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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Unveils Plans 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, MS, and Alzheimer's, BCLI is valued at $1.00/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (03/06/24)	$0.35
Valuation	**$1.00**

OUTLOOK

On March 4, 2024, BrainStorm Cell Therapeutics, Inc. (BCLI) presented a poster at the MDA Clinical and Scientific Conference with the proposed design for a Phase 3b trial of NurOwn® in amyotrophic lateral sclerosis (ALS). The design calls for a two-part, multicenter, Phase 3b trial in which eligible patients will initially enter a 24-week randomized, double blind, placebo controlled period (Part A) followed by a 24-week open-label extension period (Part B). Eligible patients will be those with mild-to-moderate ALS and the primary endpoint will be based on the ALSFRS-R. BrainStorm submitted a Special Protocol Assessment (SPA) request to the U.S. FDA. An SPA would indicate concurrence by the FDA with the adequacy and acceptability of the overall protocol design. Final details of the trial will occur following receipt of input from the FDA.

SUMMARY DATA

52-Week High	**$3.30**
52-Week Low	**$0.15**
One-Year Return (%)	**-82.93**
Beta	**0.22**
Average Daily Volume (sh)	**768,113**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$17**
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 2024 Estimate	**N/A**
P/E using 2025 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)
2022	-$0.15 A	-$0.20 A	-$0.19 A	-$0.13 A	-$0.67 A
2023	-$0.14 A	-$0.28 A	-$0.03 A	-$0.15 E	-$0.70 E
2024					-$0.47 E
2025					-$0.47 E

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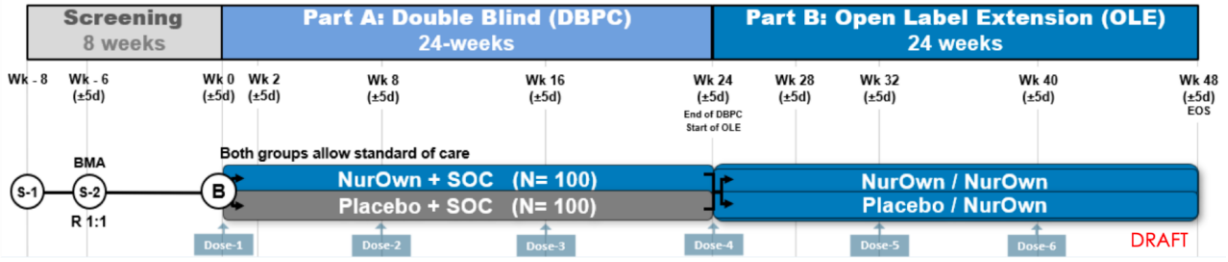
WHAT'S NEW

Business Update

Phase 3b Trial Design Announced; SPA Submitted to the FDA

On March 4, 2024, BrainStorm Cell Therapeutics, Inc. (BCLI) presented a poster at the MDA Clinical and Scientific Conference with an outline of the proposed design for a Phase 3b trial of NurOwn® (debamestrocel) in amyotrophic lateral sclerosis (ALS).

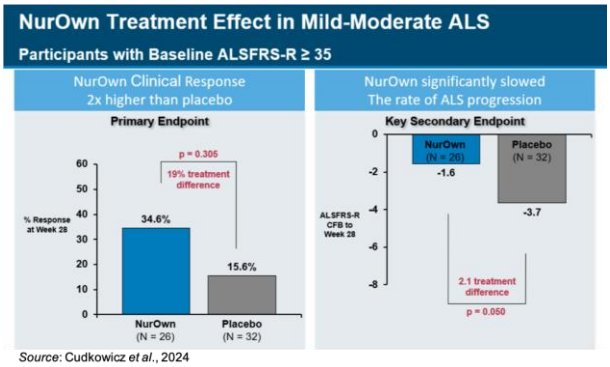
The following figure gives an overview of the proposed trial design, which is now under review by the U.S. Food and Drug Administration (FDA). Up to approximately 200 patients with mild-to-moderate ALS will be enrolled into the two-part study: Part A will be a 24-week, randomized, double blind period while Part B will be a 24-week open-label extension period. The primary endpoint will be based on the Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R). Patients will be treated at Weeks 0, 8, and 16 during Part A and then Weeks 24, 32, and 40 in Part B.



Source: Cudkowicz *et al.*, 2024

In February 2024, BrainStorm announced it submitted a Special Protocol Assessment (SPA) to the U.S. FDA regarding the design of the Phase 3b trial. Participating in the SPA program will allow BrainStorm to reach a consensus with the FDA on the Phase 3b trial design and ensure that the study is considered adequate by the FDA to support a future marketing evaluation. A response from the FDA is anticipated within 45 days of submission and the company will then take any feedback into consideration before finalizing the design of the trial.

