November 12, 2025

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

- First anticipated ZEVASKYN® patient treatment shifted to 4Q 2025 following implementation of optimized release assay -

- Strong and growing patient demand and treatment site network, along with broad market access provide foundation for sustainable commercial success -

- $207.5M in cash, cash equivalents, restricted cash and short-term investments as of September 30, 2025 expected to fund operations for over two years -

CLEVELAND, Nov. 12, 2025 (GLOBE NEWSWIRE) -- Abeona Therapeutics Inc. (Nasdaq: ABEO) today reported financial results and business highlights for the third quarter of 2025 and shared recent operational progress.

“We are scaling the ZEVASKYN launch to meet patient needs,” said Vish Seshadri, Chief Executive Officer of Abeona. “We have strong and growing patient demand. Despite a one-quarter shift in patient starts, we remain steadfast in our 2026 launch goals. Our conviction is built on our expanding treatment site network and powerful momentum from the patient and caregiver community.”

Recent Developments

ZEVASKYN (prademagene zamikeracel)

- **Product release assay optimized; patient treatment anticipated to start in 4Q’25:** During the third quarter, Abeona manufactured a full batch of drug product following patient biopsy collection in August 2025. Although the Company produced bonafide drug product, it could not be released because a rapid sterility assay, mandated by the FDA as a release assay during the final stage of the Biologics License Application (BLA) review, initially yielded a false positive result for sterility. The Company immediately implemented a temporary pause on collecting patient biopsies and worked diligently to optimize the release assay to ensure reliable results and avoid any unnecessary future lot rejections. Upon completion of assay optimization and the necessary regulatory submission for its implementation, Abeona resumed biopsy collection in November 2025. The Company now anticipates commercial product treatment starting in the fourth quarter of 2025.
- **Patients at the first two Qualified Treatment Centers (QTCs) are actively advancing through process for ZEVASKYN treatment; Patient demand growing, reflecting unmet need for ZEVASKYN:** Of the more than a dozen initial patients

identified at the first two QTCs, Abeona has already received ZEVASKYN product order forms (ZPOFs) for 12 patients and they are in the process of scheduling treatments. ZEVASKYN demand has more than doubled at QTCs, with approximately 30 eligible patients now identified.

- **Strategic expansion of the QTC network with three activated centers and others progressing through onboarding:** With the recent activation of Children's Hospital Colorado (CHCO), a highly recognized epidermolysis bullosa (EB) center, there are now three activated ZEVASKYN treatment centers along with Lurie Children's Hospital of Chicago and Lucile Packard Children's Hospital Stanford. Several additional centers across the US are in various stages of site onboarding.
- **Strong early access momentum; focused on driving continued payer engagement and provider readiness:** Following ZEVASKYN approval, there has been a steady cadence of coverage decisions from commercial health plans that account for approximately 60 percent of all RDEB patients. Policies covering ZEVASKYN have been published by all major commercial payers including United Healthcare, Cigna, Aetna, Anthem, and most Blue Cross Blue Shield plans, that account for 80 percent of lives covered by commercial insurance, signaling broad and early market acceptance. In addition, the Centers for Medicare and Medicaid Services (CMS) has established a permanent Healthcare Common Procedure Coding System (HCPCS) J-code for ZEVASKYN, J3389 (Topical administration, prademagene zamikeracel, per treatment), effective January 1, 2026.

Other corporate updates

- **Pipeline program ABO-503 selected for FDA Rare Disease Endpoint Advancement (RDEA) Pilot Program:** ABO-503 gene therapy for X-linked retinoschisis (XLRS) has been selected to participate in the FDA RDEA Pilot Program. As part of the RDEA program, Abeona will have opportunities for enhanced communication and collaboration with the FDA, including frequent advice and regular ad-hoc conversations to accelerate the development and validation of product-specific novel efficacy endpoints for Abeona's XLRS program.
- **Strengthened management team with appointment of Head of Clinical Development & Medical Affairs:** Abeona appointed James A. Gow, MD, MBA, MS, MHCM, as the Senior Vice President, Head of Clinical Development & Medical Affairs. Dr. Gow has over 20 years of industry experience in clinical development and medical affairs and is a recognized expert in gene therapy, especially in ophthalmology.

