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): April 29, 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 7.01 Regulation FD Disclosure.

Abeona Therapeutics Inc. (the "Company") will host a conference call and webcast with accompanying slides and patient videos today, Tuesday, April 29, 2025, at 8:00 a.m. ET. A copy of the presentation from the conference call and webcast is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

By furnishing the information contained in this Current Report on Form 8-K, the Company makes no admission as to the materiality of any information in this report that is required to be disclosed solely by reason of Regulation FD.

The information furnished pursuant to Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, shall not be considered "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 incorporated by reference into future filings by the Company under the Securities Act of 1933, as amended, or under the Exchange Act, unless the Company expressly sets forth in such future filings that such information is to be considered "filed" or incorporated by reference therein.

The text of the slide entitled "Note regarding forward-looking statements" is incorporated by reference into this Item 7.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Webcast Presentation dated April 29, 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: April 29, 2025

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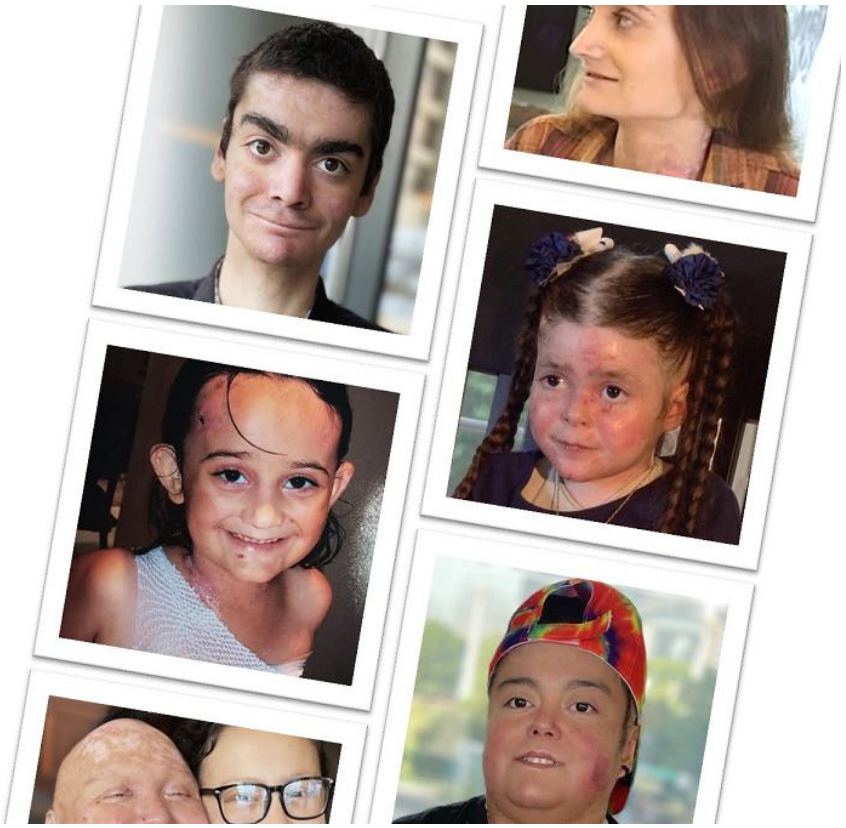

ZEVASKYN™ U.S. FDA Approval

April 29, 2025

Note regarding forward-looking statements

This presentation of Abeona Therapeutics Inc. (the "Company") 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. Such forward looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We have attempted to identify forward-looking statements by such terminology as "may," "will," "believe," "anticipate," "expect," "intend," "hope," and similar 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 and numerous risks and uncertainties, including, but not limited to, potential market opportunities and commercial launch strategies for ZEVASKYN; our ability to monetize our Priority Review Voucher; continued interest in our rare disease portfolio; the timing of studies or study manuscript submissions; our ability to enroll patients in clinical trials; the outcome of future meetings with the FDA or other regulatory agencies, including those relating to our preclinical programs; our ability to achieve or obtain necessary regulatory approvals; the impact of any changes in government, financial markets, and global economic conditions; risks relating to the decline in market price of our common stock after receipt of the Complete Response Letter; 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 forward-looking statements or to update them to reflect events or circumstances occurring after the date of this presentation, whether as a result of new information, future developments, or otherwise, except as required by the federal securities laws.

