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May 27, 2025
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Receives Regulatory Clearance to Initiate Phase 3b ALS Trial…

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 (05/27/25)	$1.08
Valuation	**$9.00**

OUTLOOK

On May 19, 2025, BrainStorm Cell Therapeutics, Inc. (BCLI) announced that the U.S. Food and Drug Administration (FDA) has cleared the company to initiate the Phase 3b clinical trial of NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS). This final regulatory clearance comes after the company submitted an amendment to the Investigational New Drug (IND) application regarding certain technical aspects of the Chemistry, Manufacturing, and Controls (CMC). The trial design was previously agreed upon with the FDA under a Special Protocol Assessment (SPA). The Phase 3b trial, known as ENDURANCE, is now listed on clinicaltrials.gov under ID NCT06973629. The company is now focused on securing the financing necessary to conduct the trial.

SUMMARY DATA

52-Week High	**$8.67**
52-Week Low	**$0.76**
One-Year Return (%)	**-86.59**
Beta	**0.35**
Average Daily Volume (sh)	**3,258,686**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$9**
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	**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)
2024	0 A	0 A	0 A	0 A	0 A
2025	0 A	0 E	0 E	0 E	0 E
2026					0 E
2027					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	-$0.79 A	-$1.31 A	-$0.51 A	$0.12 A	-$2.31 A
2025	-$0.45 A	-$0.41 E	-$0.35 E	-$0.34 E	-$1.51 E
2026					-$1.02 E
2027					-$0.83 E

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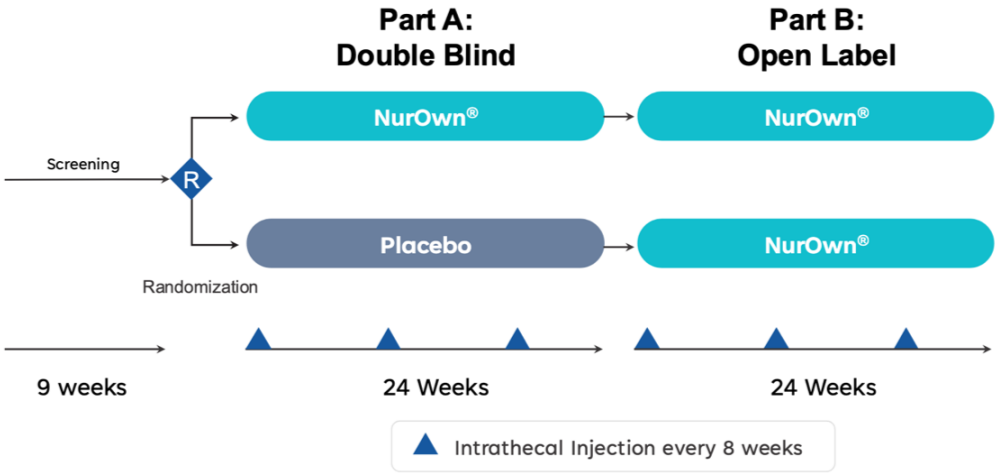
WHAT'S NEW

Business Update

Receives Regulatory Clearance to Initiate Phase 3b Trial of NurOwn® in ALS

On May 19, 2025, BrainStorm Cell Therapeutics, Inc. (BCLI) announced that the U.S. Food and Drug Administration (FDA) has cleared the company to initiate the Phase 3b trial of NurOwn® in the treatment of patients with amyotrophic lateral sclerosis (ALS). Clearance to conduct the Phase 3b trial was granted following the company filing an Investigational New Drug (IND) amendment, which concerned various technical aspects of the IND, including the tech transfer and chemistry, manufacturing and controls (CMC). The design of the trial was previously developed in consultation with the FDA under a Special Protocol Assessment (SPA), which confirms both the trial design and statistical plan.

Details of the Phase 3b trial, known as ENDURANCE, are now available at clinicaltrials.gov (NCT06973629). Included on the clinicaltrials.gov site is a list of the proposed 15 clinical trial sites. An overview of the planned Phase 3b trial is below. 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, placebo controlled period followed by Part B, which 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: BrainStorm Cell Therapeutics, Inc.

