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Abeona Therapeutics Inc. (ABEO-NASDAQ)

ABEO: BLA Submitted for Pz-Cel (EB-101); Increasing Valuation to $11.00…

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 (11/15/23)	$4.25
Valuation	**$11.00**

OUTLOOK

On November 13, 2023, Abeona Therapeutics, Inc. (ABEO) announced financial results for the third quarter of 2023 and provided a business update. The company recently submitted the Biologics License Application (BLA) for prademagene zamikeracel (pz-cel; formerly EB-101) and is awaiting the FDA decision on priority review and acceptance of the BLA. The FDA's decision on BLA acceptance typically occurs approximately 60 days following submission of the BLA, thus the company should learn about the FDA's decision in late November 2023. If accepted with Priority Review, we anticipate potential BLA approval in the second quarter of 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	**$2.25**
One-Year Return (%)	**5.20**
Beta	**1.18**
Average Daily Volume (sh)	**82,400**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$105**
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	**-2.4**
P/E using 2024 Estimate	**-2.4**

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 Submitted; Awaiting FDA Decision on Acceptance and Priority Review

On September 26, 2023, Abeona Therapeutics, Inc. (ABEO) announced that the company had submitted the Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) 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). Abeona requested Priority Review, which if granted would shorten the review time from the usual 10 months to six months from acceptance of the BLA. We anticipate the FDA's decision regarding acceptance of the BLA and whether Priority Review will be granted by the end of November 2023.

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 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.

Financial Update

On November 13, 2023, Abeona announced financial results for the third quarter of 2023. There were no revenues recorded for the third quarter of 2023 or the third quarter of 2022. Royalties for the third quarter of 2023 were $30,000 compared to $0.0 for the third quarter of 2022. The increase was due to royalties owed to the company's licensors.

R&D expenses in the third quarter of 2023 were $7.1 million compared to $5.5 million for the third quarter of 2022. The increase was primarily due to increased clinical costs and salaries. G&A expenses in the third quarter of 2023 were $4.2 million compared to $3.9 million for the third quarter of 2022. The increase was primarily due to increased non-cash stock-based compensation partially offset by a decrease in professional fees and decreased rent and utilities.

Abeona exited the third quarter of 2023 with approximately $54.1 million in cash, cash equivalents, and investments. This was due in part to a $25 million registered direct offering in July 2023. We estimate the company has sufficient capital to fund operations into the fourth quarter of 2024. As of November 1, 2023, the company had approximately 24.8 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 34.9 million.

Conclusion

The BLA filing was an important milestone for Abeona and we look forward to hearing the FDA's decision on Priority Review and acceptance of the BLA. The company appears to be getting everything in order for a successful launch of pz-cel, if approved. As a reminder, approval of pz-cel is expected to include a Priority Review Voucher (PRV), which we estimate the company will be able to sell for $100 million. Following our discussion with management we believe our pricing assumptions may have been too conservative and we have adjusted our price per treatment to $800,000, which has increased our peak sales estimate to $400 million. This has increased our valuation to $11.00 per share.

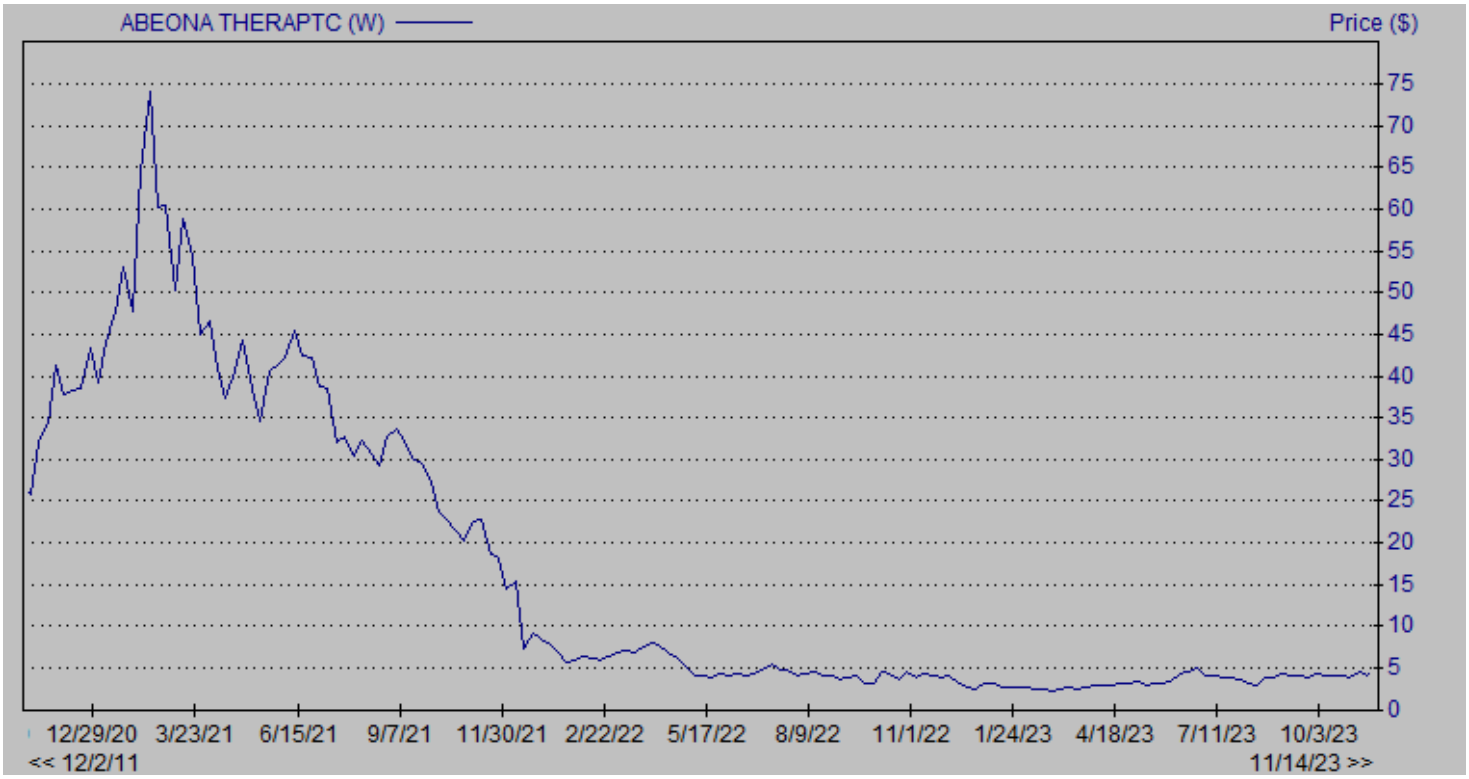
PROJECTED FINANCIALS

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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