This presentation may include industry and market data obtained through research, surveys and studies conducted by third parties and industry publications. We have not independently verified any such market and industry data from third-party sources. This presentation is provided for discussion purposes only and may not be relied upon as legal or investment advice, nor is it intended to be inclusive of all the risks and uncertainties that should be considered.

This presentation does not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act.

Readers are advised that the financial information in this presentation is based on company data available at the time of this presentation and, in certain circumstances, may not have been audited by the company's independent auditors.

Indication & Important Safety Information

Indication

- **ZEVASKYNTM (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.

Please see full Prescribing Information at https://www.abeonatherapeutics.com/ZEVASKYN_Final_PI.pdf .

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Today's speakers

Vish Seshadri
Chief Executive Officer

Madhav Vasanthavada
Chief Commercial Officer and
Head of Business Development

Brian Kevany
Chief Technical Officer &
Chief Scientific Officer

Q&A to follow

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(prademagene zamikeracel)
gene-modified cellular sheets

Welcome & introduction

Vish Seshadri
Chief Executive Officer

NOW FDA APPROVED

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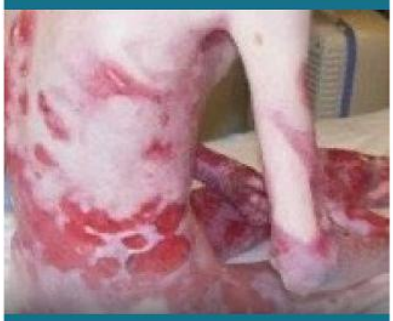
Indicated for the treatment of wounds in **adult and pediatric** patients with recessive dystrophic epidermolysis bullosa (RDEB)

Noelle's Story

RDEB causes significant clinical, economic, and humanistic burden

Clinical



Large, painful chronic wounds; risk of infection, SCC*, extracutaneous manifestations

Economic

Annual cost of RDEB wound care can be as high as ~$1M (DEBRA of America**)

Humanistic

Significant impact on quality of life

Tang, et al. SPD 2020 Poster; *SCC = squamous cell carcinoma; **2021 debra of America Brochure

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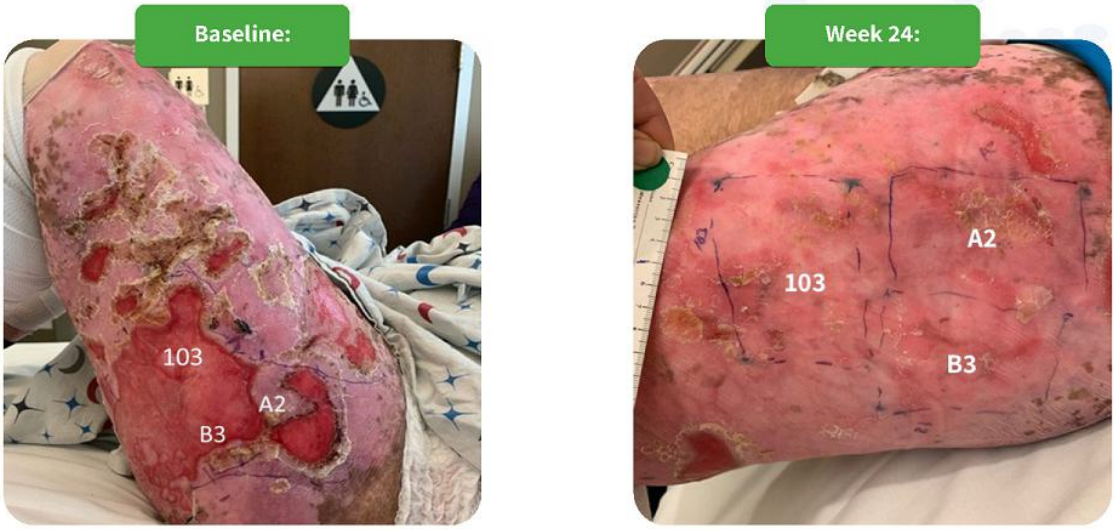
Example RDEB wounds before & after ZEVASKYN treatment



Source: Phase 3 VIITAL study patient; wounds scored as at least 75% healing at week 24; individual results vary
Wound healing scoring was investigator-assessed per predefined criteria.

