Zacks Small-Cap Research
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February 1, 2024
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Abeona Therapeutics Inc.

(ABEO-NASDAQ)

ABEO: FDA BIMO Inspection and BLA Mid-Cycle Review Complete…

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 $12.00/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 (02/01/24)	$4.07
Valuation	**$12.00**

OUTLOOK

On February 1, 2024, Abeona Therapeutics, Inc. (ABEO) announced that both the Bioresearch Monitoring (BIMO) inspection and the Biologics License Application (BLA) mid-cycle review meeting for pz-cel (prademagene zamikeracel) have completed. The BIMO inspection was conducted from January 22, 2024 through January 24, 2024 and the FDA inspector did not issue any observations or FDA Form 483s. The formal report from the FDA will be received at a later date. During the BLA mid-cycle review meeting, the FDA reaffirmed that is does not currently plan to hold an Advisory Committee meeting, that Risk Evaluation and Mitigation Strategies (REMS) are not anticipated, and reconfirmed the PDUFA target action date of May 25, 2024.

SUMMARY DATA

52-Week High	**$5.84**
52-Week Low	**$2.25**
One-Year Return (%)	**53.58**
Beta	**1.33**
Average Daily Volume (sh)	**207,303**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$101**
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	**-2.3**
P/E using 2024 Estimate	**-4.0**

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

FDA Inspection and BLA Mid-Cycle Review Meeting Completed

On February 1, 2024, Abeona Therapeutics, Inc. (ABEO) announced that, as part of the review of the Biologics License Application (BLA) for prademagene zamikeracel (pz-cel; formerly EB-101), the U.S. Food and Drug Administration (FDA) completed both a Bioresearch Monitoring (BIMO) inspection and the BLA mid-cycle review meeting. The BIMO program was established to assure the quality and integrity of data submitted to the agency in support of new product approvals and marketing applications. This is separate from the inspection of the manufacturing facility, which is expected to take place at the end of February 2024.

The BIMO inspection took place from January 22, 2024 to January 24, 2024. The FDA inspector did not issue any observations or FDA Form 483s during the inspection. An FDA Form 483 is issued when an investigator observes condition(s) that in their judgement would indicate that there are "objectionable conditions" that need to be amended. The formal report from the FDA based on the BIMO inspection will be issued at a later date.

Following the BIMO inspection, the company conducted the BLA mid-cycle review meeting with the FDA. During that meeting, the FDA reaffirmed that it does not plan on holding an Advisory Committee meeting for pz-cel. In addition, the FDA noted that Risk Evaluation and Mitigation Strategies (REMS) are not anticipated for pz-cel. Lastly, the FDA reconfirmed the PDUFA target action date of May 24, 2024.

Conclusion

The conclusion of the BIMO inspection at Abeona's headquarters in Cleveland without the issuance of any observations or FDA Form 483s is great news for the company and the FDA remains on track to issue a decision on the BLA for pz-cel on or before the PDUFA date of May 25, 2024. We have advanced our DCF model ahead by one year, which has slightly increased our valuation to $12 per share.

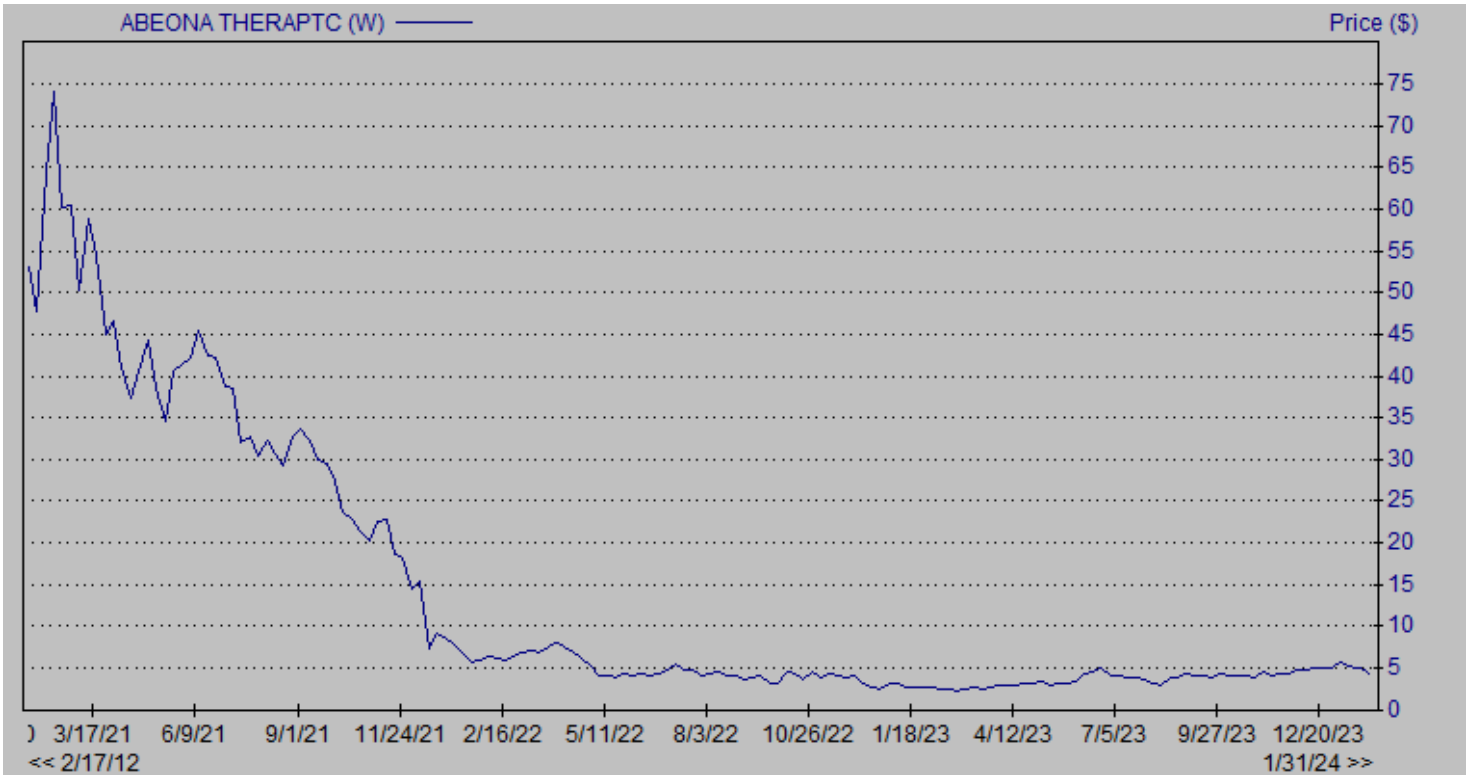
PROJECTED FINANCIALS

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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