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Abeona Therapeutics Inc.

(ABEO-NASDAQ)

ABEO: Type A Meeting with FDA Concluded; BLA Submission on Track for 2H24…

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 $7.50/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 (08/14/24)	$4.98
Valuation	**$7.50**

OUTLOOK

On August 12, 2024, Abeona Therapeutics, Inc. (ABEO) announced financial results for the second quarter of 2024 and provided a business update. The company recently completed a Type A meeting with the FDA in which data and reports addressing nearly all of the deficiencies cited in the complete response letter were shared and the FDA gave preliminary alignment pending formal review. Two remaining outstanding items remain, however validation for those issues is currently ongoing under protocols that incorporate FDA feedback. We continue to expect a resubmission of the BLA in the second half of 2024, and following acceptance of the BLA we expect a PDUFA date six months from the date of submission.

SUMMARY DATA

52-Week High	**$8.68**
52-Week Low	**$3.12**
One-Year Return (%)	**44.35**
Beta	**1.59**
Average Daily Volume (sh)	**358,164**
Shares Outstanding (mil)	**43**
Market Capitalization ($mil)	**$216**
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 2024 Estimate	**-2.5**
P/E using 2025 Estimate	**-3.8**

Risk Level	**High**
Type of Stock	**Small-Blend**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	0.0 A	3.5 A	0.0 A	0.0 A	3.5 A
2024	0.0 A	0.0 A	0.0 E	0.0 E	0.0 E
2025					10.0 E
2026					38.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.54 A	-$0.92 A	-$0.48 A	-$0.52 A	-$2.53 A
2024	-$1.16 A	$0.19 A	-$0.36 E	-$0.39 E	-$2.00 E
2025					-$1.11 E
2026					-$0.58 E

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WHAT'S NEW

Business Update

Type A Meeting with FDA Complete; BLA Resubmission in 2H24

Abeona Therapeutics, Inc. (ABEO) is currently working on the resubmission of the Biologics License Application (BLA) for pz-cel (prademagene zamikeracel) for the treatment of recessive dystrophic epidermolysis bullosa (RDEB). Recently, Abeona completed a Type A meeting with the U.S. Food and Drug Administration (FDA) to discuss the resubmission. During the meeting, Abeona shared data and reports addressing nearly all the deficiencies noted in the Complete Response Letter (CRL). The company and the FDA came to preliminary alignment on those issues pending formal review of the data. There are two remaining outstanding items related to sterility assays and identity assays, with validation currently ongoing under protocols that incorporate FDA feedback. The company remains on track to resubmit the BLA for pz-cel before the end of the year. Following acceptance of the BLA, we anticipate a PDUFA date 6 months from the date of resubmission.

In regards to commercial preparation, the company is now focused on payer discussions such that patients can have greater and faster access upon approval. The company recently announced that the Centers for Medicare and Medicaid Services (CMS) has granted a product-specific procedure code ICD-10-PCS for pz-cel. If pz-cel is approved, the code will allow for efficient and accurate documentation, billing, and analysis of inpatient hospital procedures using pz-cel. The code will go into effect on Oct. 1, 2024. In addition, CMS assigned Medicare reimbursement of pz-cel to Pre-Major Diagnostic Category, Medicare Severity Diagnosis Related Group 018 (Pre-MDC MS-DRG 018), which is among the highest available inpatient hospital reimbursement levels for cell and gene therapies.

The company reported it is continuing discussions with the payer community and these discussions are generating positive results, which is likely to lead to favorable coverage and broad patient access following approval of pz-cel. Discussions are also continuing with experienced EB centers and the company remains on track for potential launch approximately 3 months after the potential pz-cel approval.

Beacon Therapeutics to Evaluate AAV204 Capsid for Ophthalmology Indications

In July 2024, Abeona announced an agreement with Beacon Therapeutics in which Beacon will evaluate Abeona's AAV204 capsid for the development and commercialization of gene therapies for select ophthalmology indications. The agreement will give Beacon 12-months to evaluate AAV204 with an option to take a worldwide, non-exclusive license to use AAV204 in up to five gene or disease targets. Abeona will receive an upfront payment upon Beacon's exercise of its option to license AAV204, with additional payments upon certain development, regulatory, and sales milestones along with tiered royalties on sales of products incorporating AAV204. The targets that Beacon would license are distinct from those currently in development at Abeona.

Financial Update

On August 12, 2024, Abeona announced financial results for the second quarter of 2024. The company did not report any revenue in the second quarter of 2024. R&D expenses in the second quarter of 2024 were $9.2 million compared to $8.5 million for the second quarter of 2023. The increase was primarily due to increased salary and related costs partially offset by decrease clinical and development work. G&A expenses in the second quarter of 2024 were $8.6 million compared to $5.0 million for the second quarter of 2023. The increase was primarily due to increased salaries, pre-commercial preparation costs, non-cash stock-based compensation, and professional fees.

Abeona exited the second quarter of 2024 with approximately $123.0 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. As of August 2, 2024, the company had approximately 43.3 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 55.1 million.

Conclusion

The company continues to be on track to resubmit the BLA in the second half of 2024 following a successful Type A meeting with the FDA. The discussions with payers and EB centers appear to be going well, which should lead to a successful commercial launch of pz-cel, if approved. With no changes to our model our valuation remains at $7.50.

