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): November 27, 2023

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**	**The Nasdaq Capital Market**

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 November 27, 2023, Abeona Therapeutics Inc. issued a press release entitled "Abeona Therapeutics Announces FDA Accepts and Grants Priority Review for Pz-cel Biologics License Application (BLA)." A copy of the press release is attached 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.

Exhibit No.	**Description**
99.1	Press release dated November 27, 2023, entitled "Abeona Therapeutics Announces FDA Accepts and Grants Priority Review for Pz-cel Biologics License Application (BLA)."
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: November 27, 2023

Exhibit 99.1

Abeona Therapeutics Announces FDA Accepts and Grants Priority Review for Pz-cel Biologics License Application (BLA)

- PDUFA target action date is May 25, 2024 -

- FDA does not currently plan to hold Advisory Committee meeting for pz-cel BLA -

CLEVELAND, November 27, 2023 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today announced that the U.S. Food and Drug Administration (FDA) has accepted and granted Priority Review for the Biologics License Application (BLA) for pz-cel (prademagene zamikeracel), Abeona's investigational autologous, COL7A1 gene-corrected epidermal sheets for the treatment of patients with recessive dystrophic epidermolysis bullosa (RDEB). Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of May 25, 2024. The FDA also advised that it does not currently plan to convene an Advisory Committee meeting to discuss the pz-cel application.

"The FDA's acceptance of our BLA for priority review underscores the high unmet need in RDEB and the potential for pz-cel to provide meaningful benefit to these patients," said Vish Seshadri, Chief Executive Officer of Abeona. "We thank the FDA for their commitment and look forward to working with them through the BLA review, with the goal of bringing this therapy to patients as soon as possible."

The BLA is supported by clinical efficacy and safety data from the pivotal Phase 3 VIITAL™ study (NCT04227106) and confirmatory evidence from a Phase 1/2a study (NCT01263379). Both studies revealed that a one-time application of pz-cel on large and chronic wounds delivered sustained wound healing and pain reduction. Data from the VIITAL™ study were presented during the inaugural International Societies for Investigative Dermatology (ISID) Meeting in May 2023. Long-term follow up data up to eight years and quality of life data from the Phase 1/2a study were published in *Orphanet Journal of Rare Diseases*.

The grant of the Priority Review status is an important prerequisite for Abeona's eligibility for a Priority Review Voucher.

About Recessive Dystrophic Epidermolysis Bullosa

Recessive dystrophic epidermolysis bullosa (RDEB), a rare connective tissue disorder, is characterized by severe skin wounds that cause pain and can lead to systemic complications impacting the length and quality of life. People with RDEB have a defect in the COL7A1 gene, leaving them unable to produce functioning Type VII collagen, which is necessary to anchor the dermal and epidermal layers of the skin.

About pz-cel (prademagene zamikeracel)

Pz-cel (prademagene zamikeracel), Abeona's investigational autologous, COL7A1 gene-corrected epidermal sheets, is currently being developed for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), a rare connective tissue disorder caused by a defect in the COL7A1 gene that results in the inability to produce Type VII collagen. Pz-cel is designed to incorporate the functional collagen-producing COL7A1 gene into a patient's own skin cells and enable long-term gene expression by using a retroviral vector to stably integrate into the dividing target cell genome. Pz-cel is being investigated for its ability to enable normal Type VII collagen expression and to facilitate wound healing and pain reduction in even the toughest-to-treat RDEB wounds after a one-time application procedure. The pivotal Phase 3 VIITAL™ study is a randomized clinical trial that evaluated the efficacy, safety and tolerability of pz-cel in 43 large chronic wound pairs in 11 subjects with RDEB. Pz-cel has been granted Regenerative Medicine Advanced Therapy, Breakthrough Therapy, Orphan Drug and Rare Pediatric Disease designations by the U.S. FDA. Abeona produces pz-cel for the VIITAL™ study at its fully integrated gene and cell therapy manufacturing facility in Cleveland, Ohio.

About Abeona Therapeutics

Abeona Therapeutics Inc. is a clinical-stage biopharmaceutical company developing cell and gene therapies for serious diseases. Abeona's lead clinical program is pz-cel, its investigational autologous, COL7A1 gene-corrected epidermal sheets currently in development for recessive dystrophic epidermolysis bullosa. 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 cell and gene therapy cGMP manufacturing facility produced pz-cel for the pivotal Phase 3 VIITAL™ study and is capable of clinical and potential 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," "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 outcome of our Biologics License Application submission to the FDA for pz-cel; the FDA's grant of a Priority Review Voucher; 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:

Greg Gin
VP, Investor Relations and Corporate Communications
Abeona Therapeutics
ir@abeonatherapeutics.com
