Zacks Small-Cap Research
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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Advisory Panel Votes Against Recommending Approval of NurOwn®…

Based on our probability adjusted DCF model that takes into account potential future revenues from NurOwn® in ALS, MS, and Alzheimer's, BCLI is valued at $0.50/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (10/02/23)	$0.20
Valuation	**$0.50**

OUTLOOK

On September 27, 2023, the U.S. FDA held an Advisory Committee (AdCom) meeting regarding BrainStorm Cell Therapeutics, Inc. (BCLI) BLA for NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS). Following a full day of discussion, the Committee voted that NurOwn did not demonstrate substantial evidence of effectiveness for the treatment of mild to moderate ALS. The FDA will render a decision about whether or not to approve NurOwn on or before the PDUFA date of December 8, 2023, however given the negative vote from the AdCom we no longer anticipate approval of NurOwn at this time. The company will explore all its options over the next few weeks for how to move NurOwn forward.

SUMMARY DATA

52-Week High	**$4.42**
52-Week Low	**$0.20**
One-Year Return (%)	**-95.47**
Beta	**-0.21**
Average Daily Volume (sh)	**1,310,647**
Shares Outstanding (mil)	**45**
Market Capitalization ($mil)	**$9**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**21**
Insider Ownership (%)	**10**
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 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**

Risk Level	**Above Avg.**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0 A	0 A	0 A	0 A	0 A
2023	0 A	0 A	0 E	0 E	0 E
2024					20 E
2025					258 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.15 A	-$0.20 A	-$0.19 A	-$0.13 A	-$0.67 A
2022	-$0.14 A	-$0.28 A	-$0.14 E	-$0.15 E	-$0.70 E
2023					-$0.54 E
2024					$2.51 E

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WHAT'S NEW

Business Update

Negative Advisory Committee Meeting Outcome for NurOwn

On September 27, 2023, the U.S. Food and Drug Administration (FDA) convened a meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee (AdCom) to review the Biologics License Application (BLA) for NurOwn®. Following a full day of discussion, the Committee voted 17-1 that NurOwn did not demonstrate substantial evidence of effectiveness for the treatment of mild to moderate amyotrophic lateral sclerosis (ALS). The FDA will still need to render a decision about whether or not to approve NurOwn on or before the PDUFA date of December 8, 2023, however given the outcome of the AdCom we no longer are anticipating approval of NurOwn at this time.

Conclusion

This is an unfortunate outcome to the AdCom as we believe BrainStorm's team did what was necessary to help the members of the Advisory Committee understand the totality of the data, however in the end it appeared that committee members had too many questions and there was insufficient time to have all the questions answered. We anticipate the company considering all of its options over the next few weeks before deciding next steps for the NurOwn program. Since we now anticipate that the FDA will not approve NurOwn and we are unsure of how the company plans to proceed, our valuation has been lowered to $0.50.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
MSC-NTF Stem Cells	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$20**	**$258**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$20**	**$258**
YOY Growth	-					-	-	-
Cost of Goods / Services	$0.0	$0	$0	$0	$0	$0.0	$2.0	$25.0
Product Gross Margin	-	-	-	-	-	-	*90%*	*90%*
R&D	$14.0	$2.9	$5.7	$3.6	$3.9	$16.1	$15.0	$20.0
% R&D	-	-	-	-		-	-	-
SG&A	$10.9	$2.2	$4.9	$2.9	$3.2	$13.2	$30.0	$75.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($24.8)	($5.2)	($10.6)	($6.5)	($7.1)	($29.4)	($27.0)	$138.0
Net Other Income	$0.5	$0.1	($0.2)	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($24.3)	($5.1)	($10.8)	($6.5)	($7.1)	($29.4)	($27.0)	$138.0
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($24.3)	($5.1)	($10.8)	($6.5)	($7.1)	($29.4)	($27.0)	$138.0
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.67)**	**($0.14)**	**($0.28)**	**($0.14)**	**($0.15)**	**($0.70)**	**($0.54)**	**$2.51**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	36.5	36.7	38.2	45.0	47.0	41.7	50.0	55.0

