

**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): November 3, 2022

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.)

**1330 Avenue of the Americas, 33rd Floor,
New York, NY 10019**

(Address of principal executive offices) (Zip Code)

(646) 813-4712

(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	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") hereby furnishes the Phase 3 VIITAL Study Topline Results Presentation the Company expects to present to analysts and investors on or after November 3, 2022. The Company expects to use the Phase 3 VIITAL Study Topline Results Presentation, in whole or in part, and possibly with modifications, from time to time in connection with presentations to potential investors, strategic partners, industry analysts and others. The Phase 3 VIITAL Study Topline Results Presentation is attached hereto as Exhibit 99.1 and is incorporated by reference herein, and is available under the "Company Information" tab in the "Investors & Media" section of the Company's website, located at www.abeonatherapeutics.com.

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 contained in the Phase 3 VIITAL Study Topline Results Presentation is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission ("SEC") filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, except as may be required by the federal securities laws, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

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.

Item 8.01 Other Events.

On November 3, 2022, the Company issued a press release entitled “Abeona Therapeutics Announces Positive Topline Results with Both Co-Primary Endpoints Met in Pivotal Phase 3 VIITAL™ Study of EB-101.” The full text of the press release is included as Exhibit 99.2 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	Phase 3 VIITAL Study Topline Results Presentation
99.2	Press release dated November 3, 2022
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: November 3, 2022



**Topline results from
EB-101 pivotal phase 3
VIITAL™ study**



Note regarding forward-looking statements

This presentation contains certain statements that may be 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, including statements relating to the product portfolio and pipeline and clinical programs of Abeona Therapeutics Inc. (the "Company"), the market opportunities for all of the Company's products and product candidates, and the Company's goals and objectives. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "potential," "should," "target," "will," or "would" or the negative of these words or other similar terms or expressions. These statements are subject to numerous risks and uncertainties, including but not limited to our financial performance and ability to access the capital markets our ability to find a potential commercialization partner for EB-101; our ability to increase our authorized capital; our ability to fund our operating expenses and capital expenditure requirements for at least the next 12 months given our existing cash, cash equivalents and short-term investments; development of our novel AAV-based gene therapy platform technology; the outcome of any interactions with the U.S. Food and Drug Administration or other regulatory agencies relating to any of our products or product candidates; our ability to manufacture cell and gene therapy products and produce an adequate product supply to support clinical trials and potentially future commercialization; our ability to meet our obligations contained in license agreements to which we are party; as well as risks, uncertainties, and other factors described in "Risk Factors" and elsewhere in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 and other reports filed by the Company with the Securities and Exchange Commission.

This presentation does not constitute an offer or invitation for the sale or purchase of securities or to engage in any other transaction with the Company or its affiliates. The information in this presentation is not targeted at the residents of any particular country or jurisdiction and is not intended for distribution to, or use by, any person in any jurisdiction or country where such distribution or use would be contrary to local laws or regulations. The Company undertakes no obligations to make any revisions to the forward-looking statements contained in this presentation 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 law.

Agenda



Introduction

Vish Seshadri, Chief Executive Officer



Recessive dystrophic epidermolysis bullosa (RDEB) and EB-101

Vish Seshadri, Chief Executive Officer



VIITAL study topline results

Igor Grachev, M.D., Ph.D., Head of Clinical Development



Takeaways for EB-101 and next steps

Vish Seshadri, Chief Executive Officer



Q&A

Large chronic

RDEB wounds are the most painful, hard to treat wounds that inflict the greatest burden on patients & their families

EB-101's unique value proposition

EB-101 is the only investigative therapy targeting **large chronic** wounds, demonstrating **wound healing** and **pain reduction** with multiple years of **durability** after treatment^{1,2}

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1. <https://clinicaltrials.gov/ct2/show/NCT04227106> 2. So et al. Orphanet Journal of Rare Diseases (2022) 17:377

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Positive VIITAL results: EB-101 delivers clinically meaningful wound healing and pain reduction in large chronic RDEB wounds

Statistically significant improvement vs. control at 6 months:

- ≥50% wound healing rate (co-primary endpoint)
- Pain reduction (co-primary endpoint)
- ≥75% wound healing rate (exploratory endpoint)
- Complete wound healing (secondary endpoint)

