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): May 9, 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))

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 1.01 Entry into a Material Definitive Agreement

On May 9, 2025, Abeona Therapeutics Inc. (the "Company") entered into an asset purchase agreement (the "PRV Asset Purchase Agreement"), pursuant to which the Company agreed to sell a Rare Pediatric Disease Priority Review Voucher ("PRV") to the buyer. The Company was awarded the voucher by the U.S. Food and Drug Administration ("FDA") on April 28, 2025, upon approval of the Company's biologics license application for ZEVASKYN™ (prademagene zamikeracel). Pursuant to the PRV Asset Purchase Agreement, the buyer agreed to pay the Company $155 million, payable in cash, upon the closing of the sale.

The PRV Asset Purchase Agreement contains customary representations, warranties, covenants, and indemnification provisions subject to certain limitations. The transaction remains subject to customary closing conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

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 8.01 Other Events.

On May 12, 2025, Abeona Therapeutics Inc. issued a press release entitled "Abeona Therapeutics® Enters into Agreement to Sell Priority Review Voucher for $155 Million." 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 May 12, 2025, entitled "Abeona Therapeutics® Enters into Agreement to Sell Priority Review Voucher for $155 Million."
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: May 12, 2025

Exhibit 99.1

Abeona Therapeutics® Enters into Agreement to Sell Priority Review Voucher for $155 Million

CLEVELAND, May 12, 2025 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today announced it has entered into a definitive asset purchase agreement to sell its Rare Pediatric Disease Priority Review Voucher (PRV) for gross proceeds of $155 million upon the closing of the transaction. Abeona was awarded the PRV following the U.S. Food and Drug Administration (FDA) approval of ZEVASKYN™ (prademagene zamikeracel) on April 28, 2025.

"With proceeds from this PRV sale, we have sufficient cash for more than two years of operating expenses without the need for capital infusion and not accounting for ZEVASKYN sales," said Joe Vazzano, Chief Financial Officer of Abeona. "Furthermore, with ZEVASKYN becoming available to treat patients beginning third quarter of 2025, we anticipate becoming profitable in early 2026."

The transaction is subject to customary closing conditions, including expiration of the applicable waiting period under the Hart-Scott Rodino (HSR) Antitrust Improvements Act.

Stifel was lead financial advisor to Abeona on the transaction. Jefferies also served as financial advisor on the transaction.

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 successfully generate commercial sales of ZEVASKYN and generate future revenue; the successful closing of our sale transaction for the 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:

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