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

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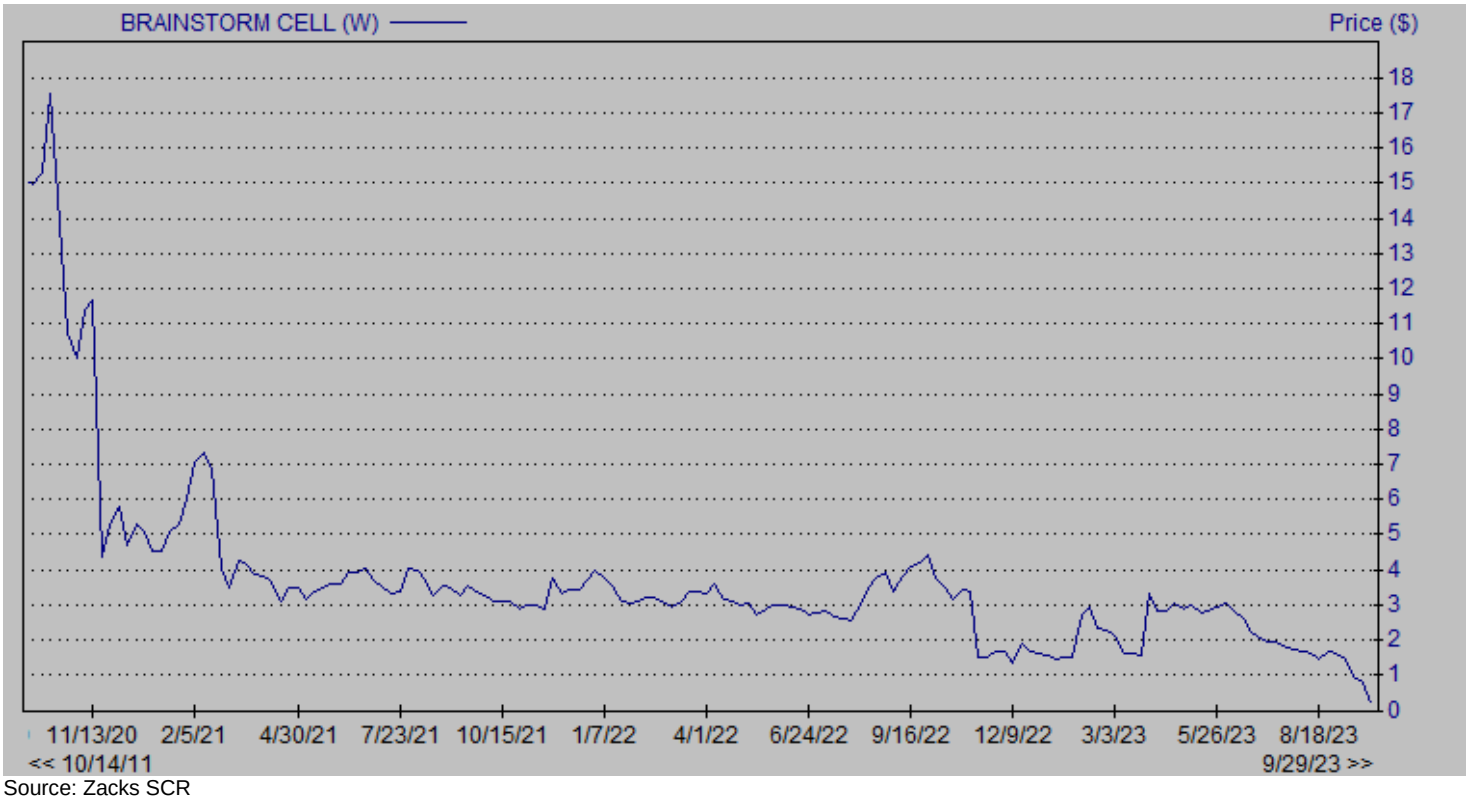
HISTORICAL STOCK PRICE



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