EB-101 was well-tolerated with no serious treatment-related adverse events observed, consistent with past clinical experience

≥50% wound healing at 6 months:¹

81% vs. 16%
EB-101 treated wounds control untreated wounds

P<0.0001

Mean pain reduction associated with wound dressing changes (using Wong-Baker FACES scale) at 6 months:²

3.07 vs. 0.90
EB-101 treated wounds control untreated wounds

P=0.0002

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1. Two-sided p-value calculated from permutation test using randomized wound pairs (n=43)
2. Two-sided p-value calculated from permutation test using randomized wound pairs (n=42)

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Recessive dystrophic epidermolysis bullosa (RDEB) and EB-101

Vish Seshadri
Chief Executive Officer

Recessive dystrophic epidermolysis bullosa (RDEB) is a painful disease with lifelong burden afflicting thousands of U.S. patients

- Inherited connective tissue disorder with debilitating pain and systemic complications leading to early death
- Primarily characterized by skin blisters and erosions
- Caused by mutations in COL7A1 gene, which encodes type VII collagen
- Estimated 3,850 U.S. patients¹
- Up to 80% of patient's body covered in wounds, leading to:
 - Severe pain and widespread scarring
 - Numerous debilitating and life-threatening systemic complications
 - Inflammation, infections, loss of heat - high metabolic rate and malnutrition
 - 75-90% risk of developing squamous cell carcinoma (SCC)
- Heavy clinical, economic and humanistic burden with no approved treatment or cure

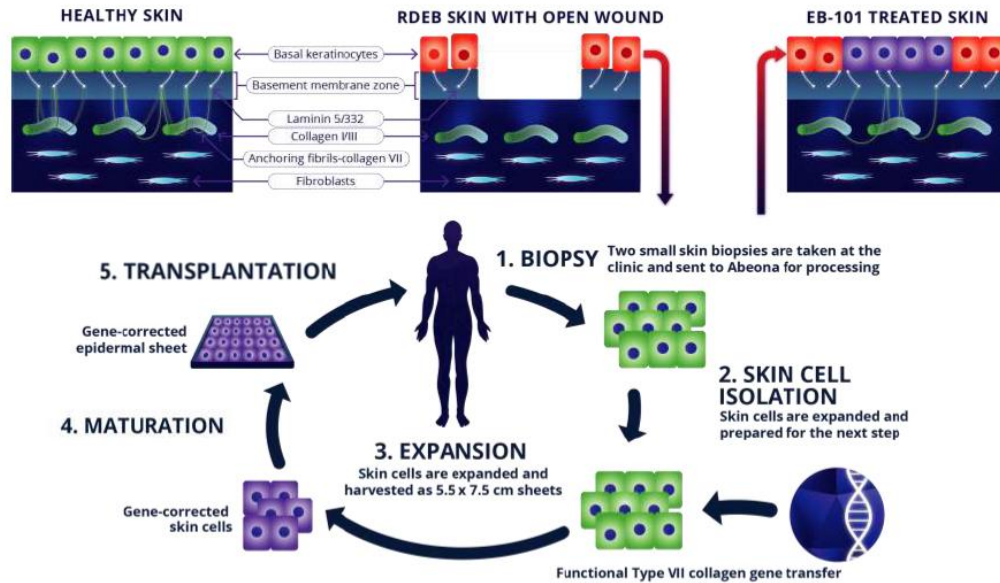


50% of generalized severe patients die before 35

75% die before 40

1. Eichstadt S, Tang JY, Solis DC, Siprashvili Z, Marinkovich MP, Whitehead N, Schu M, Fang F, Erickson SW, Ritchey ME, Colao M, Spratt K, Shaygan A, Ahn MJ, Sarin KY. From Clinical Phenotype to Genotypic Modelling: Incidence and Prevalence of Recessive Dystrophic Epidermolysis Bullosa (RDEB). Clin Cosmet Investig Dermatol. 2019 Dec 24;12:933-942. doi: 10.2147/CCID.S232547. Erratum in: Clin Cosmet Investig Dermatol. 2021 Jun 21;14:679. PMID: 31920360; PMCID: PMC6935313.

