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): August 14, 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 2.02. Results of Operations and Financial Condition.

On August 14, 2025, Abeona Therapeutics Inc. issued a press release regarding its financial results for the quarter ended June 30, 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 August 14, 2025
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: August 14, 2025

Exhibit 99.1

Abeona Therapeutics® Reports Second Quarter 2025 Financial Results and Corporate Updates

- Received FDA approval for ZEVASKYN™ (prademagene zamikeracel), the first and only autologous cell-based gene therapy for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB) -

- U.S. launch on track and first ZEVASKYN patient treatment expected in 3Q 2025, momentum building with strong patient interest at qualified treatment centers and referrals, positive insurance coverage established with multiple national and regional payers -

- $226M in cash, cash equivalents, restricted cash and short-term investments as of June 30, 2025, expected to fund operations for over two years before accounting for anticipated ZEVASKYN revenue beginning in 3Q 2025 and projected profitability in 1H 2026 -

CLEVELAND, Aug. 14, 2025 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today reported financial results and business highlights for the second quarter of 2025 and shared recent operational progress.

"ZEVASKYN's launch is demonstrating positive early momentum," said Vish Seshadri, Chief Executive Officer of Abeona. "The first ZEVASKYN patient treatment is on track for the third quarter of 2025 with multiple additional patients identified and advancing through the process to initiate treatment. The enthusiasm from the RDEB community and clinicians, alongside our substantial progress with payer coverage, affirms ZEVASKYN's crucial role in transforming patient care."

Recent Developments

FDA approval and commercial launch of ZEVASKYN

- **FDA approval of first-in-class RDEB therapy:** In April 2025, the U.S. FDA approved ZEVASKYN (prademagene zamikeracel) for the treatment of wounds in adult and pediatric patients with RDEB.
- **ZEVASKYN now available at Qualified Treatment Centers (QTCs):** RDEB patients can access ZEVASKYN at both Ann & Robert H. Lurie Children's Hospital of Chicago and Lucile Packard Children's Hospital Stanford. The Company is on track and expects to activate additional sites in 2025.
- **Strong demand for ZEVASKYN with several patients identified and treatment process initiated:** The first ZEVASKYN patient has been biopsied and treatment is expected in 3Q 2025. Demand for ZEVASKYN continues to grow with more than a dozen patients identified within the two QTCs and several advancing through the administrative process. In addition, more than three dozen patients have already been identified as candidates for ZEVASKYN at referring sites (non-QTCs).
- **Secured broad patient access:** So far, 100% of submitted prior authorization requests have been approved. Among commercial insurers that cover approximately 60% of RDEB lives, positive coverage for ZEVASKYN has been established with multiple large national and regional payers. United Healthcare, the nation's largest payer covering more than 43 million lives or approximately 16% of the U.S. insured population, published a favorable coverage policy for ZEVASKYN consistent with the FDA-approved label without imposing any additional restrictions. Abeona has entered into the National Drug Rebate Agreement (NDRA) with the U.S. Centers for Medicare and Medicaid Services (CMS) to facilitate expedited coverage and reimbursement for ZEVASKYN across all 51 state Medicaid programs and Puerto Rico. Some states have already implemented favorable coverage criteria for ZEVASKYN.

- **Ramping up supply of ZEVASKYN:** Abeona remains on-track to scale-up supply capacity for up to 10 patients per month in mid-2026.
- ***Broadening ZEVASKYN medical awareness: I***n June, *The Lancet*, a respected global medical journal, published results from the pivotal Phase 3 VIITAL™ study (NCT04227106) evaluating the efficacy and safety of ZEVASKYN for the treatment of RDEB wounds.

Other corporate updates

- **Licensing agreement for novel AAV204 capsid for ophthalmology gene therapy:** Beacon Therapeutics exercised its option to license from Abeona the AAV204 capsid for use in potential gene therapies for a range of prevalent and rare retinal diseases.
- **Secured non-dilutive capital:** Abeona closed the sale of its Rare Pediatric Disease priority review voucher (PRV) for gross proceeds of $155 million. Abeona was awarded the PRV upon FDA approval of ZEVASKYN.

