 8, 2024**

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.)

6555 Carnegie Ave, 4th Floor
Cleveland, OH 44103
(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.

The Board of Directors (the "Board") of Abeona Therapeutics Inc. (the "Company"), acting upon the recommendation of its Nominating and Corporate Governance Committee, appointed Bernhardt G. Zeiher, MD, FCCP, FACP, on August 8, 2024 and Eric Crombez, MD on August 12, 2024 as members of the Board of the Company. Dr. Zeiher and Dr. Crombez are both considered "independent" directors under relevant U.S. Securities and Exchange Commission ("SEC") and Nasdaq rules, and neither has yet been appointed to serve as a member of any Board committee. Dr. Zeiher will serve as a Class 1 director and Dr. Crombez will serve as a Class 2 director.

Dr. Zeiher spent more than 10 years at Astellas Pharma, holding multiple roles of increasing responsibility in drug development, leading up to his role as CMO, where he led early- and late-stage drug development, medical and regulatory affairs, pharmacovigilance, and quality assurance. Prior to Astellas, Dr. Zeiher held various roles leading drug development at other pharmaceutical companies including Pfizer and Eli Lilly and Company. He also practiced medicine at a tertiary medical center in Indianapolis. Dr. Zeiher currently serves on multiple public company boards, including Entrada Therapeutics and Amylyx Pharmaceuticals, Inc. He previously served on the boards of TransCelerate Biopharma, Biotechnology Innovation Organization and Astellas Global Health Foundation. Dr. Zeiher received a B.S. in biology from the University of Toledo and an MD from Case Western Reserve University School of Medicine. He completed his internal medicine residency and chief residency at University Hospitals of Cleveland and then finished his physician training as a Pulmonary and Critical Care Fellow at University of Iowa Hospitals and Clinics.

Dr. Crombez joined Ultragenyx following the acquisition of Dimension Therapeutics in November 2017. He is also an appointed industry representative on the FDA Cellular, Tissue, and Gene Therapies Advisory Committee. At Dimension Therapeutics, Dr. Crombez served as chief medical officer and led the clinical development efforts for clinical gene therapy programs in hemophilia B, hemophilia A, ornithine transcarbamylase (OTC) deficiency and glycogen storage disease type Ia (GSDIa). Previously, he worked at Shire in its Human Genetics Therapy business unit. Before joining industry, Dr. Crombez was assistant professor, Department of Pediatrics, Division of Medical Genetics at the David Geffen School of Medicine at the University of California, Los Angeles (UCLA). He is a board-certified clinical geneticist and completed residencies in pediatrics and

medical genetics and a fellowship in clinical biochemical genetics at the UCLA School of Medicine. Dr. Crombez obtained his B.S. degree in biology from the University of Michigan, Ann Arbor, and his M.D. degree from Wayne State University School of Medicine, Detroit.

There are no family relationships between Dr. Zeiher or Dr. Crombez and any other director or executive officer of the Company. Nor are there any transactions between Dr. Zeiher or Dr. Crombez or any member of their respective immediate family and the Company that would be reportable as a related party transaction under the rules of the SEC. Further, there is no arrangement or understanding between them and any other persons or entities pursuant to which they were appointed as directors of the Company.

Each of Dr. Zeiher and Dr. Crombez will receive an annual Board fee of $50,000 in cash and a one-time sign-on equity grant in the amount of $55,000 worth of Company stock, in the form of restricted stock awards (RSAs) with a one-year vesting period. Both Dr. Zeiher and Dr. Crombez will be eligible for the Board's regular 2025 equity grant, which is determined annually by the Board upon recommendation of the Compensation Committee of the Board, based on the advice of an external compensation consultant.