EB-101 restores functional collagen VII to patient's own cells



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Phase 3 VIITAL study topline results

Igor Grachev, M.D., Ph.D.
Head of Clinical Development

Phase 3 VIITAL study evaluated EB-101 for wound healing and pain reduction using intra-patient randomization of wounds



FDA-aligned endpoints include $\geq 50\%$ wound healing and mean pain reduction after 6 months

Target Enrollment:

- ~36 wound pairs in 10–15 patients
- Age ≥ 6 years
- Minimum two large chronic* wounds per patient

Randomized wound pairs

EB-101 & Control

Non-randomized wounds**

EB-101 treated, not included in primary analysis

Co-Primary Endpoints:

- $\geq 50\%$ wound healing at Week 24***
- Reduction in pain severity (Wong-Baker FACES scale) associated with wound dressing changes at Week 24

Secondary Endpoint:

- Complete wound healing at Week 24***

Select Exploratory Endpoint:

- $\geq 75\%$ wound healing at Week 24***

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*Large = $>20 \text{ cm}^2$ surface area; Chronic = Open for >6 months

** Wounds with no matching control wound

***Week 24 result confirmed at Week 26

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VIITAL study baseline characteristics

patients treated

- 11 patients (every patient biopsied received EB-101 treatment)

large chronic wounds

- 43 treated wounds vs. 43 paired untreated wounds (randomized)
- 14 non-randomized treated wounds

Age (years)

- Mean: 22.5; Range: 6 to 40

Body surface area (BSA) covered by EB-101 per patient (cm^2)

- Randomized treated: Mean (SD): 156.4 (41.8); Range: 80 to 200
- Non-randomized treated: Mean (SD): 80.0 (46.2); Range: 40 to 160

Wound duration (years remained chronically open)

- Randomized treated: Mean (SD): 6.2 years (7.0 years)
- Randomized control: Mean (SD): 6.3 years (6.7 years)
- Non-randomized treated: Mean (SD): 3.8 years (2.6 years)

Pain severity (0-10 scale)

- Randomized treated: Mean (SD): 5.12 (3.13)
- Randomized control: Mean (SD): 4.38 (3.04)
- Non-randomized treated: Mean (SD): 6.62 (3.50)

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Handling of missing data for primary analysis

≥50% wound healing rate

- Wounds with missing wound healing data are considered as “not healed” for the primary analysis
- Four randomized wound pairs from one patient fall into this category

Pain reduction analysis

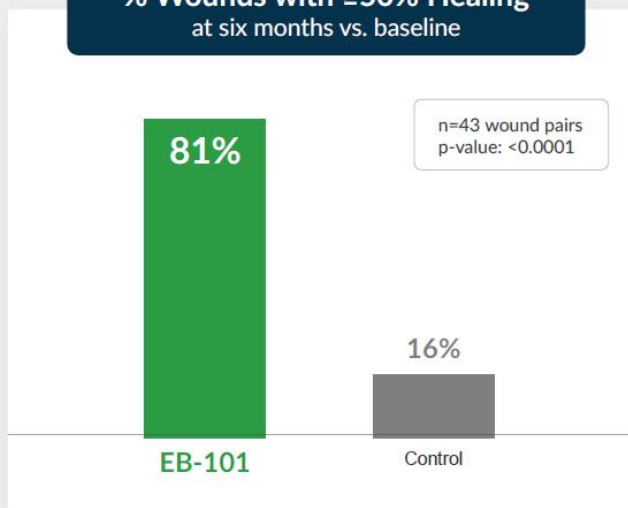
- Wound pairs with missing pain data at baseline are excluded from the primary analysis
- One randomized wound pair falls into this category

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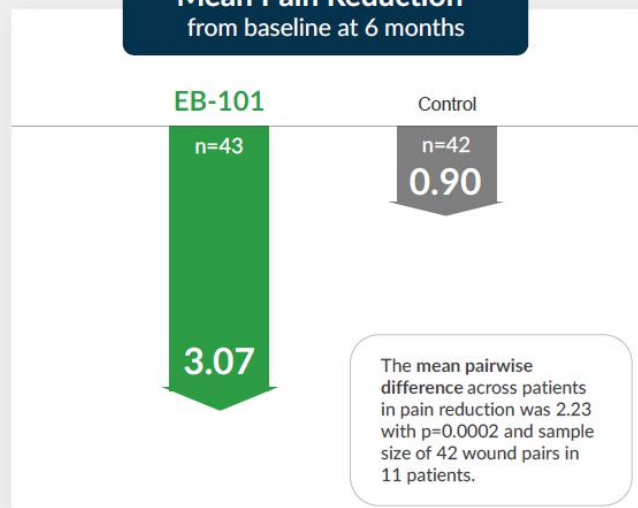
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Significantly more wounds achieved ≥50% healing and showed significant pain reduction with EB-101

% Wounds with ≥50% Healing at six months vs. baseline



Mean Pain Reduction* from baseline at 6 months



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* Pain severity on 0-10 scale with scoring in increments of 2 (ie. 0, 2, 4, 6, 8, 10).