Financial Results

Cash, cash equivalents, restricted cash and short-term investments totaled $207.5 million as of September 30, 2025. 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.

Research and development (R&D) spending for the three months ended September 30, 2025 was $4.2 million, compared to $8.9 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 selling, general, and administrative (SG&A) following FDA approval of ZEVASKYN. SG&A expenses were $19.3 million for the three months ended September 30, 2025, compared to $6.4 million for the

same period of 2024. In addition to the reclassification of select R&D expenses to SG&A, the increase in SG&A reflects increased headcount and professional costs associated with the commercial launch of ZEVASKYN.

Net loss was $(5.2) million for the third quarter of 2025, or $(0.10) per basic and diluted common share. Net loss in the third quarter of 2024 was $(30.3) million, or $(0.63) per basic and diluted common share.

Conference Call Details

The Company will host a conference call and webcast on Wednesday, November 12, 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: 922481 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 successfully commercialize and market ZEVASKYN, including manufacturing sufficient batches of ZEVASKYN to meet demand; 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, including those resulting from changes to U.S. trade policy, such as current or future tariffs; 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.

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 September 30,		For the nine months ended September 30,	
	2025	**2024**	**2025**	**2024**
Revenues:				
License and other revenues	$ —	$ —	$ 400	$ —
Costs and expenses:				
Cost of sales	$ 488	$ —	$ 488	$ —
Royalties	—	—	100	—
Research and development	4,216	8,941	20,100	25,366
Selling, general and administrative	19,314	6,404	46,249	22,173
Total costs and expenses	24,018	15,345	66,937	47,539
Loss from operations	(24,018)	(15,345)	(66,537)	(47,539)
Interest income	1,672	1,189	4,009	3,223
Interest expense	(901)	(1,102)	(2,856)	(3,126)
Change in fair value of warrant and derivative liabilities	2,760	(15,156)	4,617	(7,530)
Gain from sale of priority review voucher, net	—	—	152,366	—
Other income	129	145	359	531

Income (loss) before income taxes	(20,358)	(30,269)	91,958	(54,441)
Income tax (benefit) expense	(15,197)	—	315	—
Net income (loss)	$ (5,161)	$ (30,269)	$ 91,643	$ (54,441)
Basic income (loss) per common share	$ (0.10)	$ (0.63)	$ 1.76	$ (1.41)
Dilutive income (loss) per common share	$ (0.10)	$ (0.63)	$ 1.35	$ (1.41)
Weighted average number of common shares outstanding:				
Basic	54,242,507	48,081,758	52,198,290	38,504,273
Dilutive	54,242,507	48,081,758	65,780,650	38,504,273
Other comprehensive income (loss):				
Change in unrealized gains related to available-for-sale debt securities	55	50	2	(18)
Comprehensive income (loss)	$ (5,106)	$ (30,219)	$ 91,645	$ (54,459)

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

	September 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 82,884	$ 23,357
Short-term investments	124,233	74,363
Restricted cash	338	338
Inventory	4,850	—
Other receivables	1,616	1,652
Prepaid expenses and other current assets	2,209	1,143
Total current assets	216,130	100,853
Property and equipment, net	10,338	4,430

Operating lease right-of-use assets	4,086	3,552
Other assets	541	96
Total assets	$ 231,095	$ 108,931
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,927	$ 3,441
Accrued expenses	6,888	6,333
Current portion of long-term debt	8,889	5,926
Current portion of operating lease liability	102	823
Accrued taxes	339	—
Other current liabilities	35	64
Total current liabilities	22,180	16,587
Long-term operating lease liabilities	4,254	3,262
Long-term debt	10,862	13,037
Warrant liabilities	22,566	32,014
Total liabilities	59,862	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 September 30, 2025 and December 31, 2024, respectively	—	—
Common stock - $0.01 par value; authorized 200,000,000 shares; 52,400,415 and 45,644,091 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	524	457
Additional paid-in capital	892,314	856,824
Accumulated deficit	(721,615)	(813,258)
Accumulated other comprehensive income	10	8
Total stockholders' equity	171,233	44,031
Total liabilities and stockholders' equity	$ 231,095	$ 108,931

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