Some of the differences between the first Phase 3 trial and the proposed Phase 3b trial are as follows:

- In the first Phase 3 trial, patients were required to have an ALSFRS-R score ≥25, which allowed for the possibility to enroll advanced-disease participants. The Phase 3b trial will focus on those with earlier-stage disease, with all participants required to have ≥2 points on each item of the ALSFRS-R.

- The primary endpoint of the first Phase 3 trial was a responder analysis, with responders being defined as having a ≥1.25 points/month improvement in the post-treatment slope vs. pre-treatment slope in ALSFRS-R at Week 28. The Phase 3b trial will utilize the change in ALSFRS-R from baseline to Week 24, which is considered the "gold standard" for ALS trials.

- The first Phase 3 trial had a 20-week screening period, including a 3-month "run-in" period while the Phase 3b trial will eliminate the "run-in" and shorten the screening period to minimize changes between screening and baseline.

- Lastly, the Phase 3b trial has a SPA agreement with the FDA, while no such agreement existed for the first Phase 3 trial.

We believe these changes help to increase the probability for success in the Phase 3b trial, while having the SPA in place decreases the regulatory risk associated with the program.

In addition to getting all of the regulatory aspects in place, BrainStorm previously announced it had entered into a Memorandum of Understanding (MOU) with Pluri Inc. to manufacture NurOwn for use in the 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.

Letter of Intent Signed with Minaris Advanced Therapies

On May 27, 2025, BrainStorm announced it had signed a Letter of Intent (LOI) with Minaris Advanced Therapies, a global Contract Development and Manufacturing Organization (CDMO) that specializes in cell and gene therapies, to manufacture NurOwn for the upcoming Phase 3b clinical trial. This partnership strengthens the company's U.S. manufacturing capabilities and compliments the previously announced agreement between BrainStorm and Pluri, Inc. in Israel. Importantly, Minaris' facility has passed FDA inspections, which decreases the regulatory risk. Lastly, these manufacturing agreements that BrainStorm has signed ensures that there is adequate capacity for NurOwn production to support the upcoming Phase 3b trial.

Pharmacogenomic Data Presented at 2025 ISCT Annual Meeting

On April 29, 2025, BrainStorm announced the acceptance of new pharmacogenomic data for oral presentation at the International Society for Cell & Gene Therapy (ISCT) 2025 Annual Meeting. Included in the presentation were data highlighting the impact of the *UNC13A* genotype on clinical outcomes for patients treated with NurOwn. A copy of the presentation can be found here.

The UNC13A protein is found in presynaptic terminals of the nervous system and is important for facilitating crucial steps in neurotransmission, enabling sustained neurotransmission, and maintaining and constructing the sites where neurotransmission can take place (Willemse *et al*., 2023). A gene variant of *UNC13A* (rs12608932 C allele) is associated with shorter survival time and more severe ALS (Diekstra *et al*., 2012; Tan *et al*., 2020). TDP-43 is a splicing protein that is responsible for binding to intronic sequences and repressing the inclusion of certain segments into mature RNA. TDP-43 cytosolic aggregates are found in up to 98% of sporadic ALS cases and are often accompanied by nuclear depletion of TDP-43 and the appearance of cryptic exons (Prasad *et al*., 2019). The rs12608932 allele is located within a *UNC13A* intron (or cryptic exon), thus loss of TDP-43 leads to an increase in the inclusion of cryptic exons in *UNC13A* (Ma *et al*., 2022). Thus, the loss of TDP-43 combined with the presence of certain risk variants leads to a large decrease in viable *UNC13A* mRNA and protein.

The data presented by BrainStorm examined the association between the rs12608932 allele and patient outcomes in the Phase 3 NurOwn trial. The following table gives the baseline characteristics for the Phase 3 trial participants stratified by genotype at rs12608932. Approximately 62% of participants had the C risk allele (either CC or CA), however only 15% of participants were homozygous CC (NurOwn n=9; placebo n=10), thus no comparative analysis was performed.