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EB-101 showed greatest pain reduction benefit in wounds with severe baseline pain

Mean Pain Reduction in EB-101 Treated Wounds
(incl Randomized and Non-randomized)
from baseline at 6 months

All treated wounds

n=53

3.51

All treated wounds
with baseline pain ≥ 6

n=27

5.70

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Greater wound healing is associated with greater magnitude in pain reduction

Mean Pain Reduction
from baseline at 6 months

<50% healing

n=8

1.75

$\geq 50\%$ healing

n=35

3.37

$\geq 75\%$ healing

n=28

3.86

Complete healing

n=7

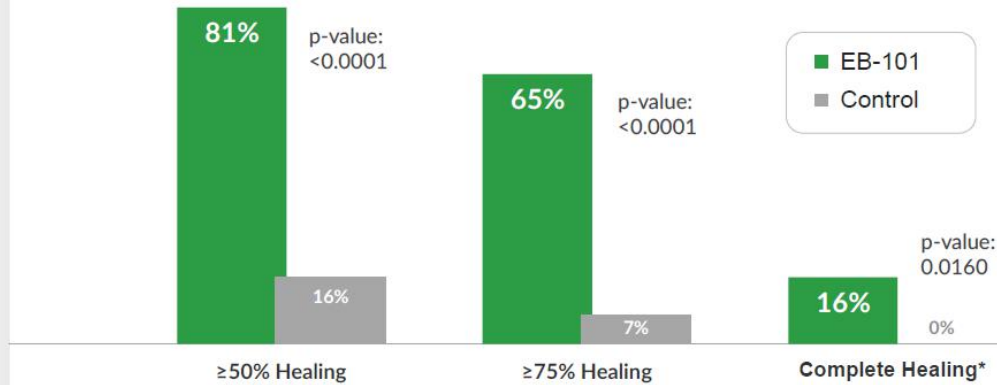
5.14

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EB-101 significantly improved wound healing vs. control across all levels of healing

% Wounds that Met or Exceeded Healing Threshold Indicated at six months vs. baseline (n=43)



16 * Complete wound healing is defined as re-epithelialization with no drainage or erosion and presence of only minor crusting.

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Stringent criteria applied to score wounds as completely healed

- Complete re-epithelialization with no drainage or erosion
- No major crusting as adjudged by investigator (subjective)
 - In VIITAL, with any crusting, inability to verify underlying epithelial formation led to wound scored as not having met complete healing
- No control wounds were scored as completely healed at week 24 (with week 26 confirmation)
- Following slides show examples of wounds that were ≥75% healed but not scored as completely healed

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Example of $\geq 75\%$ healed after EB-101 treatment (upper left thigh)

Baseline

Surgery

Week 24



Tattooed wounds scored as $>75\%$ healed but not complete wound healing at Week 24

