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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Plans Coming Together for Phase 3b Trial of NurOwn® in ALS…

Based on our probability adjusted DCF model that takes into account potential future revenues from NurOwn® in ALS, BCLI is valued at $9.00/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (01/06/25)	$2.23
Valuation	**$9.00**

OUTLOOK

On December 30, 2024, BrainStorm Cell Therapeutics, Inc. (BCLI) held a conference call to provide a corporate update. The company remains on track to conduct a Phase 3b trial of NurOwn in patients with amyotrophic lateral sclerosis (ALS) to support a potential Biologics License Application (BLA) filing. During 2024, BrainStorm reached agreement with the FDA on a Special Protocol Assessment (SPA) and the CMC aspects of the upcoming trial, which significantly de-risks the regulatory aspects of the program. In addition, the company entered a Memorandum of Understanding with Pluri, Inc. for the clinical manufacturing of NurOwn, which should enable an expedited startup for the Phase 3b trial. The company is continuing to pursue various avenues for funding the trial, and we continue to anticipate the first patient will be enrolled during the first quarter of 2025.

SUMMARY DATA

52-Week High	**$11.09**
52-Week Low	**$1.13**
One-Year Return (%)	**-47.81**
Beta	**0.29**
Average Daily Volume (sh)	**104,893**
Shares Outstanding (mil)	**6**
Market Capitalization ($mil)	**$13**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**14**
Insider Ownership (%)	**7**
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 2025 Estimate	**N/A**
P/E using 2026 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)
2023	0 A	0 A	0 A	0 A	0 A
2024	0 A	0 A	0 A	0 E	0 E
2025					0 E
2026					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$2.07 A	-$4.24 A	-$0.42 A	$0.10 A	-$5.99 A
2024	-$0.79 A	-$1.31 A	-$0.51 A	-$0.49 E	-$3.01 E
2025					-$1.60 E
2026					-$1.33 E

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WHAT'S NEW

Business Update

Update on Planned Phase 3b Trial of NurOwn® in ALS

On December 30, 2024, BrainStorm Cell Therapeutics, Inc. (BCLI) conducted an investor update call to provide a corporate update. The company is currently preparing for a Phase 3b clinical trial of NurOwn in patients with amyotrophic lateral sclerosis (ALS). During 2024, the company achieved a number of significant milestones in support of the upcoming Phase 3b trial:

- In April 2024, the company announced it had received written agreement from the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) on the design of the Phase 3b trial. The SPA agreement indicates that the FDA concurs with the adequacy and acceptability of specific elements of a protocols overall design to ensure that the trial conducted under the protocol can be considered an adequate and well-controlled study to support marketing approval.
- In June 2024, the company announced it reached alignment with the FDA on the Chemistry, Manufacturing, and Controls (CMC) aspect of the Phase 3b trial. This means that the company has resolved all previous outstanding CMC issues identified by the FDA. Given the complexities of cell therapy products, reaching alignment with the FDA ahead of the Phase 3b trial is an additional means to lower the regulatory risk for NurOwn.
- In November 2024, the company announced it has entered into a Memorandum of Understanding (MOU) with Pluri Inc. to manufacture NurOwn for use in the planned Phase 3b trial. Pluri will provide GMP-compliant manufacturing of NurOwn for the trial and the companies will explore the potential for manufacturing support for potential future commercial distribution of NurOwn, if approved.

BrainStorm has continued to indicate that the Phase 3b trial will initiate in the first quarter of 2025. However, this will be dependent upon obtaining the necessary funding to conduct the trial. The company is pursuing non-dilutive financing and grants as well as other funding opportunities.