NurOwn Phase 3 Trial: UNC13A Genetic Substudy

- **Baseline Disease Characteristics by UNC13A Genotype**
  - N= 124 participants (63 NurOwn; 61 placebo)
  - **C risk allele (CC & CA):** 77 participants (62%)
    - Homozygous CC (15%): NurOwn n= 9; Placebo n= 10; no comparative analysis were conducted
    - Heterozygous AC (47%): NurOwn n= 23; Placebo n= 35

Baseline Characteristics	NurOwn n=63			Placebo n=61		
	AA n=31	AC n=23	CC n=9	AA n=16	AC n=35	CC n=10
El Escorial Criteria (% Definite)	58	39	67	50	31	10
SVC (%), median	71	85	69	74	83	72
Bulbar Onset, %	10	17	44	19	11	50
ALSFRS-R, median	30	32	30	34	32	35
ALSFRS-R slope, median	-1.7	-1.6	-1.6	-1.2	-1.5	-1.4

Source: Dagher, 2025

The results of the analysis showed that participants with the AC genotype had a significant clinical benefit and biomarker improvement. While the overall trial showed a responder rate of 33% for NurOwn treated patients compared to 28% for placebo treated patients, for those with the AC genotype the response rate was 65% for those treated with NurOwn compared to 29% for those treated with placebo (*P*=0.011). In addition, there was a positive trend for the change in ALSFRS-R from baseline at Week 28 in those with the AC genotype, as those treated with NurOwn had a decrease of -1.90 while those treated with placebo had a decrease of -3.75 (P=0.167).

UNC13A Genetic Substudy: Primary & Key Secondary Endpoints

Endpoints	NurOwn n=63			Placebo n=61		
	AA n=31	AC n=23	CC n=9	AA n=16	AC n=35	CC n=10
Responders*, %	23%	65%	22%	25%	29%	20%
ALSFRS-R, points Change from Baseline to Week 28	-6.37	-1.90	-6.91	-4.52	-3.75	-5.18
Neurofilament Light (NfL), % % Change from Baseline	-15%	-5%	-32%	-3%	0%	6%

- **Primary Endpoint Analysis (% Response)**
  - CC genotype Responders: NurOwn 22% vs Placebo 20%
  - AC genotype Responders: NurOwn 65% vs Placebo 29%; p= 0.011
- **Key Secondary Endpoint (ALSFRS-R change from baseline at Week-28)**
  - CC genotype: NurOwn -6.91 vs Placebo -5.18 points
  - AC genotype: NurOwn -1.90 vs Placebo -3.75 points; p= 0.167

* Responder definition: ≥ 1.25 points/month improvement in post-treatment vs pre-treatment slope in ALSFRS-R at Week 28

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brainstorm cell therapeutics

Source: Dagher, 2025

These results are the first pharmacogenomic analysis of Phase 3 data from an ALS trial and provide additional insight into treatment effects in different subpopulations based on genotype.

Financial Update

On May 15, 2025, BrainStorm announced financial results for the first quarter of 2025. As anticipated, the company did not report any revenues for the first quarter of 2025. Net R&D expenses for the first quarter of

2025 were $1.3 million, compared to $1.0 million for the first quarter of 2024. The increase was primarily due to increased payroll expenses and stock-based compensation. G&A expenses for the first quarter of 2025 were $1.8 million compared to $1.5 million for the first quarter of 2024. The increase was primarily due to higher stock-based compensation and consultant costs partially offset by a decrease in payroll expenses, rent, and investor relations activities.

The company exited the first quarter of 2025 with approximately $1.8 million in cash, cash equivalents, and restricted cash. The company is currently exploring various mechanisms to secure funding for the Phase 3b trial, including non-dilutive grants. As of May 11, 2025, BrainStorm had approximately 7.9 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 11.5 million.

Conclusion

Now that the FDA has given clearance to the company to initiate the Phase 3b trial of NurOwn in ALS patients, we look forward to updates regarding how the trial will be financed, site activation, and the enrollment of the first patient. Importantly, the company has also secured additional manufacturing capabilities to ensure there will be adequate production of NurOwn to support the trial. We have made no changes to our model and our valuation remains at $9 per share.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2024 A	Q1 A	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 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	$4.7	$1.3	$1.4	$1.5	$1.5	$5.7	$7.0	$8.0
% R&D	-	-	-	-		-	-	-
SG&A	$7.0	$1.8	$1.9	$2.0	$2.2	$7.9	$8.3	$8.5
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($11.7)	($3.1)	($3.3)	($3.5)	($3.7)	($13.6)	($15.3)	($16.5)
Net Other Income	$0.1	$0.2	$0.0	$0.0	$0.0	$0.2	$0.0	$0.0
Pre-Tax Income	($11.623)	($2.9)	($3.3)	($3.5)	($3.7)	($13.4)	($15.3)	($16.5)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($11.6)	($2.9)	($3.3)	($3.5)	($3.7)	($13.4)	($15.3)	($16.5)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.31)**	**($0.45)**	**($0.41)**	**($0.35)**	**($0.34)**	**($1.51)**	**($1.02)**	**($0.83)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	5.0	6.3	8.0	10.0	11.0	8.8	15.0	20.0