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Source: VIITAL patient

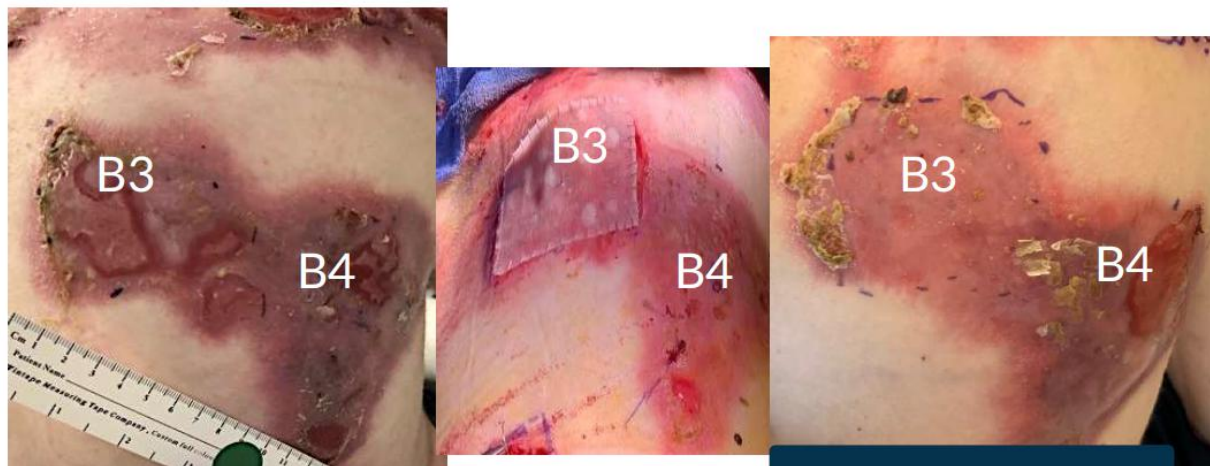
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Example of $\geq 75\%$ healed after EB-101 treatment (right medial and lateral scapula)

Baseline

Surgery

Week 24



B3 scored as $>75\%$ healed but not complete wound healing at Week 24

B3 (treated wound)
B4 (untreated control)

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Source: VIITAL patient

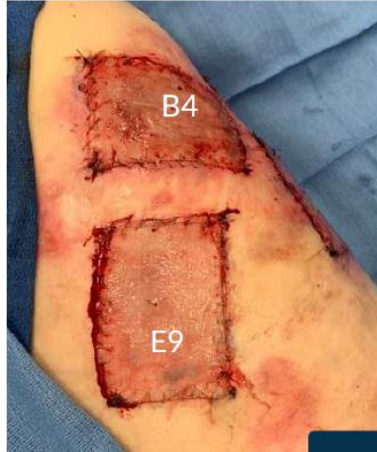
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Examples of $\geq 75\%$ and complete wound healing after EB-101 treatment (upper trunk)

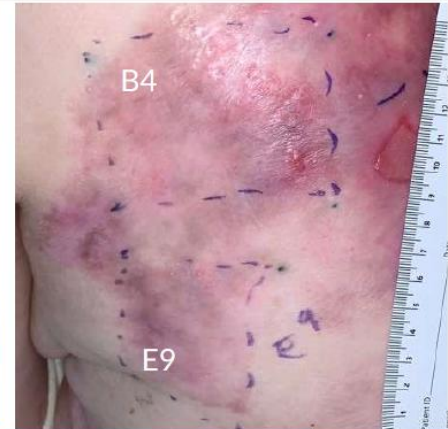
Baseline



Surgery



Week 24



B4 scored as $>75\%$ healed at Week 24
E9 scored as complete wound healing at Week 24

B4 (treated wound)
E9 (treated wound)

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Source: VIITAL patient

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EB-101 was shown to be well tolerated in VIITAL, consistent with past clinical trial experience

- There were **no treatment-related serious adverse events (SAEs)** reported and no safety signal observed in the VIITAL study nor in the duration of the clinical development program. Two subjects (2/11, 18.2%) reported at least one serious adverse event (SAE) unrelated to EB-101.
- No deaths, **no instances of positive replication-competent retrovirus (RCR)** results and **no systemic immunologic responses** were reported during the study, as well as **no SCC at treatment sites** after application of EB-101 treatment.
- Four subjects (4/11, 36.4%) reported related treatment emergent adverse events (TEAEs), including procedural pain, muscle spasms and pruritis.
- Infections not related to EB-101 were observed in 8 subjects (72.7%).
- Wound related TEAEs were reported in 9/100 (9.0%) wounds.

