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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Abeona Therapeutics Inc.

(ABEO-NASDAQ)

ABEO: Countdown to PDUFA Date of April 29, 2025…

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 $9.50/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 (03/24/25)	$5.15
Valuation	**$9.50**

OUTLOOK

On March 20, 2025, Abeona Therapeutics, Inc. (ABEO) announced financial results for the fourth quarter and full year of 2024 and provided a business update. Preparations continue for the potential approval of prademagene zamikeracel (pz-cel), which has a PDUFA date of April 29, 2025. Abeona disclosed that it received draft prescribing information on the label for pz-cel, which was in-line with company expectations. If approved, the company may be eligible for a Priority Review Voucher (PRV), which have recently been selling for approximately $150 million. In preparation for a potential commercial launch, Abeona is continuing its efforts towards having five qualified treatment centers available, engaging payers to ensure patient access, and continuing patient/physician education.

SUMMARY DATA

52-Week High	**$8.05**
52-Week Low	**$3.17**
One-Year Return (%)	**-32.33**
Beta	**1.79**
Average Daily Volume (sh)	**405,466**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$250**
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 2025 Estimate	**-10.6**
P/E using 2026 Estimate	**-5.9**

Risk Level	**Below Avg.**
Type of Stock	**Small-Growth**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2025	0.0 E	0.0 E	0.0 E	15.0 E	15.0 E
2026					57.0 E
2027					95.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	-$1.16 A	$0.19 A	-$0.63 A	-$0.19 A	-$1.55 A
2025	-$0.34 E	-$0.33 E	-$0.34 E	-$0.04 E	-$1.05 E
2026					-$0.20 E
2027					$0.40 E

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WHAT'S NEW

Business Update

Countdown to Apr. 29, 2025 PDUFA for pz-cel

Abeona Therapeutics, Inc. (ABEO) is continuing preparations for the potential commercial launch of prademagene zamikeracel (pz-cel), which has a PDUFA target action date of April 29, 2025. The company resubmitted the Biologics License Application (BLA) following receipt of a Complete Response Letter (CRL) in 2024 in which the FDA identified the need for additional Chemistry, Manufacturing and Controls (CMC) data pertaining to the validation of certain manufacturing and release testing methods. Abeona aligned with the FDA on the content necessary for resubmission of the BLA and is confident that it met all of the agency's requests. In the CRL, the FDA did not identify any deficiencies related to the clinical efficacy or clinical safety data, there were no requests for additional clinical data or any new clinical trials, and the FDA does not plan on conducting an Advisory Committee meeting regarding the BLA.

In preparation for the potential commercialization of pz-cel, Abeona is in discussions with five epidermolysis bullosa treatment centers to onboard them for pz-cel treatment. The company has targeted these five centers as they are geographically dispersed and each has a large cohort of patients under care. Abeona expects that it will take approximately three months post-approval of pz-cel to onboard the centers. During the conference call, management indicated that it will target up to 10 treatment centers in total over time.

Regarding patient access, the company reported that its payer interactions have been very favorable thus far. Abeona estimates that approximately 60-65% of potential patients are covered by commercial insurance plans, 30-35% are covered by Medicaid, and the remainder are covered by Medicare. Following approval, the company plans to file for the Medicaid Drug Rebate Application and apply for a specific J code for pz-cel such that Medicaid programs will be able to reimburse for pz-cel separate from the bundle payment methodology, which should speed up access and reimbursement.

For commercial manufacturing, the company stated that during the early launch phase of pz-cel there will be capacity for four treatments per month, which will be gradually ramped up to six treatments per month by early 2026 and then reaching the full capacity of the facility (10 treatments per month) by mid-2026. The long term plan is to build out enough manufacturing capacity to support approximately 200 pz-cel treatments per year by the second half of 2027.

We continue to be very encouraged by the progress that the company has made in preparation for the commercial launch of pz-cel and we are confident Abeona is well prepared for a successful launch for pz-cel, if approved.

Financial Update

On March 20, 2025, Abeona announced financial results for 2024. The company did not report any revenue in 2024 compared to $3.5 million in 2023. The revenue in 2023 resulted from a milestone from a sublicense agreement with Taysha Gene Therapies. R&D expenses in 2024 were $34.4 million compared to $31.1 million for 2023. The increase was primarily due to increased salary and related costs along with increased non-cash, stock-based compensation. G&A expenses in 2024 were $29.9 million compared to $19.0 million for 2023. The increase was primarily due to increased salaries, pre-commercial preparation costs, non-cash stock-based compensation, and professional fees.

Abeona exited 2024 with approximately $98.1 million in cash, cash equivalents, short term investments, and restricted cash. We estimate the company now has sufficient capital to fund operations into 2026, which does not take into account any potential revenue from commercial sales of pz-cel, if approved, or proceeds from the sale of a Priority Review Voucher (PRV), if awarded by the FDA. We continue to model for Abeona to sell the PRV for approximately $100 million, however we do note that recently PRVs have sold for $150 million.

As of March 11, 2025, the company had approximately 48.5 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 62.6 million.

Conclusion

We look forward to the FDA's decision on pz-cel, which is set to occur on or before April 29, 2025. We are confident the company has fully addressed all of the FDA's findings in the CRL and the advancements achieved in the pre-commercialization activities further strengthen our confidence in a successful commercial launch for pz-cel. As we await the FDA's decision our valuation remains at $9.50 per share.

