
**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 17, 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))

| <u>Title of Each Class</u> | <u>Trading Symbol</u> | <u>Name of each exchange on which registered</u> |
|---------------------------------------|-----------------------|--|
| Common Stock, \$0.01 par value | ABEO | 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 2.02. Results of Operations and Financial Condition.

On March 17, 2026, Abeona Therapeutics Inc. issued a press release regarding its financial results for the year ended December 31, 2025. The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein.

The information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed “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 deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

| Exhibit No. | Description |
|--------------------|---|
| 99.1 | Press release dated March 17, 2026 |
| 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 17, 2026



Abeona Therapeutics® Reports Full Year 2025 Financial Results and Corporate Updates

- First ZEVASKYN® commercial patient treatment completed in December -

- ZEVASKYN launch momentum building in first quarter 2026 –

- \$191.4M in cash, cash equivalents and short-term investments as of December 31, 2025 -

CLEVELAND, Mar. 17, 2026 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today reported financial results for the full year of 2025 and recent operational progress.

“2026 is about building a steady cadence of biopsies and treatments,” said Vish Seshadri, Chief Executive Officer of Abeona. “We are focused on ensuring every ZEVASKYN patient has a seamless experience throughout their treatment journey. Establishing these commercial foundations will position us to scale-up ZEVASKYN in 2026 and beyond.”

ZEVASKYN (prademagene zamikeracel) updates

- **First ZEVASKYN commercial patient treatment completed in December; launch momentum building in first quarter 2026:** 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 annual manufacturing facility shutdown. Since resuming manufacturing in late January 2026, multiple biopsies have been collected with additional biopsies expected this month. One patient has completed treatment with ZEVASKYN so far in 2026, and other collected biopsies are at various stages in the manufacturing process.
 - **Growing ZEVASKYN treatment experience expected to catalyze further ZEVASKYN demand:** Growing ZEVASKYN treatment experience across the initial Qualified Treatment Center (QTC) network is establishing the institutional workflows and scalable foundation necessary to accelerate patient throughput and streamline the referral-to-treatment timeline. As the RDEB community shares in the positive experiences of the initial ZEVASKYN patients, the Company believes this will continue to catalyze sustained demand for ZEVASKYN.
 - **Abeona expands patient access to ZEVASKYN across Texas and the Gulf Coast region with activation of its newest QTC:** In December, the Company announced activation of The University of Texas Medical Branch (UTMB), in Galveston, Texas, as the fourth QTC for ZEVASKYN. UTMB is a major academic medical center renowned for its expertise in comprehensive complex skin disease and wound care.
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Full Year 2025 Financial Results

Abeona reported total revenue of \$5.8 million for the year ended December 31, 2025. This was comprised of \$3.4 million in license and other revenues and \$2.4 million in net product revenue. License and other revenues were driven by a clinical milestone reached under the October 2020 sublicense agreement with Taysha Gene Therapies for its investigational Rett syndrome gene therapy.

Net product revenue reflects the single patient treatment in December. While net product revenue reflects Medicaid coverage for the patient treated in December, the Company expects average net revenues to normalize over time as the payer mix expands to include commercially insured patients. Cash was received from the December treatment in the first quarter 2026.

Cost of sales for 2025 was \$1.5 million, primarily driven by the first commercial ZEVASKYN treatment in December and costs from an August production batch that was not released due to technical challenges related to the FDA-mandated rapid sterility lot release assay.

Total research and development (R&D) spending for 2025 decreased \$7.6 million to \$26.8 million, compared to \$34.4 million in 2024. This reduction was primarily driven by the April 2025 FDA approval of ZEVASKYN, which resulted in certain production costs being capitalized into inventory and engineering runs that are no longer classified as R&D expense.

Selling, general and administrative (SG&A) expenses for 2025 were \$65.0 million, an increase of \$35.1 million over 2024. This increase primarily reflects Abeona's commercial transition following the April 2025 FDA approval of ZEVASKYN, including \$18.6 million in personnel and stock-based compensation and \$2.3 million in direct commercialization costs. Additionally, certain engineering and training expenses previously classified as R&D were transitioned to SG&A post-approval.

In May 2025, Abeona sold the Rare Pediatric Disease Priority Review Voucher (PRV) awarded following the FDA's approval of ZEVASKYN. The Company received \$155.0 million in gross proceeds from the sale in June 2025, resulting in a \$152.4 million gain net of \$2.6 million in transaction costs.

Net income was \$71.2 million for the year ended December 31, 2025, or \$1.34 per basic and \$1.01 per diluted common share. Net loss in 2024 was \$(63.7) million, or \$(1.55) per basic and diluted common share.

Cash, cash equivalents and short-term investments totaled \$191.4 million as of December 31, 2025.