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Takeaways for EB-101 and next steps

Vish Seshadri
Chief Executive Officer

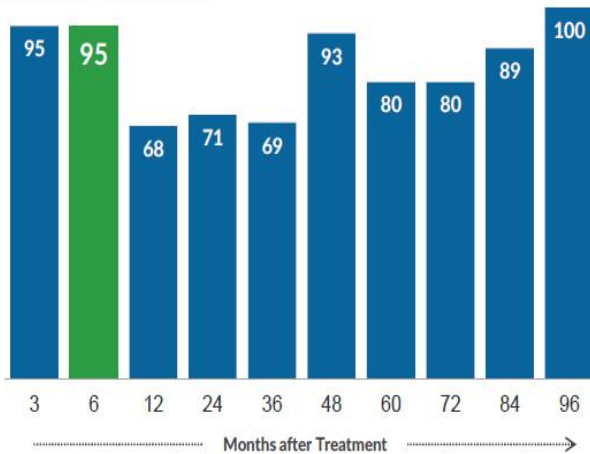
Positive VIITAL results reinforce EB-101 value proposition

- ✓ Statistically significant and clinically meaningful results across endpoints in VIITAL
 - Wound healing by investigator assessment at all levels vs. control
 - Pain reduction reported by patient vs. control
- ✓ More pronounced pain reduction for wounds with severe baseline pain
- ✓ No serious treatment-related adverse events observed, consistent with past clinical experience
- ✓ Further details with additional exploratory endpoints will be presented at a future scientific meeting
- ✓ VIITAL results along with the Phase 1/2a long term follow-up results¹ form the basis for the value proposition of EB-101 with potential for durable wound healing and pain reduction with a one-time treatment

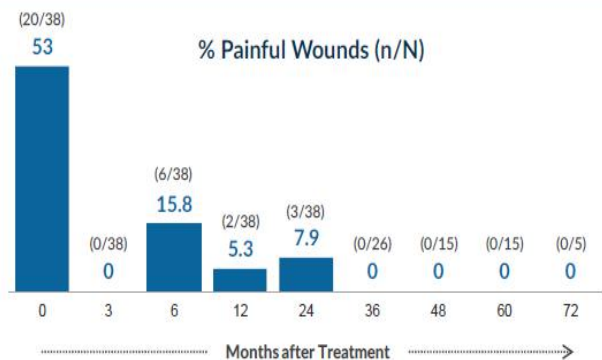
Phase 1/2a data complements VIITAL with evidence of multi-year wound healing and pain reduction after EB-101

% of Wounds with ≥50% Healing

6-month timepoint agreed with FDA for efficacy primary endpoints



Overall Wound Pain: Relief Associated with EB-101



Key Findings from Phase 1 / 2 Study

- Average surface area healed per patient: >130 cm² and >120 cm² at 3 and 6 months, respectively
- Evidence for healing of extremely large wounds (up to 400 cm²) that were open for 16+ years
- Considerable reduction in wound burden at mean 5.9 years follow-up
- Long-term symptomatic relief, including reduction in pain

EB-101

Anticipated Next Steps

Regulatory

- BLA filing in 2Q 2023
- Application for Priority Review Voucher at time of BLA filing
- Potential BLA approval in 1Q 2024

Commercial Launch

- Initiate launch preparation activities in 1Q 2023 while continuing to explore partnership opportunities



Q&A



Abeona Therapeutics Announces Positive Topline Results with Both Co-Primary Endpoints Met in Pivotal Phase 3 VIITAL™ Study of EB-101

Co-primary endpoint measuring $\geq 50\%$ wound healing, other endpoints measuring $\geq 75\%$ and complete wound healing at six months all met

Co-primary endpoint measuring pain reduction at six months met; greater magnitude of pain reduction benefit was observed in post-hoc analysis of EB-101 treated wounds with severe baseline pain

EB-101 was well-tolerated with no serious treatment-related adverse events, consistent with past clinical experience

Plans to submit Biologics License Application (BLA) to U.S. FDA

Conference call on November 3, 2022 at 8:30 a.m. EDT

NEW YORK and CLEVELAND, November 3, 2022 – Abeona Therapeutics Inc. (Nasdaq: ABEO) today announced positive topline data from its pivotal Phase 3 VIITAL study assessing the safety and efficacy of EB-101 for the treatment of patients with recessive dystrophic epidermolysis bullosa (RDEB). The VIITAL study met its two co-primary efficacy endpoints demonstrating statistically significant, clinically meaningful improvements in wound healing and pain reduction in large chronic RDEB wounds.

