
**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): March 9, 2026

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.)

**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))

Title of Each Class

Common Stock, \$0.01 par value

Trading Symbol

ABEO

Name of each exchange on which registered

The Nasdaq Capital Market

Securities registered pursuant to Section 12(b) of the Act:

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 March 9, 2026, Abeona Therapeutics Inc. issued a press release entitled “Abeona Therapeutics® Provides Business Update Highlighting Building Momentum in ZEVASKYN® Commercial Launch.” 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 March 9, 2026, entitled “Abeona Therapeutics® Provides Business Update Highlighting Building Momentum in ZEVASKYN® Commercial Launch.”
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: March 9, 2026



Abeona Therapeutics® Provides Business Update Highlighting Building Momentum in ZEVASKYN® Commercial Launch

CLEVELAND, March 9, 2026 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today announced an update on the building momentum in the Company’s launch of FDA-approved ZEVASKYN (prademagene zamikeracel), a first-of-its-kind, autologous gene therapy for treating wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB).

Following the optimization of a release assay in 2025, ZEVASKYN commercial launch activities commenced in the fourth quarter, with the first patient treatment completed in December prior to a mandatory scheduled facility shutdown. Since resuming manufacturing in late January 2026, multiple biopsies have been collected, a patient has completed treatment with ZEVASKYN, and there are ongoing manufacturing runs. Additional biopsies are scheduled for the remainder of this quarter.

“We are building toward a regular cadence of biopsy collections and are gaining visibility into more patients entering the ZEVASKYN treatment funnel,” said Dr. Madhav Vasanthavada, Chief Commercial Officer of Abeona. “As a result of this momentum, our initial Qualified Treatment Centers (QTCs) are becoming familiar with navigating the administrative process and we are observing growing interest in ZEVASKYN among patients and physicians. We anticipate these early positive patient experiences to catalyze sustained demand for ZEVASKYN.”

Strong access momentum; driving continued payer engagement and provider readiness

Policies covering ZEVASKYN have been published by all major commercial payers including United Healthcare, Cigna, Aetna, Anthem, and most Blue Cross Blue Shield plans, that account for 80 percent of lives covered by commercial insurance, signaling broad and early market acceptance. ZEVASKYN has also secured coverage across all Medicaid programs. In addition, the Centers for Medicare and Medicaid Services (CMS) has established a permanent Healthcare Common Procedure Coding System (HCPCS) J-code for ZEVASKYN, J3389 (Topical administration, prademagene zamikeracel, per treatment), effective January 1, 2026. A J-code plays a vital role in streamlining the medical billing and reimbursement processes related to drug administration.

About recessive dystrophic epidermolysis bullosa

Recessive dystrophic epidermolysis bullosa (RDEB), a rare blistering disorder without a cure, 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 both copies of 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 ZEVASKYN® (prademagene zamikeracel) gene-modified cellular sheets

ZEVASKYN is the first and only autologous cell sheet-based gene therapy for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB). RDEB is a severe skin disease caused by a defect in both copies of the COL7A1 gene resulting in the inability to produce functional type VII collagen. Without functional type VII collagen and anchoring fibrils, the skin is fragile and blisters easily, leading to wounds that continually open and close, or fail to heal altogether. Patients often have large open wounds that can lead to serious life-threatening complications. ZEVASKYN incorporates the functional type VII collagen-producing COL7A1 gene into a patient’s own skin cells, ex vivo, using a replication-incompetent retroviral vector to produce functional type VII collagen in treated wounds. ZEVASKYN has demonstrated clinically meaningful wound healing and pain reduction with a single surgical application. For more information, visit www.ZEVASKYN.com.

Indication

ZEVASKYN[®] (prademagene zamikeracel) is an autologous cell sheet-based gene therapy indicated for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB).

Important Safety Information

- Serious allergic reactions to ZEVASKYN can occur. Patients should get medical help right away if they experience symptoms like itching, swelling, hives, difficulty breathing, runny nose, watery eyes, or nausea. In rare cases, a severe reaction called anaphylaxis may happen.
- There is a potential risk that treatment with ZEVASKYN may contribute to the development of cancer because of how the therapy works. Patients should be monitored for the rest of their lives to check for any signs of cancer.
- ZEVASKYN is made using human and animal materials. Although these materials are tested before use, the risk of passing on infections cannot be eliminated.
- The most common side effects are pain from the procedure and itching.

This is not a complete list of side effects. Patients should call their care team for medical advice about side effects. Side effects may be reported to Abeona at 1-844-888-2236 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See full [Prescribing Information](#).

About Abeona Therapeutics

Abeona Therapeutics Inc. is a commercial-stage biopharmaceutical company developing cell and gene therapies for serious diseases. Abeona's ZEVASKYN[®] (prademagene zamikeracel) is the first and only autologous cell-based gene therapy for the treatment of wounds in adults and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB). The Company's fully integrated cell and gene therapy cGMP manufacturing facility in Cleveland, Ohio serves as the manufacturing site for ZEVASKYN commercial production. The Company's development portfolio features adeno-associated virus (AAV)-based gene therapies for ophthalmic diseases with high unmet medical need. Abeona's novel, next-generation AAV capsids are being evaluated for a variety of devastating diseases. For more information, visit www.abeonatherapeutics.com.

ZEVASKYN[®], Abeona Assist[®], Abeona Therapeutics[®], and their related logos are trademarks of Abeona Therapeutics Inc.

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," and similar words or 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, our ability to successfully commercialize and market ZEVASKYN, including manufacturing sufficient batches of ZEVASKYN to meet demand; the therapeutic potential of ZEVASKYN; whether the unmet need and market opportunity for ZEVASKYN are consistent with the Company's expectations; continued interest in our rare disease portfolio; the outcome of future meetings with and inspections by the FDA or other regulatory agencies, including any relating to the cGMP manufacturing of ZEVASKYN; our ability to execute on our key business priorities; the impact of any changes in the financial markets and global economic conditions, including those resulting from changes to U.S. or other countries' trade policy, such as current or future tariffs; 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 these 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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