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Phase 3 VIITAL study clinical experience[1]

Wound healing and pain reduction with a single surgical application – even in tough RDEB wounds

- 81% (35/43) of treated wounds achieved 50% or more healing vs 16% (7/43) of control wounds at week 24

Established safety profile

- Most common adverse reactions (incidence ≥5%) were procedural pain and pruritus
- No grade 3 adverse reactions were reported

- Wounds assessed at baseline had been **open for a median of 5 years** (range of 0.5 to 21 years) prior to study enrollment
- **Multiple, different anatomical positions and locations** were treated
- **Large wound areas** (up to 240 cm^2) were treated

1. Phase 3 VIITAL study: 43 treated wounds vs matched control wounds in 11 patients with RDEB in a multicenter, randomized, intrapatient-controlled study.

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Commercial opportunity & launch preparation

Madhav Vasanthavada
Chief Commercial Officer and Head of Business Development

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Abeona® THERAPEUTICS

Working together to find a cure.

Geovanna's Story

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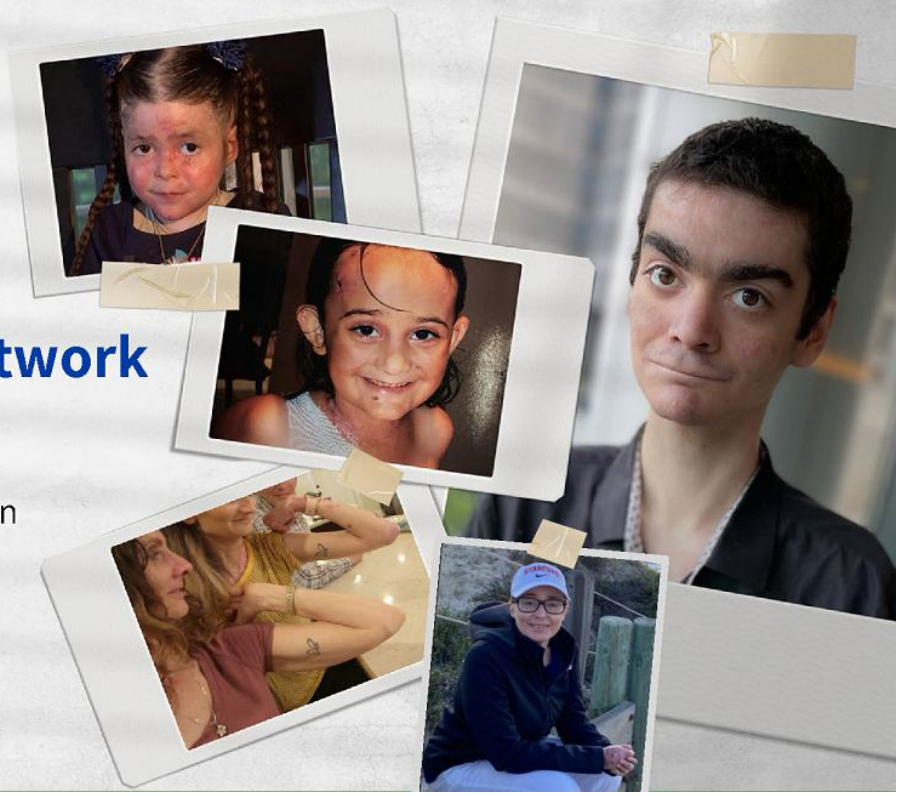

Strong Together Network

- Find Support & Connection
- Hear Real Stories
- Get Helpful Insights

Robust US commercial opportunity

- ~1,500 ZEVASKYN treatment opportunities based on current prevalent pool
- $3.1M WAC reflects demonstrated value with a single treatment application