PROJECTED FINANCIALS

Abeona Therapeutics Inc.	2023 A	Q1 A	Q2 A	Q3 E	Q4 E	2024 E	2025 E	2026 E
EB-101	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$10.0	$38.0
License and other revenues	$3.5	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$3.5**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$10.0**	**$38.0**
Cost of revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.6	$3.8
Gross Margin	*100%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*84%*	*90%*
Royalties	$1.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Research & development	$31.1	$7.2	$9.2	$8.0	$8.0	$32.4	$35.0	$37.0
General & administrative	$19.0	$7.1	$8.6	$7.0	$8.0	$30.8	$28.0	$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	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Impairment of right-of-use lease asset	($1.1)	$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	($47.1)	($14.3)	($17.9)	($15.0)	($16.0)	($63.2)	($53.0)	($29.0)
Operating Margin	*-1346.7%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-530.0%*	*-76.3%*
Non-Operating Expenses (Net)	($7.1)	($17.2)	$25.3	$0.0	$0.0	$8.0	($2.3)	($2.9)
Pre-Tax Income	($54.2)	($31.6)	$7.4	($15.0)	($16.0)	($55.2)	($55.3)	($31.9)
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	**($54.2)**	**($31.6)**	**$7.4**	**($15.0)**	**($16.0)**	**($55.2)**	**($55.3)**	**($31.9)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.53)**	**($1.16)**	**$0.19**	**($0.36)**	**($0.39)**	**($1.47)**	**($1.11)**	**($0.58)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	21.4	27.3	40.0	41.3	41.4	37.5	50.0	55.0

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

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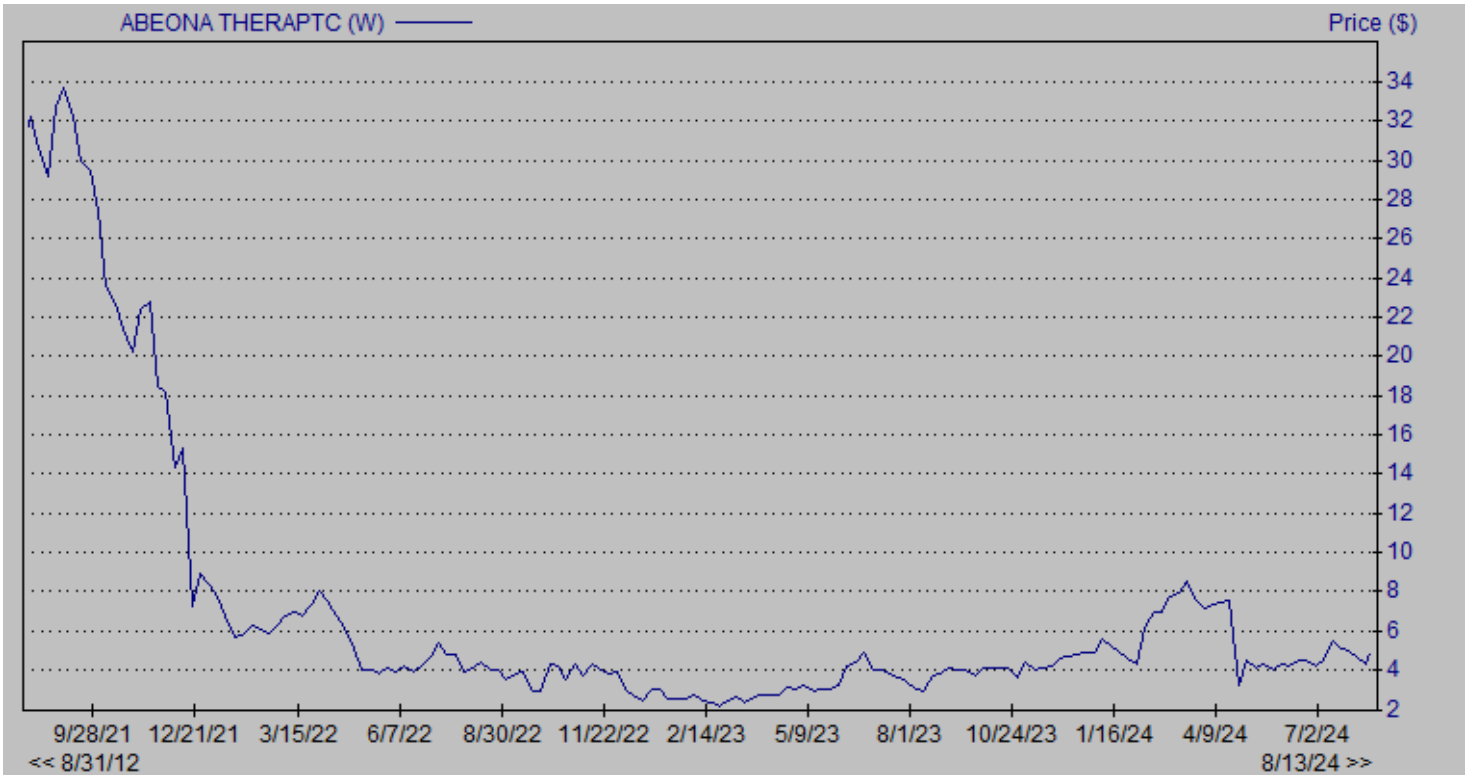

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