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Abeona Therapeutics Inc.

(ABEO-NASDAQ)

ABEO: On Track to File BLA in 3Q23…

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 $8.00/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 (08/11/23)	$2.99
Valuation	**$8.00**

OUTLOOK

On August 8, 2023, Abeona Therapeutics, Inc. (ABEO) announced financial results for the second quarter of 2023 an provided a business update. The company remains on track to file a Biologics License Application (BLA) for EB-101 in the third quarter of 2023. In support of this, the company recently completed multiple CMC activities required for BLA submission. Abeona submitted the briefing package for the pre-BLA meeting with the FDA in August 2023. A BLA submission in the third quarter of 2023 could lead to approval for EB-101 in the first half of 2023. The company also recently completed a $25 million registered direct offering to allow for initiation of pre-commercial launch activities. With the current cash position, we estimate that Abeona has sufficient capital to fund operations into the fourth quarter of 2024.

SUMMARY DATA

52-Week High	**$5.65**
52-Week Low	**$2.25**
One-Year Return (%)	**-35.84**
Beta	**1.35**
Average Daily Volume (sh)	**133,629**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$56**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**40**
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	**-1.4**
P/E using 2024 Estimate	**-1.4**

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 E	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	-$0.51 E	-$0.51 E	-$2.42 E
2024					-$1.65 E
2025					-$0.67 E

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WHAT'S NEW

Business Update

BLA Filing for EB-101 on Track for 3Q23

Abeona Therapeutics, Inc. (ABEO) is developing EB-101, an autologous cell therapy for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). In November 2022, Abeona announced positive topline results from the Phase 3 VIITAL™ study showing EB-101 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 EB-101 improved would healing in as early as six weeks, a significant reduction in pain for EB-101-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 second quarter conference call, Abeona's management indicated that the company has completed the process performance qualification manufacturing runs for both the retroviral vector (RVV) and EB-101 drug product. These manufacturing runs were designed to show that the manufacturing process for EB-101 is robust and ready for commercial production. In addition, the FDA had requested additional data supporting the comparability between the two RVV sources used in EB-101 clinical studies. Both of those sets of data will be included in the chemistry, manufacturing, and controls (CMC) module for the BLA submission. Abeona has submitted the briefing package for the pre-BLA meeting with the FDA in August 2023. This should set the company up for filing the BLA in the third quarter of 2023.

Financial Update

On August 8, 2023, Abeona announced financial results for the second quarter of 2023. The company reported $3.5 million in license and other revenues in the second quarter of 2022 compared to $1.0 million for the second quarter of 2022. The revenue in both periods resulted from clinical milestones achieved under a sublicense agreement with Taysha Gene Therapies in October 2020 relating to an investigational AAV-based gene therapy for Rett syndrome. Royalties for the second quarter of 2023 were $1.6 million compared to $0.4 million for the second quarter of 2022. The increase was due to royalties the company owed to its licensors resulting from the milestone due from Taysha related to Rett syndrome.

R&D expenses in the second quarter of 2023 were $8.5 million compared to $6.7 million for the second quarter of 2022. The increase was primarily due to increased clinical costs, salaries, and other costs. G&A expenses in the second quarter of 2023 were $5.0 million compared to $3.4 million for the second quarter of 2022. The increase was primarily due to increased salaries, non-cash stock-based compensation, professional fees, and other costs.

Abeona exited the second quarter of 2023 with approximately $36.8 million in cash, cash equivalents, and investments. Subsequent to the end of the quarter, the company raised $25 million in gross proceeds from a registered direct offering. Following the offering, we estimate the company has sufficient capital to fund operations into the fourth quarter of 2024. As of August 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 37.0 million.

Conclusion

We are glad to see that the company remains on track to file the BLA for EB-101 in the third quarter of 2023 and we look forward to continued updates from the company regarding the acceptance of the BLA and other news during the review process. We remind investors that approval of EB-101 could be accompanied by issuance of a priority review voucher (PRV), which is likely to sell in the $100 million range based on sales of PRV's over the past three years. Following the recent financing our valuation now stands at $8.00.