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- Value and pricing story resonates with large national and regional payers
- Committed to innovative outcomes-based arrangements with private and public payers

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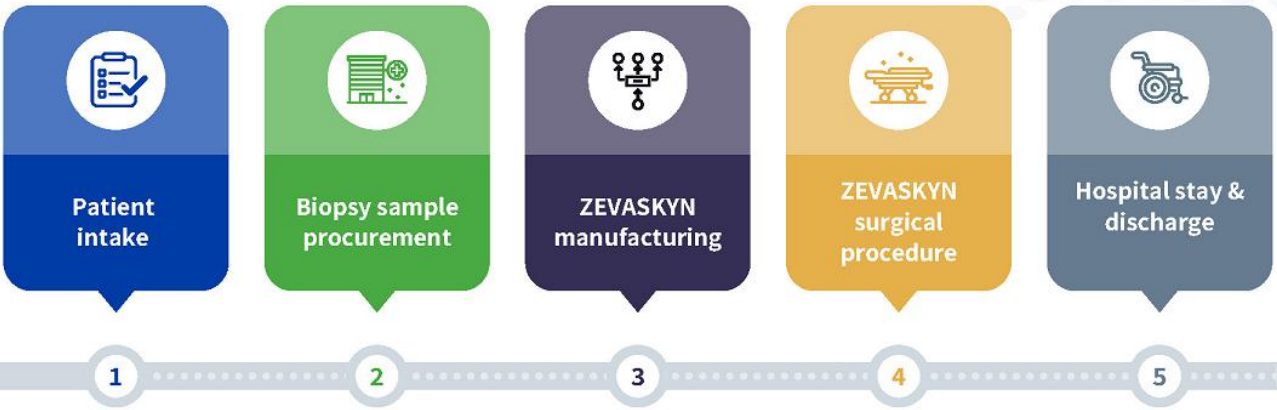
ZEVASKYN patient journey



Abeona THERAPEUTICS

Focused on delivering exceptional ZEVASKYN treatment experience for patients

Patient support hub

Abeona Assist™
Your partner in navigation and support

Personalized support when you need it
(**1-855-ABEONA-1**)

Abeona Assist

Patient-to-patient communication and engagement

Talk to ZEVASKYN patients and caregivers about their experience

Strong Together Network

Learn more about ZEVASKYN

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www.ZEVASKYN.com

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Partnering with well-recognized EB Centers of Excellence (COEs) to drive successful ZEVASKYN launch

Site activation process ongoing:

- First activated qualified treatment center (QTC) anticipated approx 3 mos post approval
- First biopsy anticipated 3Q 2025
- First ZEVASKYN treatment anticipated 3Q 2025

2025 expectation:

- Ensure broad and timely market access
- Activate **5 EB QTCs**
- Treat **10 to 14 patients**

* Pre-approval information exchange

Commercial manufacturing

Brian Kevany

Chief Technical Officer & Chief Scientific Officer

Commercial manufacturing for ZEVASKYN™

GMP Commitment

Annual maintenance of equipment and facility for quality assurance and compliance

Near Term Ramp-Up

Supply ramp-up at current GMP facility to match projected initial demand

Long Term Expansion

Production capacity expansion for ZEVASKYN growth

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"I am very happy. This trial changed my life completely."

Guadalupe, living with RDEB

"The benefit is I saw healing, compared to other treatment, where I didn't see healing before."

Mohamed, living with RDEB

"It was the first time I saw pink skin. Beautifully, beautifully healed skin like I've never seen before in my life. It was totally life changing to see."

Antonio, living with RDEB

"My kids know it was a life altering moment, because then their mom was more available. Their mom was now able to do more things and their mom was there more."

Lara, living with RDEB

"I still would definitely do it again. It gets so many wounds closed and it's been amazing… The amount of time it saves, not having open wounds, not having to do bandages, not having to worry about infections… it makes such a difference."

Noelle, living with RDEB

"I think that the thing that people don't understand with EB is it's all the time... 24/7... and we take for granted so much that our skin stays on our body. But someone with EB does not take that for granted."

Noelle's mother

Questions & Answers

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