May 15, 2025

# Abeona Therapeutics® Reports First Quarter 2025 Financial Results and Corporate Updates

*- Received approval by U.S. Food and Drug Administration (FDA) 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 of ZEVASKYN underway with activation of first qualified treatment center (QTC) -*

*- Entered into sales agreement for priority review voucher (PRV) for $155 million -*

CLEVELAND, May 15, 2025 (GLOBE NEWSWIRE) -- Abeona Therapeutics Inc. (Nasdaq: ABEO) today reported financial results and business highlights for the first quarter of 2025 and shared recent operational progress.

“ZEVASKYN's approval just a few weeks ago is a landmark achievement for recessive dystrophic epidermolysis bullosa patients and signifies Abeona's transition to a commercial-stage cell and gene therapy company,” said Vish Seshadri, Chief Executive Officer of Abeona. “We are rapidly advancing the launch of ZEVASKYN and building positive momentum. Patients can now start their treatment journey with Lurie Children's activated as our initial treatment center ready to identify patients and our scheduling system is operational. In addition, we are collecting patient registrations through our patient support program, Abeona Assist™, and have entered into agreements with commercial payer groups ensuring broad access to ZEVASKYN.”

**Recent Developments**

*ZEVASKYN FDA approval, commercial launch progress and new data*

- **FDA approval of first-in-class RDEB therapy:** On April 28, 2025, the U.S. FDA approved ZEVASKYN (prademagene zamikeracel) gene-modified cellular sheets, also known as pz-cel, as the first and only autologous cell-based gene therapy for the treatment of wounds in adult and pediatric patients with RDEB. There is no cure for RDEB and ZEVASKYN is the only FDA-approved product to treat RDEB wounds with a single application.
- **Activation of first ZEVASKYN Qualified Treatment Center (QTC):** Following approval, ZEVASKYN is now commercially available in the U.S. after the activation of Ann & Robert H. Lurie Children’s Hospital of Chicago, a top-ranked hospital, as the first of five QTCs for ZEVASKYN. The first patient is expected to be treated in the third

quarter of 2025. Abeona expects to activate all five QTCs by the end of 2025.

- **High interest from patients and caregivers:** Since approval, approximately 30 patients and caregivers have started registering in the Abeona Assist patient services program.
- **Increasing enthusiasm from healthcare professionals:** New data from two posters were presented at the 2025 Society for Investigative Dermatology (SID) Annual Meeting. One poster presentation details the potential progenitor cell populations within ZEVASKYN that may contribute to long-term wound closure and persistent COL7A1 expression observed after a single treatment. A second poster presentation details the absence of insertional oncogenesis and replication competent retrovirus in clinical and pre-clinical experience with ZEVASKYN.
- **Securing broad patient access:** Abeona has executed value-based agreements with several commercial payer groups representing dozens of downstream plans and approximately 100 million commercially-insured lives. In addition, Abeona is in active discussions with multiple commercial and government payers to further expand ZEVASKYN access to eligible patients in the U.S.

*Key corporate updates*

- **Secured non-dilutive capital:** Abeona entered into a definitive asset purchase agreement to sell its Rare Pediatric Disease PRV for gross proceeds of $155 million upon the closing of the transaction. Abeona was awarded the PRV following the FDA approval of ZEVASKYN.

“The proceeds from our PRV sale fully fund our operations for over two years, extending our runway through our projected ZEVASKYN-driven profitability in early 2026,” said Joe Vazzano, Chief Financial Officer of Abeona. “This robust financial footing, achieved even before ZEVASKYN revenues, eliminates the need for additional capital to reach this crucial commercial milestone.”

**Financial Results**

Cash, cash equivalents, restricted cash and short-term investments totaled $84.5 million as of March 31, 2025, before accounting for the proceeds pending the close of the PRV sale. As of December 31, 2024, cash, cash equivalents, restricted cash and short-term investments totaled $98.1 million.

Research and development spending for the three months ended March 31, 2025 was $9.9 million, compared to $7.2 million for the same period of 2024. The increase was primarily due to increased headcount related to scale-up of manufacturing capacity in preparation for the planned ZEVASKYN commercial launch and pre-clinical development work. General and administrative expenses were $9.8 million for the three months ended March 31, 2025, compared to $7.1 million for the same period of 2024. The increase was primarily due to increased headcount associated with the planned launch of ZEVASKYN.

Net loss was $12.0 million for the first quarter of 2025, or $0.24 loss per common share. Net loss in the first quarter of 2024 was $31.6 million, or $1.16 loss per common share.

**Conference Call Details**

The Company will host a conference call and webcast on Thursday, May 15, 2025, at 8:30 a.m. ET, to discuss the financial results and corporate progress. To access the call, dial 877-545-0523 (U.S. toll-free) or 973-528-0016 (international) and Entry Code: 292299 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 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; 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.*

**ABEONA THERAPEUTICS INC. AND SUBSIDIARIES**
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

| | For the three months ended March 31, | |
|---|---|---|
| | **2025** | **2024** |
| Revenues: | | |
| License and other revenues | $ — | $ — |
| Expenses: | | |
| Research and development | 9,941 | 7,207 |
| General and administrative | 9,786 | 7,123 |
| Total expenses | 19,727 | 14,330 |
| Loss from operations | (19,727) | (14,330) |
| Interest income | 1,310 | 843 |
| Interest expense | (998) | (952) |
| Change in fair value of warrant and derivative liabilities | 7,245 | (17,301) |
| Other income | 141 | 162 |
| Net loss | $ (12,029) | $ (31,578) |
| Basic and diluted loss per common share | $ (0.24) | $ (1.16) |
| Weighted average number of common shares outstanding - basic and diluted | 49,778,801 | 27,315,537 |
| Other comprehensive income (loss): | | |
| Change in unrealized gains related to available-for-sale debt securities | (75) | (118) |
| Comprehensive loss | $ (12,104) | $ (31,696) |

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

| | March 31, 2025 | December 31, 2024 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 15,936 | $ 23,357 |
| Short-term investments | 68,219 | 74,363 |
| Restricted cash | 338 | 338 |
| Other receivables | 1,617 | 1,652 |
| Prepaid expenses and other current assets | 2,011 | 1,143 |
| Total current assets | 88,121 | 100,853 |
| Property and equipment, net | 6,947 | 4,430 |
| Operating lease right-of-use assets | 4,239 | 3,552 |
| Other assets | 57 | 96 |
| Total assets | $ 99,364 | $ 108,931 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 5,018 | $ 3,441 |
| Accrued expenses | 3,887 | 6,333 |
| Current portion of long-term debt | 8,148 | 5,926 |
| Current portion of operating lease liability | 613 | 823 |
| Other current liabilities | 317 | 64 |
| Total current liabilities | 17,983 | 16,587 |
| Long-term operating lease liabilities | 4,078 | 3,262 |
| Long-term debt | 11,138 | 13,037 |
| Warrant liabilities | 24,769 | 32,014 |
| Total liabilities | 57,968 | 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 March 31, 2025 and December 31, 2024, respectively | — | — |
| Common stock - $0.01 par value; authorized 200,000,000 shares; 48,953,171 and 45,644,091 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively | 490 | 457 |
| Additional paid-in capital | 866,260 | 856,824 |
| Accumulated deficit | (825,287) | (813,258) |
| Accumulated other comprehensive loss | (67) | 8 |
| Total stockholders' equity | 41,396 | 44,031 |

| | | |
|---|---|---|
| Total liabilities and stockholders' equity | $ 99,364 | $ 108,931 |

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Source: Abeona Therapeutics Inc.