Positive Survival Data Presented at 2024 NEALS Meeting

In October 2024, BrainStorm presented a poster, titled 'Debamestrocel Long-Term Benefits on Survival and Neurodegeneration in ALS Expanded Access Program' (Dagher *et al*., 2024), which discussed the results achieved with ALS patients that participated in the Expanded Access Program (EAP) for NurOwn. Highlights from the poster include:

- A total of ten participants (6 debamestrocel, 4 placebo) from BrainStorm's prior Phase 3 trial enrolled in the EAP, which took place over two 28-week periods. Participants received debamestrocel every eight weeks for a maximum of six doses over the two periods.
- A comparable cohort was identified from the PRO-ACT database through a comparison of baseline characteristics using propensity score matching (PSM).
- At the final visit in the EAP, 9/10 participants were alive. A comparison of the survival curves showed a statistically significant difference in favor of debamestrocel (P=0.0379) with a median survival time of 46.6 months compared to 41.1 months for the matched control group.
- For the participants that received placebo in the Phase 3 trial, the group median change in neurofilament light (NfL) was 37%, indicating worsening neurodegeneration. However, after those participants received debamestrocel in the EAP, the majority showed a stabilization in NfL levels.

New Patent Issued for Exosome Platform

On December 3, 2024, BrainStorm announced that the U.S. Patent and Trademark Office (USPTO) issued a Notice of Allowance for patent application 16/981,757, which covers the company's proprietary exosome technology. Exosomes are membrane-bound extracellular vesicles that are released from cells and can be utilized to transport various compounds between and to cells. BrainStorm produces exosomes from MSC-NTF

cells that contain at least one of the following neurotrophic factors (LIF, VEGFA, GDF-15) along with additional proteins or microRNA molecules. The exosomes produced by BrainStorm express characteristic exosomal and MSC markers and are isolated using a unique method developed by BrainStorm. The patent is expected to provide protection until April 10, 2039, not including standard term adjustments.

Financial Update

On November 14, 2024, BrainStorm announced financial results for the third quarter of 2024. As anticipated, the company did not report any revenues during the third quarter of 2024. Net R&D expenses for the third quarter of 2024 were $1.0 million, compared to $3.3 million during the third quarter of 2023. The decrease was primarily due to decreased costs related to the Phase 3 clinical trial and payroll expenses. G&A expenses for the third quarter of 2024 were $2.0 million compared to $2.7 million for the third quarter of 2023. The decrease was primarily due to lower payroll, stock-based compensation, and other costs.

The company exited the third quarter of 2024 with approximately $0.35 million in cash, cash equivalents, and short-term deposits. As of November 12, 2024, BrainStorm had approximately 5.7 million common shares outstanding (as a result of the 1:15 reverse split on Sep. 30, 2024) and, when factoring in stock options and warrants, a fully diluted share count of approximately 7.3 million.

Conclusion

BrainStorm remains on track to initiate the Phase 3b trial of NurOwn in ALS patients as the regulatory aspects of the program have been de-risked through reaching alignment with the FDA on the CMC aspects of the trial and having a SPA in place. We look forward to additional updates on the Phase 3b trial, including the potential for nondilutive funding, as the company gets closer to initiating it. Following the reverse split our valuation is now $9.00 per share.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 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	$10.7	$1.0	$1.9	$1.0	$1.1	$5.0	$13.0	$15.0
% R&D	-	-	-	-		-	-	-
SG&A	$10.7	$1.5	$3.6	$2.0	$1.5	$8.6	$11.0	$11.5
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($21.4)	($2.5)	($5.5)	($3.0)	($2.6)	($13.6)	($24.0)	($26.5)
Net Other Income	$4.2	($0.9)	($0.5)	$0.3	$0.0	($1.1)	$0.0	$0.0
Pre-Tax Income	($17.2)	($3.4)	($5.9)	($2.7)	($2.6)	($14.7)	($24.0)	($26.5)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($17.2)	($3.4)	($5.9)	($2.7)	($2.6)	($14.7)	($24.0)	($26.5)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($5.99)**	**($0.79)**	**($1.31)**	**($0.51)**	**($0.49)**	**($3.01)**	**($1.60)**	**($1.33)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	2.9	4.3	4.5	5.3	5.3	4.9	15.0	20.0