Conference Call Details

The Company will host a conference call and webcast on Tuesday, March 17, 2026 at 8:30 a.m. ET to discuss its 2025 financial results and corporate progress. To access the call, dial 888-506-0062 (U.S. toll-free) or 973-528-0011 (international) and Entry Code: 977217 five minutes prior to the start of the call. A live, listen-only webcast and archived replay of the call can be accessed on the Investors & Media section of Abeona's website at <https://investors.abeonatherapeutics.com/events>. The archived webcast replay will be available for 30 days following the call.

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," "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, 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; our ability to enroll patients in clinical trials; the outcome of future meetings with and inspections by the FDA or other regulatory agencies, including those relating to preclinical programs and to the cGMP manufacturing of ZEVASKYN; the ability to achieve or obtain necessary regulatory approvals for our pre-clinical programs; 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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ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Income (Loss)
(In thousands, except share and per share amounts)

| | For the years ended December 31, | |
|--|---|--------------------|
| | 2025 | 2024 |
| Revenues: | | |
| Product revenue, net | \$ 2,420 | \$ — |
| License and other revenues | 3,400 | — |
| Total revenues | <u>5,820</u> | <u>—</u> |
| Costs and expenses: | | |
| Cost of sales | 1,532 | — |
| Royalties | 1,893 | — |
| Research and development | 26,812 | 34,360 |
| Selling, general and administrative | 65,031 | 29,851 |
| Total costs and expenses | <u>95,268</u> | <u>64,211</u> |
| Loss from operations | (89,448) | (64,211) |
| Interest income | 5,556 | 4,246 |
| Interest expense | (3,740) | (4,208) |
| Change in fair value of warrant and derivative liabilities | 6,139 | (755) |
| Gain from sale of priority review voucher, net | 152,366 | — |
| Other income, net | 410 | 1,194 |
| Income (loss) before income taxes | 71,283 | (63,734) |
| Income tax (benefit) expense | 100 | — |
| Net income (loss) | <u>\$ 71,183</u> | <u>\$ (63,734)</u> |
| Basic income (loss) per common share | <u>\$ 1.34</u> | <u>\$ (1.55)</u> |
| Dilutive income (loss) per common share | <u>\$ 1.01</u> | <u>\$ (1.55)</u> |
| Weighted average number of common shares outstanding: | | |
| Basic | <u>52,952,917</u> | <u>41,048,206</u> |
| Dilutive | <u>66,135,821</u> | <u>41,048,206</u> |
| Other comprehensive income (loss): | | |
| Change in unrealized gains related to available-for-sale debt securities | 130 | 74 |
| Comprehensive income (loss) | <u>\$ 71,313</u> | <u>\$ (63,660)</u> |

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

| | <u>December 31, 2025</u> | <u>December 31, 2024</u> |
|--|--------------------------|--------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 78,437 | \$ 23,357 |
| Short-term investments | 112,967 | 74,363 |
| Restricted cash | — | 338 |
| Accounts receivable, net | 6,147 | — |
| Inventory | 5,493 | — |
| Other receivables | 568 | 1,652 |
| Prepaid expenses and other current assets | 1,294 | 1,143 |
| Total current assets | <u>204,906</u> | <u>100,853</u> |
| Property and equipment, net | 9,921 | 4,430 |
| Operating lease right-of-use assets | 3,962 | 3,552 |
| Other assets | 781 | 96 |
| Total assets | <u>\$ 219,570</u> | <u>\$ 108,931</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 7,889 | \$ 3,441 |
| Accrued expenses | 8,467 | 6,333 |
| Current portion of long-term debt | 12,222 | 5,926 |
| Current portion of operating lease liability | 864 | 823 |
| Accrued taxes | 126 | — |
| Other current liabilities | 2 | 64 |
| Total current liabilities | <u>29,570</u> | <u>16,587</u> |
| Long-term operating lease liabilities | 4,069 | 3,262 |
| Long-term debt | 7,813 | 13,037 |
| Warrant liabilities | 18,902 | 32,014 |
| Total liabilities | <u>60,354</u> | <u>64,900</u> |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock - \$0.01 par value; authorized 2,000,000 shares; No shares issued and outstanding as of December 31, 2025 and 2024, respectively | — | — |
| Common stock - \$0.01 par value; authorized 200,000,000 shares; 55,043,413 and 45,644,091 shares issued and outstanding as of December 31, 2025 and 2024, respectively | 550 | 457 |
| Additional paid-in capital | 900,603 | 856,824 |
| Accumulated deficit | (742,075) | (813,258) |
| Accumulated other comprehensive loss | 138 | 8 |
| Total stockholders' equity | <u>159,216</u> | <u>44,031</u> |
| Total liabilities and stockholders' equity | <u>\$ 219,570</u> | <u>\$ 108,931</u> |