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Abeona Therapeutics Inc.

(ABEO-NASDAQ)

ABEO: BLA for Pz-Cel (EB-101) Accepted with Priority Review; PDUFA Date of May 25, 2024…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB-101 and selling a PRV, ABEO is valued at $11.00/share. This model is highly dependent upon the continued clinical and commercial success of EB-101 and will be adjusted accordingly based on future results.

Current Price (11/29/23)	$4.96
Valuation	**$11.00**

OUTLOOK

On November 27, 2023, Abeona Therapeutics, Inc. (ABEO) announced that the U.S. Food and Drug Administration (FDA) has accepted and granted Priority Review for the Biologics License Application (BLA) for pz-cel (prademagene zamikeracel) with a PDUFA action target date of May 25, 2024. The FDA also indicated that it is not currently planning to hold an Advisory Committee meeting to discuss the pz-cel BLA. In anticipation of a potential approval in May 2024, the company has already initiated U.S. commercial launch activities for pz-cel, including discussions with EB treatment sites, payer engagement, and hiring various commercial roles.

SUMMARY DATA

52-Week High	**$5.27**
52-Week Low	**$2.25**
One-Year Return (%)	**30.18**
Beta	**1.18**
Average Daily Volume (sh)	**166,227**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$123**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**44**
Insider Ownership (%)	**3**
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 2023 Estimate	**-2.5**
P/E using 2024 Estimate	**-2.8**

Risk Level	**Above 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)
2022	0.3 A	1.0 A	0.0 A	0.1 A	1.4 A
2023	0.0 A	3.5 A	0.0 A	0.0 E	3.5 E
2024					11.0 E
2025					44.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$3.54 A	-$2.08 A	-$1.48 A	-$0.08 A	-$5.53 A
2023	-$0.54 A	-$0.92 A	-$0.48 A	-$0.51 E	-$2.38 E
2024					-$1.65 E
2025					-$0.67 E

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WHAT'S NEW

Business Update

BLA Accepted with Priority Review; PDUFA Action Date of May 25, 2024

On November 27, 2023, Abeona Therapeutics, Inc. (ABEO) announced that the U.S. Food and Drug Administration (FDA) has accepted with Priority Review the Biologics License Application (BLA) to seek approval for prademagene zamikeracel (pz-cel; formerly EB-101), the company's engineered cell therapy being developed for recessive dystrophic epidermolysis bullosa (RDEB). The FDA has set a PDUFA action date of May 25, 2024 and indicated that it does not currently plan to hold an Advisory Committee meeting to discuss the BLA. The granting of Priority Review is an important prerequisite for the company's eligibility for a Priority Review Voucher (PRV), which we expect to be issued if pz-cel is approved. PRV's have consistently sold over the past few years for approximately $100 million each.

In November 2022, Abeona announced positive topline results from the Phase 3 VIITAL™ study showing pz-cel met the two co-primary endpoints while exhibiting a clean safety and tolerability profile. In May 2023, Abeona announced additional data from the Phase 3 VIITAL™ study, including data showing pz-cel improved would healing in as early as six weeks, a significant reduction in pain for pz-cel-treated wounds compared to control wounds, and numerous quality of life improvements. For a full discussion of the Phase 3 VIITAL data please see our initiation report (here) and our previous update (here).

During the recent third quarter conference call, the company reiterated that it will have the capacity at launch to treat approximately 120 patients per year. Abeona will be onboarding approximately five to seven treatment centers, which are each equipped to care for one to two EB patients per month and are geographically dispersed across the U.S. The company recently conducted an advisory board meeting with eight prominent physicians, at which time there was a discussion concerning patient and caregiver testimonials, the clinical data and care coordination needed for surgical application of pz-cel was discussed, and before and after pictures were shared. The physician's provided very constructive feedback and expressed interest in initiating onboarding discussions.

The company is also working with commercial and government health insurance systems to ensure broad access for all patients. Early feedback has been positive and the company is currently using a "7-digit price point" for peak sales estimates, which the company currently puts at $500 million. Abeona will look to ramp up production over time from the initial 120 patients per year based on the experience with the initial treatment centers and the peak sales estimate was made assuming capacity will expand to approximately 500 patients per year over the next five years.

Conclusion

The acceptance of the BLA and granting of Priority Review is fantastic news for Abeona and brings the company one step closer to becoming a commercial entity. We look forward to updates from the company as the PDUFA date of May 25, 2024 gets closer. With no changes to our model our valuation remains at $11 per share.