Financial Results

Cash, cash equivalents, restricted cash and short-term investments totaled $225.9 million as of June 30, 2025, including net proceeds from the PRV sale. The current cash position, without accounting for anticipated revenue from ZEVASKYN, is expected to be sufficient to fund current and planned operations for over two years.

As Abeona transitions into a commercial organization, its second quarter financial results show the reclassification of certain manufacturing and development costs from research and development (R&D) expense to inventory or selling, general, and administrative (SG&A) expenses.

R&D spending for the three months ended June 30, 2025 was $5.9 million, compared to $9.2 million for the same period of 2024. The reduction in R&D expense was primarily due to costs capitalized into inventory and select costs, such as engineering runs and other production costs, reclassified as SG&A following FDA approval of ZEVASKYN. SG&A expenses were $17.1 million for the three months ended June 30, 2025, compared to $8.6 million for the same period of 2024. In addition to the reclassification of select R&D expense to SG&A, the increase in SG&A reflects increased headcount and professional costs associated with the commercial launch of ZEVASKYN.

Net income was $108.8 million for the second quarter of 2025, or $2.07 per basic and $1.71 per diluted common share, including the gain from the sale of the PRV. Net income in the second quarter of 2024 was $7.4 million, or $0.19 per basic and a net loss of $(0.26) per diluted common share.

Conference Call Details

The Company will host a conference call and webcast on Thursday, August 14, 2025, at 8:30 a.m. ET, to discuss the financial results and corporate progress. To access the call, dial 877-545-0320 (U.S. toll-free) or 973-528-0002 (international) and Entry Code: 829076 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.

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 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; 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 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
Condensed Consolidated Statements of Operations and Comprehensive Income
(In thousands, except share and per share amounts)
(Unaudited)

	For the three months ended June 30,	
	2025	**2024**
Revenues:		
License and other revenues	$ 400	$ —
Expenses:		
Royalties	100	—
Research and development	5,943	9,218
Selling, general and administrative	17,149	8,646
Total expenses	23,192	17,864
Loss from operations	(22,792)	(17,864)
Interest income	1,027	1,191
Interest expense	(957)	(1,072)
Change in fair value of warrant and derivative liabilities	(5,388)	24,927
Gain from sale of priority review voucher, net	152,366	—
Other income	89	224
Income before income taxes	124,345	7,406
Income tax expense	15,512	—
Net income	$ 108,833	$ 7,406
Basic income per common share	$ 2.07	$ 0.19
Dilutive income (loss) per common share	$ 1.71	$ (0.26)
Weighted average number of common shares outstanding:		
Basic	52,524,510	40,010,481
Dilutive	66,640,620	51,226,715
Other comprehensive income:		
Change in unrealized gains related to available-for-sale debt securities	22	50
Comprehensive income	$ 108,855	$ 7,456

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	June 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 163,535	$ 23,357
Short-term investments	61,983	74,363
Restricted cash	338	338
Inventory	2,686	—
Other receivables	1,630	1,652
Prepaid expenses and other current assets	2,090	1,143
Total current assets	232,262	100,853
Property and equipment, net	9,489	4,430
Operating lease right-of-use assets	4,144	3,552
Other assets	338	96
Total assets	$ 246,233	$ 108,931
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,337	$ 3,441
Accrued expenses	5,495	6,333
Current portion of long-term debt	5,556	5,926
Current portion of operating lease liability	537	823
Accrued taxes	15,512	—
Other current liabilities	80	64
Total current liabilities	34,517	16,587
Long-term operating lease liabilities	3,978	3,262
Long-term debt	14,005	13,037
Warrant liabilities	30,157	32,014
Total liabilities	82,657	64,900
Commitments and contingencies		
Stockholders' equity:		
Preferred stock - $0.01 par value; authorized 2,000,000 shares; No shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	—	—
Common stock - $0.01 par value; authorized 200,000,000 shares; 51,248,032 and 45,644,091 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	512	457
Additional paid-in capital	879,563	856,824
Accumulated deficit	(716,454)	(813,258)
Accumulated other comprehensive (income) loss	(45)	8
Total stockholders' equity	163,576	44,031
Total liabilities and stockholders' equity	$ 246,233	$ 108,931