PROJECTED FINANCIALS

Abeona Therapeutics Inc.	2024 A	Q1 E	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 E
EB-101	$0.0	$0.0	$0.0	$0.0	$15.0	$15.0	$57.0	$95.0
License and other revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$15.0**	**$15.0**	**$57.0**	**$95.0**
Cost of revenues	$0.0	$0.0	$0.0	$0.0	$1.5	$1.5	$5.7	$9.5
Gross Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*90%*	*90%*	*90%*	*90%*
Royalties	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Research & development	$34.4	$8.5	$8.5	$8.7	$8.9	$34.6	$35.0	$36.0
General & administrative	$29.9	$7.8	$7.9	$8.0	$8.2	$31.9	$33.0	$36.0
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	$0.0	$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	($64.2)	($16.3)	($16.4)	($16.7)	($2.1)	($51.5)	($11.0)	$23.0
Operating Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-14.0%*	*-343.5%*	*-19.3%*	*24.2%*
Non-Operating Expenses (Net)	$0.5	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($63.8)	($16.3)	($16.4)	($16.7)	($2.1)	($51.5)	($11.0)	$23.0
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	**($63.8)**	**($16.3)**	**($16.4)**	**($16.7)**	**($2.1)**	**($51.5)**	**($11.0)**	**$23.0**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.55)**	**($0.34)**	**($0.33)**	**($0.34)**	**($0.04)**	**($1.05)**	**($0.20)**	**$0.40**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	41.0	48.5	49.0	49.5	50.0	49.3	55.0	57.0

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

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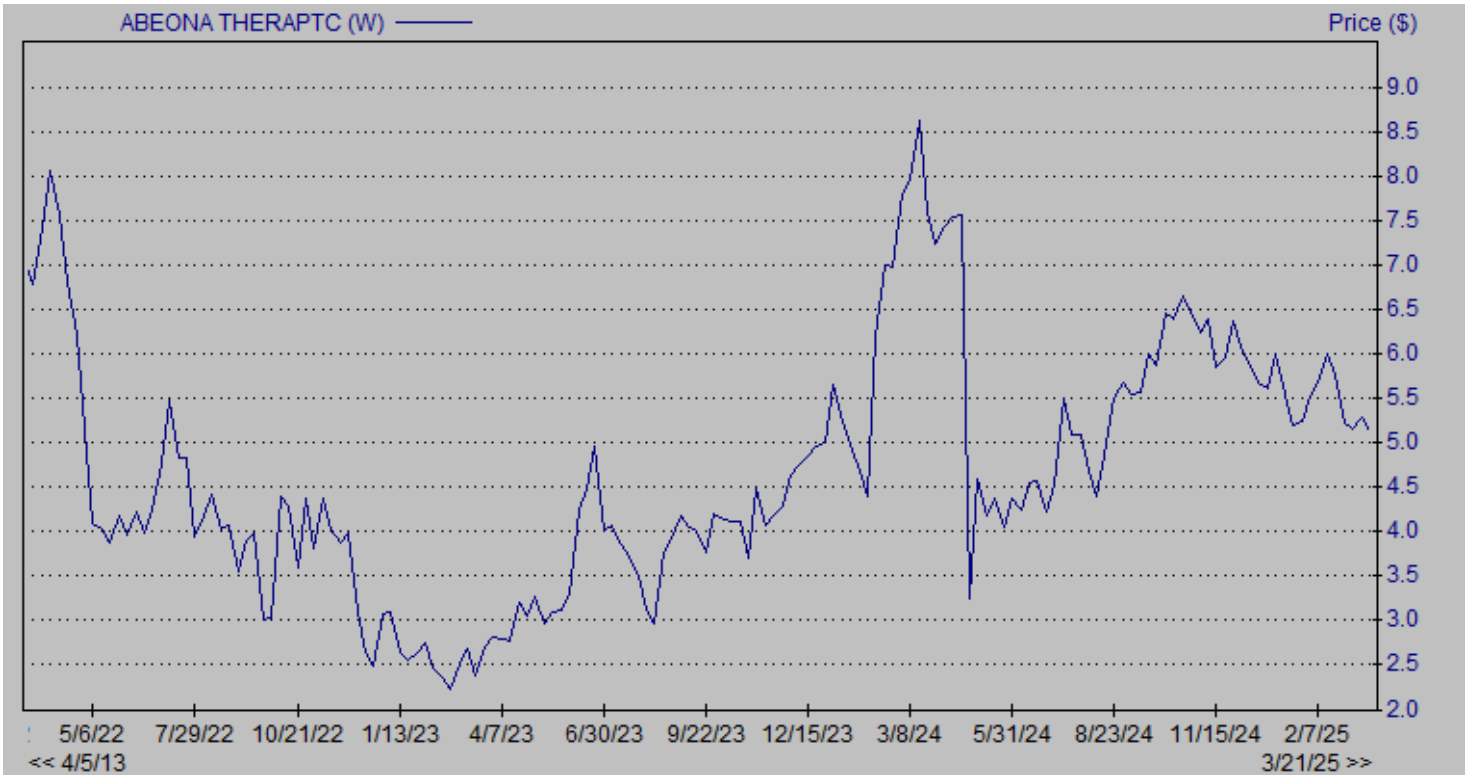

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