“We are very pleased with the topline results from our pivotal VIITAL study, which reinforce the strong value proposition of EB-101 as a potential one-time therapy to both significantly improve wound healing and reduce pain for the most disabling, challenging to treat wounds in patients with RDEB,” said Vish Seshadri, Chief Executive Officer of Abeona. “The VIITAL study is differentiated from any other pivotal study in RDEB by the co-primary endpoint measuring patient-reported pain. We believe the significant result in this endpoint supports EB-101’s potential for improving the daily life of RDEB patients. Based on the efficacy and safety profile of EB-101 in VIITAL, we are looking forward to sharing the VIITAL study results with the FDA and progressing toward submission of a BLA. We are grateful to the patients, their families, caregivers, and the patient advocacy groups for their support of this study, and are also thankful for the clinical investigators, study site personnel, and the entire Abeona team who collectively contributed to this milestone achievement.”

Summary of Topline Results: All Evaluated Endpoints Successfully Achieved

The pivotal Phase 3 VIITAL study evaluated the efficacy, safety and tolerability of EB-101 in 43 large chronic wound pairs in 11 subjects with RDEB. The large chronic wounds randomized and treated in VIITAL measured greater than 20 cm² of surface area and had remained open for a minimum of six months and a maximum of 21 years (mean 6.2 years). The co-primary endpoints of the study were: 1) the proportion of RDEB wound sites with greater than or equal to 50% healing from baseline, comparing randomized treated with matched untreated (control) wound sites at the six-month timepoint, as determined by direct investigator assessment; and 2) pain reduction associated with wound dressing change assessed by the mean differences in scores of the Wong-Baker FACES scale between randomized treated and matched untreated (control) wounds at the six-month timepoint. The study allowed for wounds not included in the randomized primary efficacy analysis to receive EB-101 treatment (n=14 non-randomized wounds). The tables below summarize the topline primary efficacy results:

- **Wound Healing Endpoints:** EB-101 significantly improved wound healing vs. control at six months

Wound Healing Level from Baseline (investigator assessed)	% Randomized Treated Wounds (n=43)	% Randomized Untreated Control Wounds (n=43)	p-value*
50% or greater (co-primary endpoint)	81.4%	16.3%	<0.0001

* Two-sided p-value calculated from permutation test using randomized wound pairs (n=43 pairs).

Other VIITAL study endpoints measuring proportion of wounds achieving 75% or greater wound healing and complete wound healing at six months also achieved statistical significance.

- **Pain Endpoint:** EB-101 showed significant pain reduction associated with wound dressing changes vs. control at six months

	Randomized Treated Wounds (n=43)	Randomized Untreated Control Wounds (n=42)	p-value**
Mean pain reduction from baseline* (co-primary endpoint)	3.07	0.90	0.0002

* Based on patient reported outcomes assessing pain severity on 0-10 scale in increments of 2 (i.e., 0, 2, 4, 6, 8, 10).

** Two-sided p-value calculated from permutation test using randomized wound pairs (n=42 pairs).

- **Post-Hoc Analysis of Pain Data**

In addition to meeting the co-primary pain endpoint, in a post-hoc analysis of the EB-101 treated severe wounds (baseline pain score of 6 or greater), including randomized and non-randomized (n=27), a mean pain reduction from baseline at six months of 5.70 was observed, as compared to a mean pain reduction of 3.51 for all treated randomized and non-randomized wounds for which pain was evaluated (n=53).

- **Safety Results**

EB-101 was shown to be well-tolerated with no serious treatment-related adverse events observed, consistent with past clinical experience. There were no deaths or instances of positive replication-competent retrovirus (RCR) results, and no systemic immunologic responses were reported during the study, as well as no squamous cell carcinoma (SCC) at treatment sites after application of EB-101. Two subjects reported at least one serious adverse event (SAE) unrelated to EB-101. Four subjects reported related treatment emergent adverse events (TEAEs), including procedural pain, muscle spasms and pruritis. Infections unrelated to EB-101 were observed in eight patients.

Abeona anticipates submitting results from this study, including further details with additional exploratory endpoints and the Week 12 results, for presentation at future medical meetings and for publication in a peer-reviewed journal. The Week 12 results are similar to Week 24 results, achieving statistical significance for pain reduction and wound healing at all levels.

