

August 8, 2023



# Abeona Therapeutics Reports Second Quarter 2023 Financial Results

*On track for Biologics License Application (BLA) submission in third quarter of 2023*

*Proceeds from \$25 million registered direct offering in July allow initiation of pre-commercial launch activities for EB-101*

*Cash on hand plus proceeds from registered direct offering projected to fund operations into the fourth quarter of 2024*

CLEVELAND, Aug. 08, 2023 (GLOBE NEWSWIRE) -- Abeona Therapeutics Inc. (Nasdaq: ABEO) today reported financial results for the second quarter of 2023 and provided an update on progress toward achieving key corporate objectives.

“Abeona is at a pivotal moment in our history as we are busy finalizing and planning to soon submit the BLA for EB-101 for the treatment of recessive dystrophic epidermolysis bullosa,” said Vish Seshadri, Chief Executive Officer of Abeona. “The recent capital raise allows us to initiate preparations for the commercial launch of EB-101 in the U.S., while also extending our cash runway well beyond the anticipated regulatory approval time for EB-101.”

## **Second Quarter and Recent Progress**

*Strengthened balance sheet, preparing for commercialization of EB-101 in the U.S.*

- In July, Abeona raised \$25 million in a registered direct offering priced at-the-market with select existing investors to primarily fund initiation of the Company’s launch preparations in anticipation of the EB-101 BLA submission and potential approval.

*EB-101 for recessive dystrophic epidermolysis bullosa (RDEB)*

- Completed the Process Performance Qualification manufacturing runs for both retroviral vector (RVV) and EB-101 drug product manufacturing to demonstrate Abeona’s validated process and readiness for commercial production. This data will be included in the chemistry, manufacturing, and controls (CMC) module for the EB-101 BLA submission.
- Generated the additional data requested by the U.S. Food and Drug Administration (FDA) that supports comparability between two RVV sources used in EB-101 clinical studies. This data will be included in the CMC module for the EB-101 BLA submission.
- Submitted the briefing package for the pre-BLA meeting with the FDA in August 2023 for its anticipated BLA submission of EB-101 in the treatment of RDEB. Abeona anticipates submitting the BLA in the third quarter of 2023.
- Additional efficacy and safety data from the pivotal Phase 3 VIITAL study of investigational EB-101 in RDEB were presented at the International Societies for

Investigative Dermatology (ISID) and Society for Pediatric Dermatology (SPD) meetings. The positive top-line data from the VIITAL study were reported in November 2022.

### *Preclinical programs*

- Completed pre-Investigational New Drug Application (IND) meetings with the FDA regarding the preclinical development plans and regulatory requirements to support first-in-human trials for two preclinical gene therapy product candidates from Abeona's adeno-associated virus (AAV) ophthalmology programs. The Company intends to initiate IND-enabling studies in the second half of 2023.
- Presented new preclinical data at the 26<sup>th</sup> Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT), including data on three internally developed preclinical gene therapy product candidates from its AAV ophthalmology programs.

### **Second Quarter Financial Results**

Cash, cash equivalents, restricted cash and short-term investments totaled \$37.1 million as of June 30, 2023, prior to the \$25 million registered direct offering in July 2023, as compared to \$40.7 million as of March 31, 2023. Abeona estimates that its cash and cash equivalents, restricted cash and short-term investments as of June 30, 2023, in addition to the proceeds from the \$25 million registered direct offering in July 2023, are sufficient resources to fund operations into the fourth quarter of 2024.

License and other revenues in the second quarter of 2023 were \$3.5 million, compared to \$1.0 million in the second quarter of 2022. Research and development expenses for the three months ended June 30, 2023 were \$8.5 million, compared to \$6.7 million for the same period of 2022. General and administrative expenses were \$5.0 million for the three months ended June 30, 2023, compared to \$3.5 million for the same period of 2022. Net loss attributable to common shareholders was \$16.7 million for the second quarter of 2023, or \$0.92 loss per common share as compared to a net loss attributable to common shareholders of \$7.9 million, or \$1.36 loss per common share, in the second quarter of 2022.

