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

BCLI: Phase 3b Trial Details to be Discussed with FDA…

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 (11/16/23)	$0.18
Valuation	**$0.50**

OUTLOOK

On November 14, 2023, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the third quarter of 2023 and provided a business update. The company will be meeting with the U.S. FDA, which has invited the company to request an expedited face-to-face meeting to discuss the regulatory path forward for NurOwn® as a treatment for amyotrophic lateral sclerosis (ALS). BrainStorm will be conducting a Phase 3b trial for NurOwn in ALS and we anticipate details of the trial after the company meets with the FDA.

SUMMARY DATA

52-Week High	**$3.30**
52-Week Low	**$0.15**
One-Year Return (%)	**-89.11**
Beta	**-0.24**
Average Daily Volume (sh)	**1,201,405**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$9**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**21**
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 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**

Risk Level	**High**
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 A	0 E	0 E
2024					0 E
2025					0 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	-$0.03 A	-$0.15 E	-$0.70 E
2023					-$0.47 E
2024					-$0.47 E

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WHAT'S NEW

Business Update

Meeting with the FDA to Discuss Development Plan for NurOwn® in ALS

On October 18, 2023, BrainStorm Cell Therapeutics, Inc. (BCLI) announced that the U.S. Food and Drug Administration (FDA) has invited the company to request an expedited meeting to discuss the path forward for NurOwn® as a treatment for amyotrophic lateral sclerosis (ALS). The company also announced that it is withdrawing the Biologics License Application (BLA) for NurOwn. This was not a surprising decision following the negative outcome to the Advisory Committee meeting and the FDA is viewing it as a withdrawal without prejudice. BrainStorm remains committed to advancing NurOwn as a therapy for ALS, with a registrational Phase 3b trial necessary in order to seek regulatory approval.

Financial Update

On November 14, 2023, BrainStorm announced financial results for the third quarter of 2023. As anticipated, the company did not report any revenues during the third quarter of 2023. Net R&D expenses for the third quarter of 2023 were $3.3 million, compared to $3.8 million during the third quarter of 2022. The decrease was primarily due to decreased costs related to the Phase 3 clinical trial and decreased payroll expense, travel, materials, depreciation, and other activities. G&A expenses for the third quarter of 2023 were $2.7 million compared to $3.1 million for the third quarter of 2022. The decrease was primarily due to decreased payroll and stock-based compensation expenses.

The company exited the third quarter of 2023 with approximately $1.2 million in cash, cash equivalents, and short-term deposits. In October 2024, the company announced a strategic realignment to support the company's plan to conduct a double blind, placebo controlled Phase 3b U.S. clinical trial for NurOwn in ALS while continuing to publish data from NurOwn's Phase 3 clinical trial. BrainStorm is actively exploring various options to raise capital to fund the Phase 3b trial, and the company undertook a targeted reduction in headcount along with streamlining clean room operations to cut costs.

As of November 10, 2023, BrainStorm had approximately 49.0 million common shares outstanding and, when factoring in stock options, warrants, and restricted stock, a fully diluted share count of approximately 55.2 million.

Conclusion

We look forward to the outcome of the company's meeting with the FDA regarding the design of the Phase 3b trial of NurOwn in ALS. Following receipt of the meeting minutes, which should occur approximately 30 days following the date of the meeting, we anticipate the company sharing details of the meeting along with projected timelines. While we await word on plans for the Phase 3b meeting we have made no changes to our model and our valuation remains at $0.50 per share.