As a reminder, when examining patients with a baseline ALSFRS-R ≥ 35 in the Phase 3 trial, patients treated with NurOwn exhibited a clinical response 2x higher than placebo and had a significantly slower rate of ALS progression, as shown in the following figure. This supports the company's decision to include patients with mild-to-moderate ALS in the Phase 3b trial.



Source: Cudkowicz *et al.*, 2024

Conclusion

We look forward to an update regarding the FDA's feedback on the SPA and the finalized design for the Phase 3b trial along with guidance on when the trial is expected to initiate. Participating in the SPA program is a smart strategic move as agreement with the FDA on the design for a Phase 3 program will help to de-risk certain regulatory aspects of the program. With the SPA being submitted and a response expected soon from the FDA, we have increased our valuation to $1.00 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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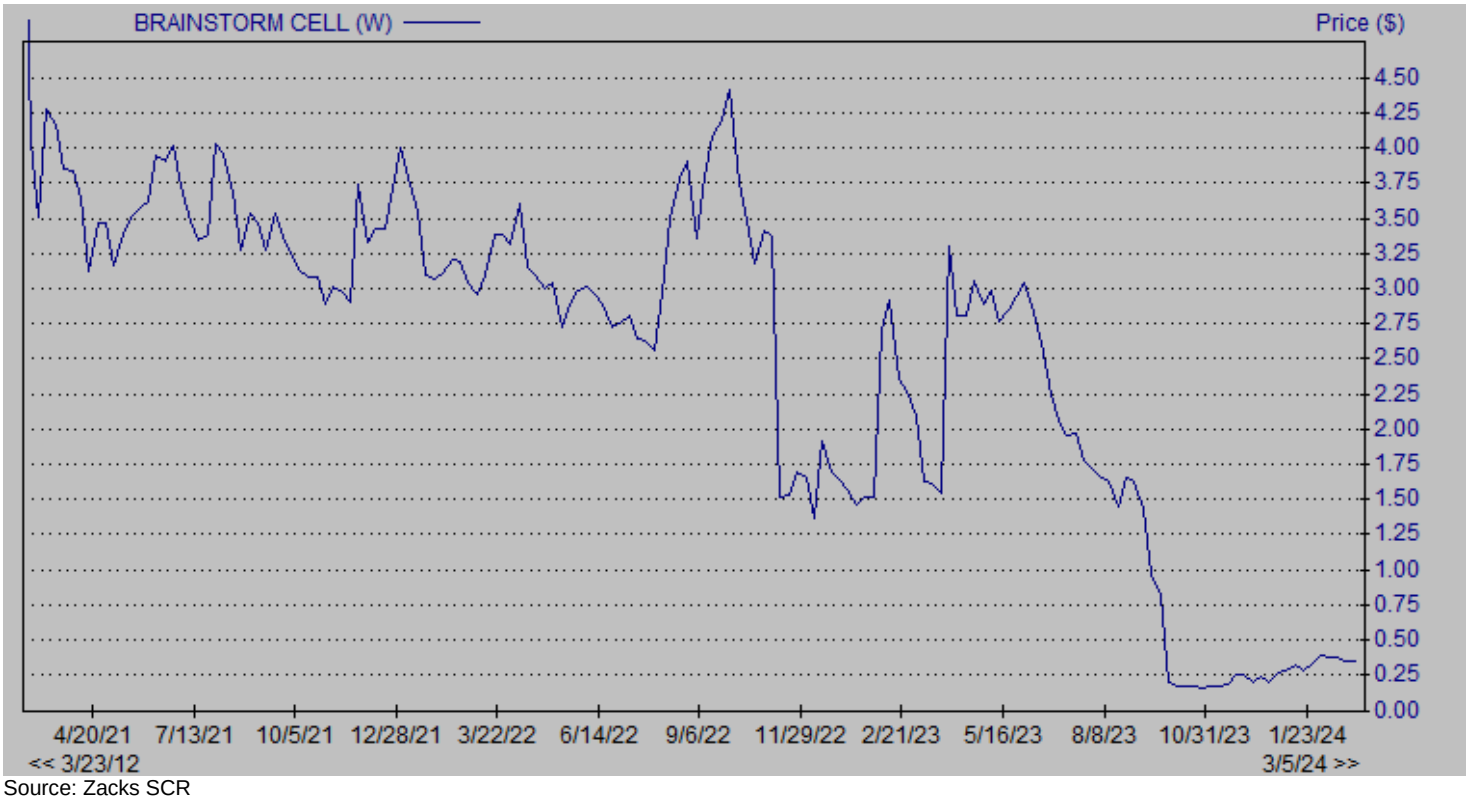
HISTORICAL STOCK PRICE



Source: Zacks SCR

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