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

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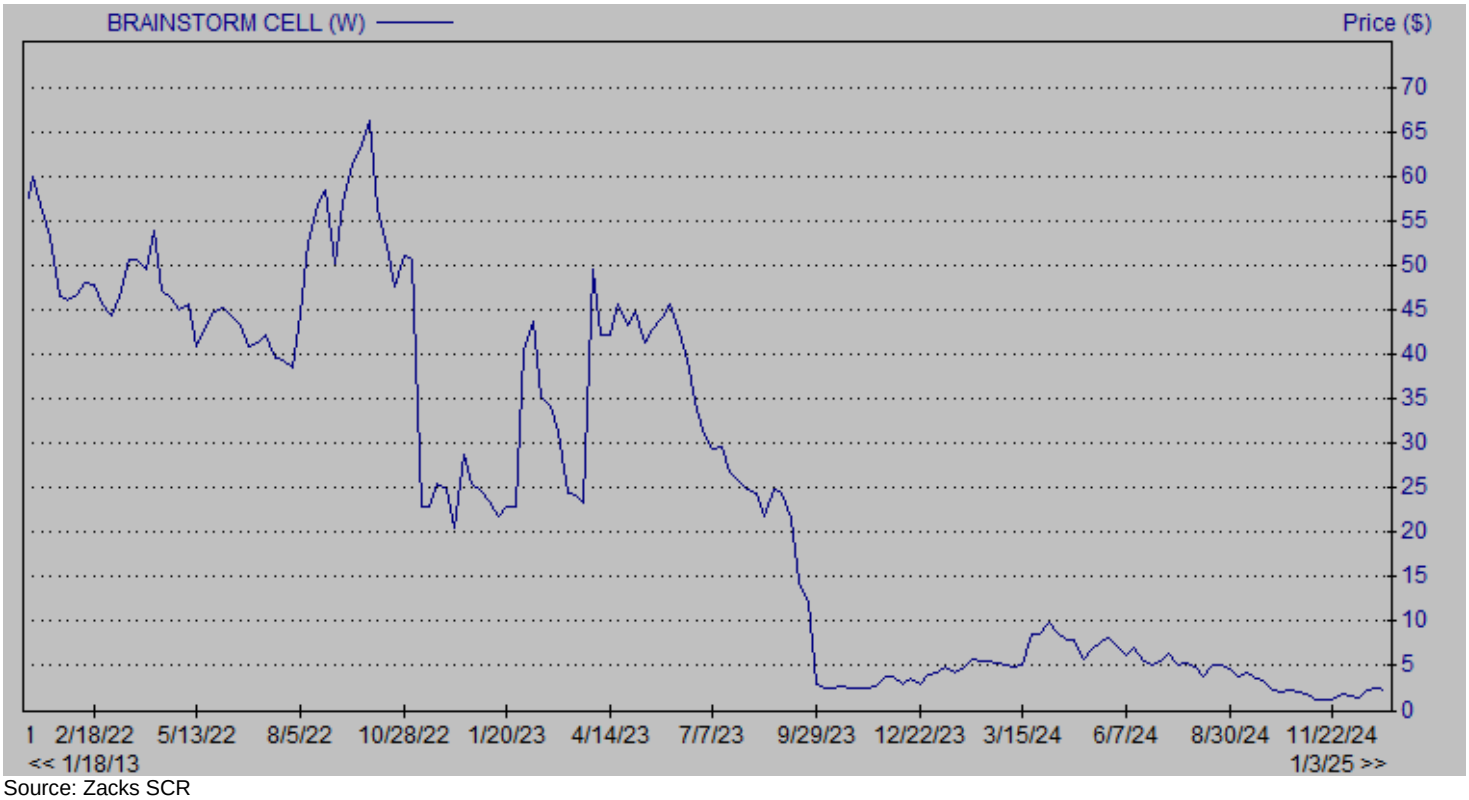

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