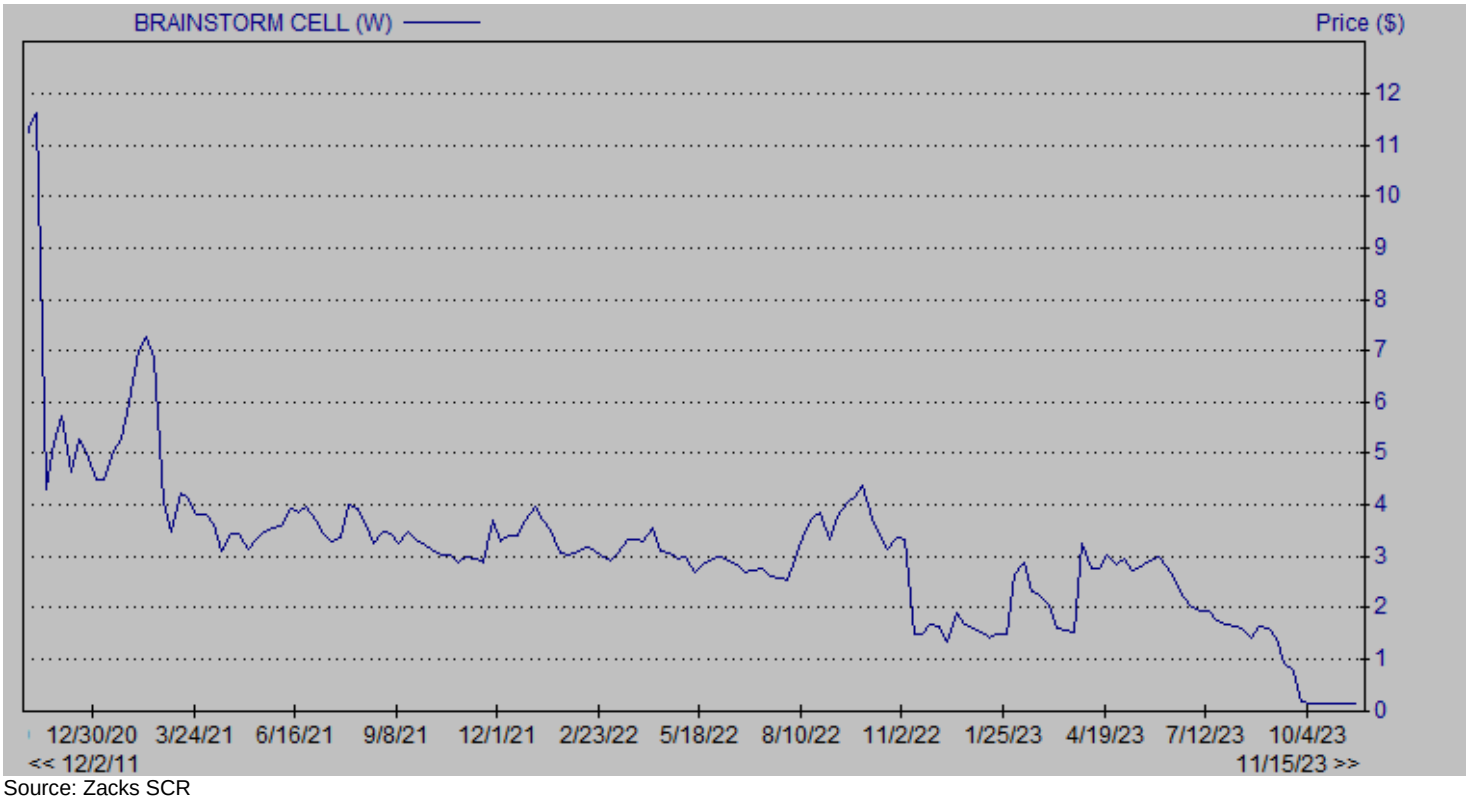
PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2022 A	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 E
MSC-NTF Stem Cells	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-					-	-	-
Cost of Goods / Services	$0.0	$0	$0	$0	$0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$14.0	$2.9	$5.7	$3.3	$3.9	$15.9	$15.0	$20.0
% R&D	-	-	-	-		-	-	-
SG&A	$10.9	$2.2	$4.9	$2.7	$3.2	$13.0	$13.0	$13.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($24.8)	($5.2)	($10.6)	($6.0)	($7.1)	($28.9)	($28.0)	($33.0)
Net Other Income	$0.5	$0.1	($0.2)	$4.8	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($24.3)	($5.1)	($10.8)	($1.2)	($7.1)	($28.9)	($28.0)	($33.0)
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)	($1.2)	($7.1)	($28.9)	($28.0)	($33.0)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.67)**	**($0.14)**	**($0.28)**	**($0.03)**	**($0.15)**	**($0.70)**	**($0.47)**	**($0.47)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	36.5	36.7	38.2	44.3	47.0	41.6	60.0	70.0

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

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