### **Conference Call Details**

Abeona Therapeutics will host a conference call and webcast today, August 8, 2023, at 8:30 a.m. ET, to discuss its financial results and business update. To access the call, dial 888-506-0062 (U.S. toll-free) or 973-528-0011 (international) and Entry Code: 446072 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](http://www.abeonatherapeutics.com). The archived webcast replay will be available for 30 days following the call.

### **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 produced 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](http://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, 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 future meetings with 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 June 30,		For the six months ended June 30,	
	2023	2022	2023	2022
Revenues:				
License and other revenues	\$ 3,500	\$ 1,000	\$ 3,500	\$ 1,346
Expenses:				
Royalties	1,575	350	1,575	350
Research and development	8,523	6,658	16,564	17,203
General and administrative	5,021	3,460	9,018	7,684
Impairment of licensed technology	—	—	—	1,355

Loss/(gain) on right-of-use lease assets	(1,065)	—	(1,065)	1,561
Impairment of construction-in-progress	—	(1,460)	—	1,792
Total expenses	<u>14,054</u>	<u>9,008</u>	<u>26,092</u>	<u>29,945</u>
Loss from operations	(10,554)	(8,008)	(22,592)	(28,599)
Interest income	417	31	781	38
Interest expense	(103)	(200)	(204)	(401)
Change in fair value of warrant liabilities	(8,629)	4,198	(6,364)	2,945
Other income (expense)	2,215	(118)	2,618	(124)
Net loss	<u>\$ (16,654)</u>	<u>\$ (4,097)</u>	<u>\$ (25,761)</u>	<u>\$ (26,141)</u>
Deemed dividends related to Series A and Series B Convertible Redeemable Preferred Stock	—	(3,782)	—	(3,782)
Net loss attributable to Common Shareholders	<u>\$ (16,654)</u>	<u>\$ (7,879)</u>	<u>\$ (25,761)</u>	<u>\$ (29,923)</u>
Basic and diluted loss per common share	<u>\$ (0.92)</u>	<u>\$ (1.36)</u>	<u>\$ (1.48)</u>	<u>\$ (5.16)</u>
Weighted average number of common shares outstanding – basic and diluted	18,017,874	5,806,473	17,464,026	5,800,822
Other comprehensive income (loss):				
Change in unrealized gains (losses) related to available-for-sale debt securities	(30)	(4)	34	(7)
Comprehensive loss	<u>\$ (16,684)</u>	<u>\$ (7,883)</u>	<u>\$ (25,727)</u>	<u>\$ (29,930)</u>

**ABEONA THERAPEUTICS INC. AND SUBSIDIARIES**

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	<b>December 31,</b>
<b>June 30, 2023</b>	<b>2022</b>
<b>(Unaudited)</b>	

## ASSETS

### Current assets:

Cash and cash equivalents	\$	6,225	\$	14,217
Short-term investments		30,547		37,932
Restricted cash		338		338
Accounts receivable		3,500		—
Other receivables		2,227		188
Prepaid expenses and other current assets		1,201		424
Total current assets		44,038		53,099
Property and equipment, net		4,489		5,741
Right-of-use lease assets		4,915		5,331
Other assets		108		43
Total assets	\$	53,550	\$	64,214

## LIABILITIES AND STOCKHOLDERS' EQUITY

### Current liabilities:

Accounts payable	\$	3,477	\$	1,811
Accrued expenses		4,161		3,991
Current portion of lease liability		1,597		1,773
Other current liabilities		205		204
Total current liabilities		9,440		7,779
Payable to licensor		4,367		4,163
Long-term lease liabilities		4,377		5,854
Warrant liabilities		26,021		19,657
Total liabilities		44,205		37,453

### 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, 2023 and December 31, 2022, respectively

— —

Common stock - \$0.01 par value; authorized 200,000,000 shares; 21,478,157 and 17,719,720 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively

215 177

Additional paid-in capital

730,322 722,049

Accumulated deficit

(721,097) (695,336)

Accumulated other comprehensive loss

(95) (129)

Total stockholders' equity

9,345 26,761

Total liabilities and stockholders' equity

\$ 53,550 \$ 64,214

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Source: Abeona Therapeutics Inc.