The full text of the press release announcing Dr. Zeiher's or Dr. Crombez's appointment is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated August 14, 2024, entitled "Abeona Therapeutics® Announces Appointment of Bernhardt Zeiher, MD, FCCP, FACP, and Eric Crombez, MD to its Board of Directors"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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/ Joseph Vazzano*
Name: Joseph Vazzano
Title: Chief Financial Officer

Date: August 14, 2024

Exhibit 99.1

Abeona Therapeutics® Announces Appointment of Bernhardt Zeiher, MD, FCCP, FACP, and Eric Crombez, MD to its Board of Directors

CLEVELAND, August 14, 2024 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today announced the appointment of Bernhardt G. Zeiher, MD, FCCP, FACP, and Eric Crombez, MD as new independent members to its Board of Directors. Dr. Zeiher brings more than 20 years of drug development experience where, in various roles, he oversaw the approval of 15 new treatments that addressed unmet needs in serious diseases with few to no treatment options. Dr. Crombez currently serves as Chief Medical Officer of Ultragenyx Pharmaceutical Inc. and brings extensive expertise in the development and execution of clinical development programs for rare genetic disorders.

Michael Amoroso, Chairman of Abeona's Board of Directors, said, "We are delighted to welcome both Bernie Zeiher and Eric Crombez to our Board during this important period in Abeona's history. As recognized and dynamic life sciences leaders, they bring a wealth of diverse drug development expertise to Abeona. We look forward to their valuable insights as we continue to both focus on bringing pz-cel to patients with recessive dystrophic epidermolysis bullosa and as we seek to advance and expand our pipeline."

Dr. Zeiher spent more than 10 years at Astellas Pharma, holding multiple roles of increasing responsibility in drug development, leading up to his role as CMO, where he led early- and late-stage drug development, medical and regulatory affairs, pharmacovigilance, and quality assurance. Prior to Astellas, Dr. Zeiher held various roles leading drug development at other pharmaceutical companies including Pfizer and Eli Lilly and Company. He also practiced medicine at a tertiary medical center in Indianapolis. Dr. Zeiher currently serves on multiple public company boards, including Entrada Therapeutics and Amylyx Pharmaceuticals, Inc. He previously served on the boards of TransCelerate Biopharma, Biotechnology Innovation Organization and Astellas Global Health Foundation. Dr. Zeiher received a B.S. in biology from the University of Toledo and an MD from Case Western Reserve University School of Medicine. He completed his internal medicine residency and chief residency at University Hospitals of Cleveland and then finished his physician training as a Pulmonary and Critical Care Fellow at University of Iowa Hospitals and Clinics.

Dr. Crombez joined Ultragenyx following the acquisition of Dimension Therapeutics in November 2017. He is also an appointed industry representative on the FDA Cellular, Tissue, and Gene Therapies Advisory Committee. At Dimension Therapeutics, Dr. Crombez served as chief medical officer and led the clinical development efforts for clinical gene therapy programs in hemophilia B, hemophilia A, ornithine transcarbamylase (OTC) deficiency and glycogen storage disease type Ia (GSDIa). Previously, he worked at Shire in its Human Genetics Therapy business unit. Before joining industry, Dr. Crombez was assistant professor, Department of Pediatrics, Division of Medical Genetics at the David Geffen School of Medicine at the University of California, Los Angeles (UCLA). He is a board-certified clinical geneticist and completed residencies in pediatrics and medical genetics and a fellowship in clinical biochemical genetics at the UCLA School of Medicine. Dr. Crombez obtained his B.S. degree in biology from the University of Michigan, Ann Arbor, and his M.D. degree from Wayne State University School of Medicine, Detroit.

About Abeona Therapeutics

Abeona Therapeutics Inc. is a clinical-stage biopharmaceutical company developing cell and gene therapies for serious diseases. Prademagene zamikeracel (pz-cel) is Abeona's investigational autologous cell-based gene therapy currently in development for recessive dystrophic epidermolysis bullosa. The Company's fully integrated cell and gene therapy cGMP manufacturing facility served as the manufacturing site for pz-cel used in its Phase 3 VIITAL™ trial, and is capable of supporting commercial production of pz-cel upon FDA approval. 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. 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," "anticipate," "expect," "intend," "potential," and similar words and 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 timing and results of ongoing testing and other corrective actions being performed in response to the FDA's identified deficiencies, which could delay the Company's BLA resubmission; the timing and outcome of the FDA's review of our resubmission; the FDA's grant of a Priority Review Voucher upon approval; continued interest in our rare disease portfolio; our ability to enroll patients in clinical trials; the outcome of future meetings with the FDA or other regulatory agencies, including those relating to preclinical programs; the ability to achieve or obtain necessary regulatory approvals; the impact of any 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 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.

Investor and Media Contact:

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