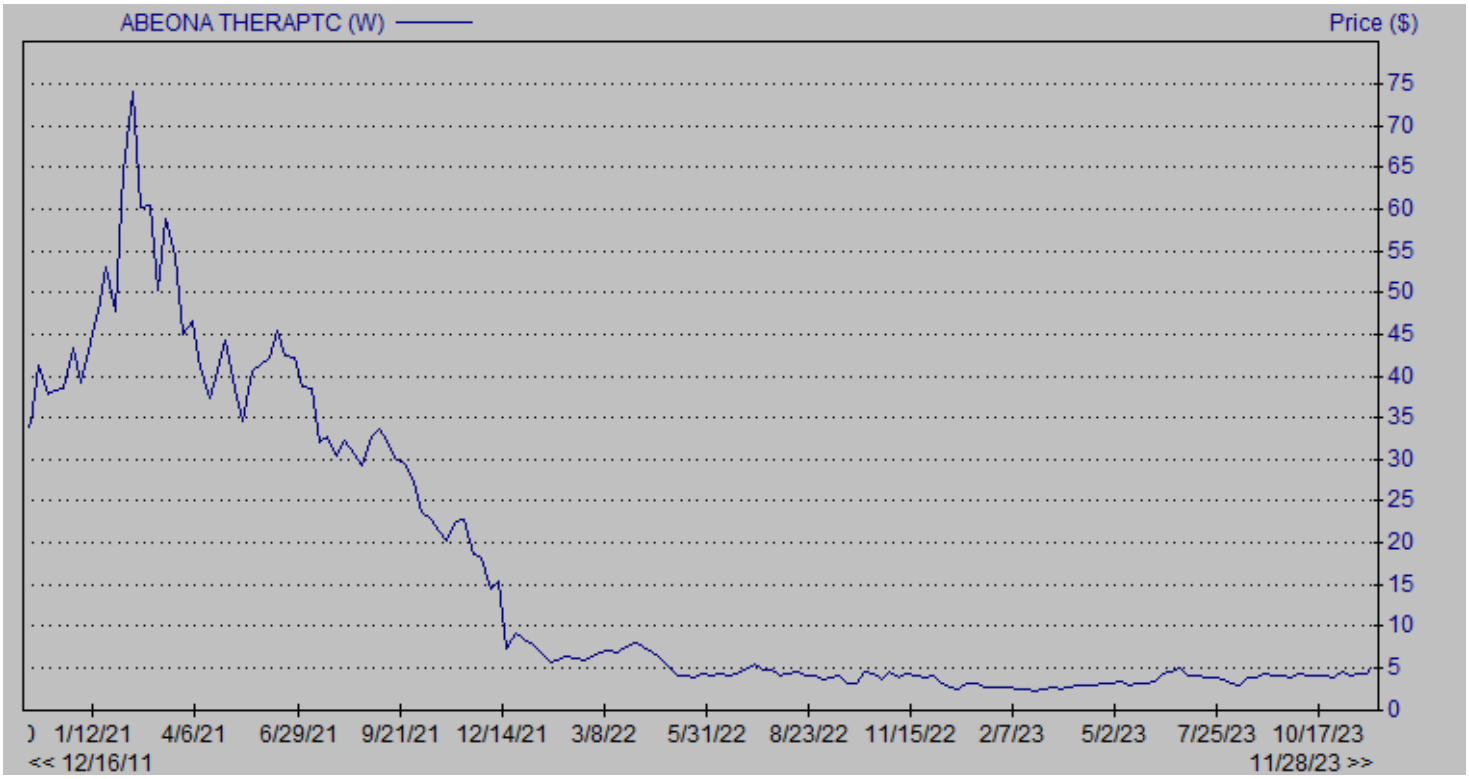
PROJECTED FINANCIALS

Abeona Therapeutics Inc.	2022 A	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 E
EB-101	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$11.0	$44.0
License and other revenues	$1.4	$0.0	$3.5	$0.0	$0.0	$3.5	$0.0	$0.0
Total Revenues	**$1.4**	**$0.0**	**$3.5**	**$0.0**	**$0.0**	**$3.5**	**$11.0**	**$44.0**
Cost of revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0	$4.0
Gross Margin	*100%*	*#DIV/0!*	*100%*	*#DIV/0!*	*#DIV/0!*	*100%*	*91%*	*91%*
Royalties	$0.5	$0.0	$1.6	$0.0	$0.0	$1.6	$0.0	$0.0
Research & development	$29.0	$8.0	$8.5	$7.1	$8.0	$31.7	$35.0	$37.0
General & administrative	$17.3	$4.0	$5.0	$4.2	$4.7	$17.9	$25.0	$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	$1.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Impairment of right-of-use lease asset	$2.5	$0.0	($1.1)	$0.0	$0.0	($1.1)	$0.0	$0.0
Impairment of construction-in-progress	$1.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($50.9)	($12.0)	($10.6)	($11.3)	($12.7)	($46.6)	($49.0)	($23.0)
Operating Margin	*-3600.8%*	*#DIV/0!*	*-301.5%*	*#DIV/0!*	*#DIV/0!*	*-1332.2%*	*-445.5%*	*-52.3%*
Non-Operating Expenses (Net)	$11.2	$2.9	($6.1)	($0.5)	($0.1)	($3.8)	($0.5)	($0.5)
Pre-Tax Income	($39.7)	($9.1)	($16.7)	($11.8)	($12.8)	($50.4)	($49.5)	($23.5)
Deemed Dividends Series A and B Preferred Stock	$3.8	$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	**($43.5)**	**($9.1)**	**($16.7)**	**($11.8)**	**($12.8)**	**($50.4)**	**($49.5)**	**($23.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($5.53)**	**($0.54)**	**($0.92)**	**($0.48)**	**($0.51)**	**($2.38)**	**($1.65)**	**($0.67)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	7.9	16.9	18.0	24.8	25.0	21.2	30.0	35.0

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

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HISTORICAL STOCK PRICE



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