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Abeona Therapeutics Inc. (ABEO-NASDAQ)

ABEO: BLA Resubmission in 2H24…

Based on our probability adjusted DCF model that takes into account potential future revenues of pz-cel and selling a PRV, ABEO is valued at $7.50/share. This model is highly dependent upon the continued clinical and commercial success of pz-cel and will be adjusted accordingly based on future results.

Current Price (05/28/24)	$4.06
Valuation	**$7.50**

OUTLOOK

On May 15, 2024, Abeona Therapeutics, Inc. (ABEO) announced financial results for the first quarter of 2024 and provided a business update. The company is planning to resubmit the Biologics License Application (BLA) for pz-cel for the treatment of patients with recessive dystrophic epidermolysis bullosa (RDEB) in the second half of 2024 following the receipt of a Complete Response Letter (CRL) in April 2024. The CRL did not identify any deficiencies related to the clinical efficacy or clinical safety data but did request additional CMC information. The company believes that all of the CMC deficiencies noted in the CRL will be addressed in late Q2 or early Q3 2024. A Type A meeting with the FDA will be conducted in Q3 2024 to ensure the company has addressed the outstanding issues raised in the CRL. Abeona recently closed a $75 million financing that extends the company's cash runway into 2026, which does not take into account any potential revenue from sales of pz-cel or the sale of a PRV, if awarded by the FDA.

SUMMARY DATA

52-Week High	**$8.68**
52-Week Low	**$2.98**
One-Year Return (%)	**29.30**
Beta	**1.59**
Average Daily Volume (sh)	**918,324**
Shares Outstanding (mil)	**41**
Market Capitalization ($mil)	**$167**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**81**
Insider Ownership (%)	**5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**-2.4**
P/E using 2025 Estimate	**-2.8**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	0.0 A	3.5 A	0.0 A	0.0 A	3.5 A
2024	0.0 A	0.0 E	0.0 E	0.0 E	0.0 E
2025					10.0 E
2026					38.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.54 A	-$0.92 A	-$0.48 A	-$0.52 A	-$2.53 A
2024	-$1.16 A	-$0.32 E	-$0.36 E	-$0.39 E	-$2.00 E
2025					-$1.11 E
2026					-$0.58 E

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WHAT'S NEW

Business Update

BLA for Pz-cel to be Resubmitted in 2H24

Abeona Therapeutics, Inc. (ABEO) is currently working on the resubmission of the Biologics License Application (BLA) for pz-cel (prademagene zamikeracel) for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). In April 2024, the company received a Complete Response Letter (CRL) based on the need for additional CMC information before the BLA could be approved. The information requested pertained to validation requirements for certain manufacturing and release testing methods. Importantly, the CRL did not identify any deficiencies or issues with the clinical efficacy or clinical safety data and no new clinical trials were requested. During the quarterly conference call, management noted that is has completed the matrix interference study to validate the replication competent retrovirus (RCR) assay and the container closure integrity testing for the RVV. The company is on track to have all the remaining deficiencies noted in the CRL addressed in late 2Q or early 3Q 2024 and plans to resubmit the BLA in the second half of 2024. Abeona is also planning to conduct a Type A meeting with the FDA in early 3Q 2024 to gain alignment with the agency on the sufficiency of the data to address the CMC issues raised in the CRL.

In regards to commercial preparation, the company is now focused on payer discussions such that patients can have greater and faster access upon approval. Nearly a dozen one-on-one engagements through pre-approval information exchange have taken place thus far. In addition, physician education will be another priority in order to strengthen medical awareness of pz-cel. In support of that, the company recently presented an abstract at the Society for Investigative Dermatology Annual Meeting that included long-term safety data with up to 11 years of follow-up. If approved, pz-cel would have one of the longest durations of safety follow-up for available gene therapies. The company also has an active Phase 3b study that is currently enrolling new and previously treated RDEB patients, with four patients treated to date and all of whom elected to come back as repeat pz-cel patients for their previously untreated wounds. The study also allows patients to have received or are currently receiving recently approved therapies for dystrophic EB. Lastly, the company is continuing to work with the initial network of five to seven high-volume EB centers to refine and strengthen launch readiness.

Financial Update

On May 15, 2024, Abeona announced financial results for the first quarter of 2024. The company did not report any revenue in the first quarter of 2024. R&D expenses in the first quarter of 2024 were $7.2 million compared to $8.0 million for the first quarter of 2023. The decrease was primarily due to decreased clinical and development work for the cell and gene therapy product candidates partially offset by increased salaries and stock compensation expenses. G&A costs in the first quarter of 2024 were $7.1 million compared to $4.0 million for the first quarter of 2023. The increase was primarily due to increased salaries, pre-commercial preparation costs, non-cash stock-based compensation, and professional fees, rent, and recruiting.

Abeona exited the first quarter of 2024 with approximately $62.7 million. On May 7, 2024, the company closed an underwritten offering of 12,285,056 shares and 6,142,656 pre-funded warrants at an offering price of $4.07 per share. Net proceeds were approximately $70.2 million. We estimate the company now has sufficient capital to fund operations into 2026. As of May 10, 2024, the company had approximately 41.2 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 59.4 million.

Conclusion

The company appears to be on track to resubmit the BLA in the second half of 2024. We anticipate an update following the Type A meeting with the FDA early in the third quarter of 2024. Assuming the BLA is submitted in the second half of 2024 that should lead to a PDUFA date in the first half of 2025. We've made a slight adjustment to our model following the company's recent financing, which has reduced our valuation to $7.50.

