# 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): June 27, 2025

# 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))

| Title of Each Class | Trading Symbol | Name of each exchange on which registered |
|---|---|---|
| **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 2.01 Completion of Acquisition or Disposition of Assets.**

On June 27, 2025, Abeona Therapeutics Inc. (the "Company") completed the previously disclosed sale (the "Asset Sale") of its Rare Pediatric Disease Priority Review Voucher ("PRV") to the buyer. The Company was awarded the voucher on April 28, 2025, under a U.S. Food and Drug Administration ("FDA") program intended to encourage the development of certain rare pediatric disease product applications. The Company received the PRV upon approval of the Company's biologics license application for ZEVASKYN™ (prademagene zamikeracel).

The Asset Sale was completed pursuant to the terms of an asset purchase agreement dated May 9, 2025 (the "PRV Asset Purchase Agreement"). Pursuant to the PRV Asset Purchase Agreement, the Company received gross proceeds of $155 million from the buyer upon the closing of the Asset Sale.

The foregoing description of the PRV Asset Purchase Agreement does not purport to be complete and is qualified in its entirety by the full text of the PRV Asset Purchase Agreement, a copy of which will be filed with the Company's Quarterly Report on Form 10-Q for the three months ended June 30, 2025.

**Item 2.02 Results of Operations and Financial Condition.**

On July 2, 2025, the Company issued a press release in relation to the Asset Sale, in which the Company announced that as of June 30, 2025, including the net proceeds from the Asset Sale, the Company's unaudited cash, cash equivalents, restricted cash and short-term investments were approximately $225 million. The press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

The information contained in this item, including Exhibit 99.1, is being furnished and 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 filing.

**Item 8.01 Other Events.**

As noted above, on July 2, 2025, the Company announced that as of June 30, 2025, including the net proceeds from the Asset Sale, the Company's unaudited cash, cash equivalents, restricted cash and short-term investments were approximately $225 million.

The foregoing unaudited cash, cash equivalents, restricted cash and short-term investments information provided in this Current Report on Form 8-K is based on preliminary unaudited information and management estimates for the quarter ended June 30, 2025, is not a comprehensive statement of the Company's financial results as of and for the fiscal quarter ended June 30, 2025 or any other period, and is subject to completion of the Company's financial closing procedures. The Company's independent registered public accounting firm has not conducted a review of and does not express an opinion or any other form of assurance with respect to this preliminary estimate.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release dated July 2, 2025, entitled "Abeona Therapeutics® Closes Sale of Rare Pediatric Disease Priority Review Voucher for $155 Million." |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

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**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: July 2, 2025

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**Exhibit 99.1**

**Abeona Therapeutics® Closes Sale of Rare Pediatric Disease Priority Review Voucher for $155 Million**

*Cash resources totaled approximately $225 million as of June 30, 2025*

CLEVELAND, July 2, 2025 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today announced the closing of the sale of its Rare Pediatric Disease Priority Review Voucher (PRV) for gross proceeds of $155 million on June 27, 2025.

Including net proceeds from the sale of the PRV, the Company reported that unaudited cash, cash equivalents, restricted cash and short-term investments as of June 30, 2025 were approximately $225 million.

"We have reached another key milestone: the successful sale of our PRV has closed," said Joe Vazzano, Chief Financial Officer of Abeona. "The PRV proceeds, combined with our existing cash, provides Abeona with robust financial flexibility, ensuring over two years of operating capital for sustained growth without the need for further capital infusion and prior to accounting for ZEVASKYN sales. We anticipate the first ZEVASKYN patient treatment in Q3 2025, with profitability projected for early 2026."

Abeona was awarded the PRV by the U.S. Food and Drug Administration (FDA) in April 2025 in connection with the FDA's approval of ZEVASKYN™ (prademagene zamikeracel), the first and only U.S. approved autologous cell-based gene therapy for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa.

**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 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, our ability to commercialize ZEVASKYN; 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 from the FDA or other regulatory agencies, including those relating to preclinical programs; our ability to obtain necessary regulatory approvals; the impact of any changes in the financial markets or 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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