PROJECTED FINANCIALS

Abeona Therapeutics Inc.	2022 A	Q1 A	Q2 A	Q3 E	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	$8.0	$8.0	$32.6	$35.0	$37.0
General & administrative	$17.3	$4.0	$5.0	$4.5	$4.7	$18.2	$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)	($12.5)	($12.7)	($47.8)	($49.0)	($23.0)
Operating Margin	*-3600.8%*	*#DIV/0!*	*-301.5%*	*#DIV/0!*	*#DIV/0!*	*-1365.5%*	*-445.5%*	*-52.3%*
Non-Operating Expenses (Net)	$11.2	$2.9	($6.1)	($0.1)	($0.1)	($3.4)	($0.5)	($0.5)
Pre-Tax Income	($39.7)	($9.1)	($16.7)	($12.6)	($12.8)	($51.2)	($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)**	**($12.6)**	**($12.8)**	**($51.2)**	**($49.5)**	**($23.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($5.53)**	**($0.54)**	**($0.92)**	**($0.51)**	**($0.51)**	**($2.42)**	**($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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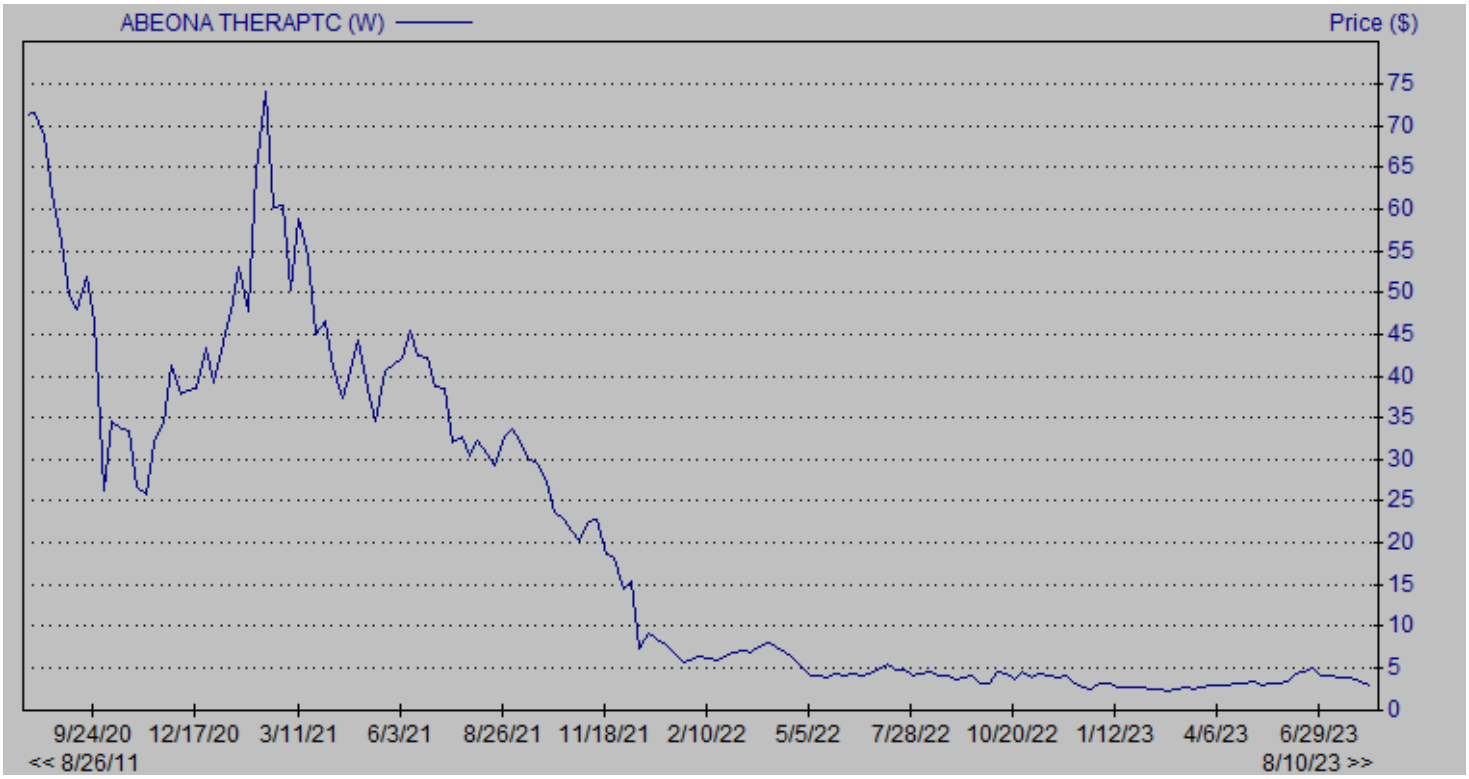

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