Jean Tang, M.D., Ph.D., Professor of Dermatology, Stanford University School of Medicine and Principal Investigator of the EB-101 pivotal Phase 3 VIITAL study said, “Large chronic RDEB wounds are the toughest to treat and often associated with intense chronic pain that significantly impacts the quality of life of RDEB patients, necessitating frequent use of opioids. In the Phase 3 VIITAL study, EB-101 has been shown to both heal such large chronic wounds and significantly reduce pain. And we continue to see durable clinical benefit of EB-101 with up to eight years of follow-up in our Phase 1/2a study.”

Brett Kopelan, Executive Director, debra of America, and father to Rafi, a 15-year-old with RDEB, said, “I am incredibly enthused to see new clinical evidence of EB-101’s potential to treat the more difficult chronic and large wounds. Our patient community needs options to address not only the healing of wounds but also the chronic pain and the acute treatment related pain of daily wound care associated with these wounds. Today’s standard of care comprises hours of brutal and painful wound care, and EB-101’s promise to be a transformational option for RDEB patients is truly exciting.”

Next Steps

Based on the positive topline results, Abeona intends to submit a Biologics License Application (BLA) for EB-101 to the U.S. Food and Drug Administration (FDA) in the second quarter of 2023. EB-101 has been granted Orphan Drug and Rare Pediatric Disease (RPD) designations by the FDA. Among the benefits of Orphan Drug designation are seven years of market exclusivity following FDA approval, potentially preventing FDA approval of another product deemed to be the same as the approved product for the same indication, waiver of application fees, and tax credits for clinical testing expenses conducted after orphan designation is received. A sponsor who receives an approval for a BLA with RPD designation may qualify for a Priority Review Voucher (PRV), subject to final determination by the FDA. The PRV can be used to receive an expedited review process of a subsequent marketing application for a different product or sold to another company.

Conference Call Details

Abeona Therapeutics will host a conference call and webcast on Thursday, November 3, 2022, at 8:30 a.m. EDT, to discuss the positive topline results from the VIITAL study. To access the call, dial 888-506-0062 (U.S. toll-free) or 973-528-0011 (international) and Entry Code: 844393 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 www.abeonatherapeutics.com. The archived webcast replay will be available for 30 days following the call.

About Recessive Dystrophic Epidermolysis Bullosa

Recessive dystrophic epidermolysis bullosa (RDEB) is a rare connective tissue disorder characterized by severe skin wounds that cause pain and can lead to systemic complications impacting the length and quality of life. People with RDEB have a defect in the COL7A1 gene, leaving them unable to produce functioning type VII collagen, which is necessary to anchor the dermal and epidermal layers of the skin. There is currently no approved treatment for RDEB.

About EB-101

EB-101 is an autologous, engineered cell therapy currently being developed for the treatment of recessive dystrophic epidermolysis bullosa (RDEB), a rare connective tissue disorder without an approved therapy. The EB-101 VIITAL™ study is a randomized clinical trial with target enrollment of at least 10 to 15 RDEB patients with approximately 36 large, chronic wound sites treated in total. Treatment with EB-101 involves using gene transfer to deliver the COL7A1 gene into a patient’s own skin cells (keratinocytes and its progenitors) and transplanting those cells back to the patient. EB-101 is being investigated for its ability to enable normal Type VII collagen expression and to facilitate wound healing. The U.S. FDA has granted Rare Pediatric Disease designation for EB-101. Abeona produces EB-101 for the VIITAL study at its fully integrated gene and cell therapy manufacturing facility in Cleveland, Ohio. EB-101 is an investigational product not yet approved by the FDA.

About Abeona Therapeutics

Abeona Therapeutics Inc. is a clinical-stage biopharmaceutical company developing cell and gene therapies for serious diseases. Abeona’s lead clinical program is EB-101, its investigational autologous, engineered cell therapy currently in development for recessive dystrophic epidermolysis bullosa. The Company’s development portfolio also features 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. Abeona’s fully integrated cell and gene therapy cGMP manufacturing facility produces EB-101 for the pivotal Phase 3 VIITAL™ study and is capable of clinical and potential commercial production of AAV-based gene therapies. 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,” 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, numerous risks and uncertainties, including but not limited to, our ability to continue as a going concern; the timing and outcome of our Biologics License Application submission to the FDA for EB-101; continued interest in our rare disease portfolio; our ability to enroll patients in clinical trials; the outcome of any future meetings with the FDA or other regulatory agencies; the ability to achieve or obtain necessary regulatory approvals; the impact of 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 other 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.

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