PROJECTED FINANCIALS

Abeona Therapeutics Inc.	2023 A	Q1 A	Q2 E	Q3 E	Q4 E	2024 E	2025 E	2026 E
EB-101	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$10.0	$38.0
License and other revenues	$3.5	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$3.5**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$10.0**	**$38.0**
Cost of revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.6	$3.8
Gross Margin	*100%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*84%*	*90%*
Royalties	$1.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Research & development	$31.1	$7.2	$8.0	$8.0	$8.0	$31.2	$35.0	$37.0
General & administrative	$19.0	$7.1	$5.0	$7.0	$8.0	$27.1	$28.0	$30.0
Depreciation and Amortization	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Impairment of licensed technology	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Impairment of right-of-use lease asset	($1.1)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Impairment of construction-in-progress	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($47.1)	($14.3)	($13.0)	($15.0)	($16.0)	($58.4)	($53.0)	($29.0)
Operating Margin	*-1346.7%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-530.0%*	*-76.3%*
Non-Operating Expenses (Net)	($7.1)	($17.2)	$0.0	$0.0	$0.0	($17.2)	($2.3)	($2.9)
Pre-Tax Income	($54.2)	($31.6)	($13.0)	($15.0)	($16.0)	($75.6)	($55.3)	($31.9)
Deemed Dividends Series A and B Preferred Stock	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($54.2)**	**($31.6)**	**($13.0)**	**($15.0)**	**($16.0)**	**($75.6)**	**($55.3)**	**($31.9)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.53)**	**($1.16)**	**($0.32)**	**($0.36)**	**($0.39)**	**($2.00)**	**($1.11)**	**($0.58)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	21.4	27.3	41.2	41.3	41.4	37.8	50.0	55.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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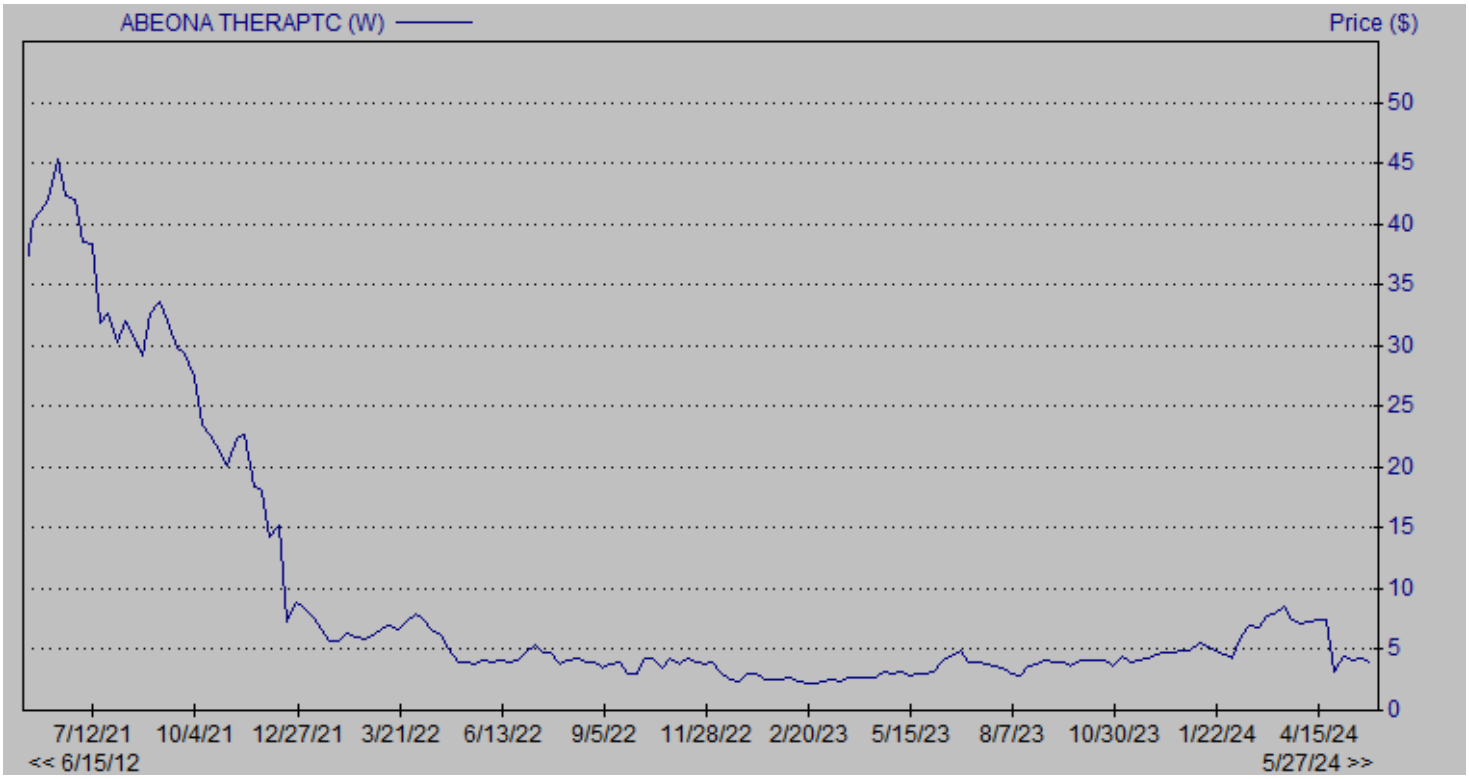

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