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

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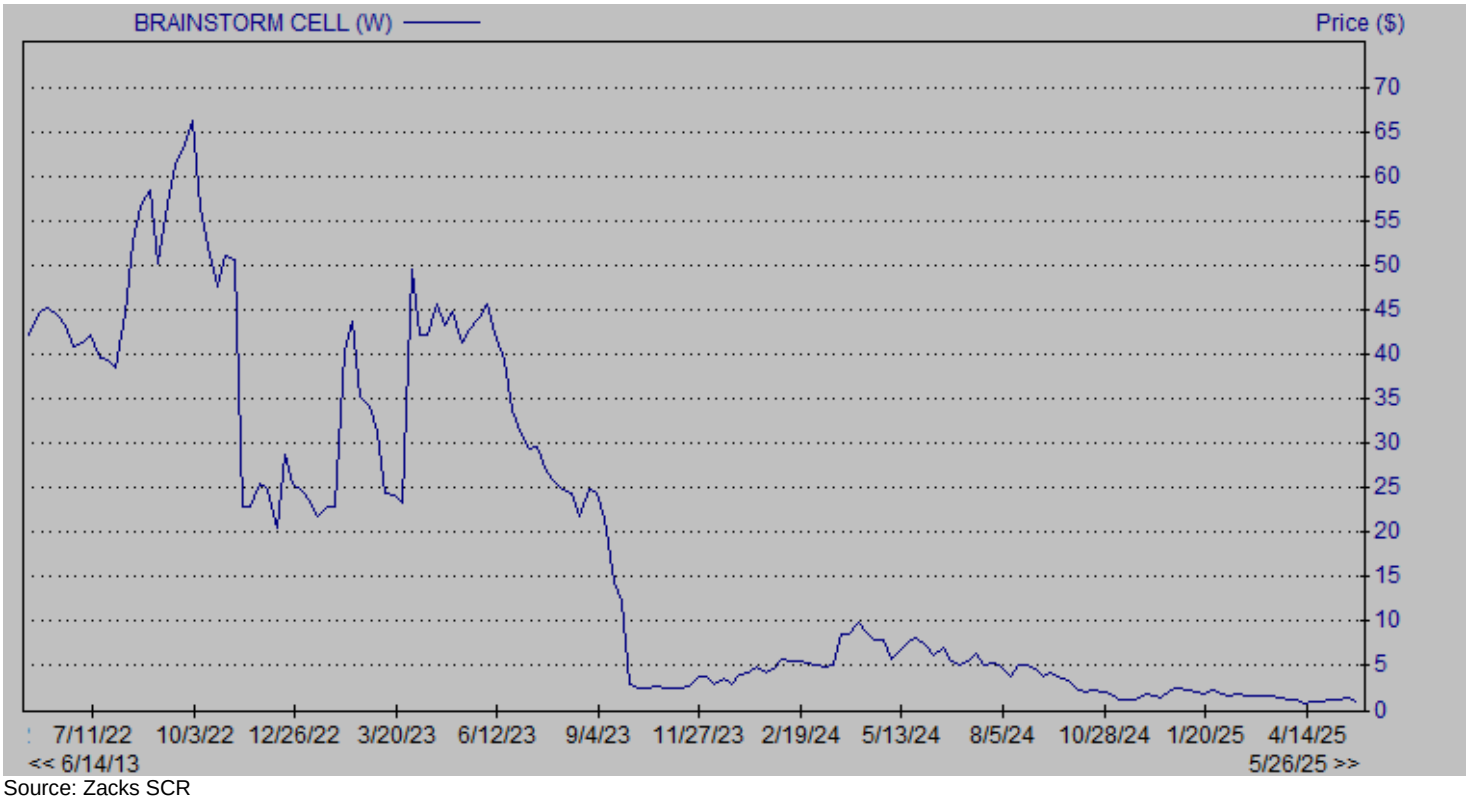
HISTORICAL STOCK PRICE



Source: Zacks SCR

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