

BrainStorm Cell Therapeutics, Inc.

(BCLI-OTCQB)

BCLI: Focused on Initiation of Phase 3b ENDURANCE 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 \$17.00/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (08/15/25) **\$0.60**
Valuation **\$17.00**

OUTLOOK

On August 14, 2025, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the second quarter of 2025 and provided a business update. The company continues to be focused on initiating the Phase 3b ENDURANCE trial of NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS). Following the filing of the Citizen's Petition in July 2025, we await a decision from the FDA regarding that petition and whether the agency will invite BrainStorm to resubmit the Biologics License Application (BLA) for NurOwn in ALS. In the meantime, BrainStorm is continuing to evaluate its funding options. A financing was delayed in July 2025 following the filing of the Citizen's Petition, which also affected the ability of the company to be eligible for the non-dilutive funding it had applied for, which required a committed secondary funding source. Thus, the company appears to be in a holding pattern until any action is taken regarding the Citizen's Petition, however key operational activities are continuing, including discussions with clinical sites along with ongoing engagement with the CDMO partners.

SUMMARY DATA

52-Week High **\$5.72**
52-Week Low **\$0.58**
One-Year Return (%) **-87.15**
Beta **0.12**
Average Daily Volume (sh) **153,709**

Shares Outstanding (mil) **11**
Market Capitalization (\$mil) **\$7**
Short Interest Ratio (days) **N/A**
Institutional Ownership (%) **14**
Insider Ownership (%) **11**

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)
2024	0 A	0 A	0 A	0 A	0 A
2025	0 A	0 A	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	-\$0.34 A	-\$0.35 E	-\$0.28 E	-\$1.37 E
2026					-\$0.85 E
2027					-\$0.75 E

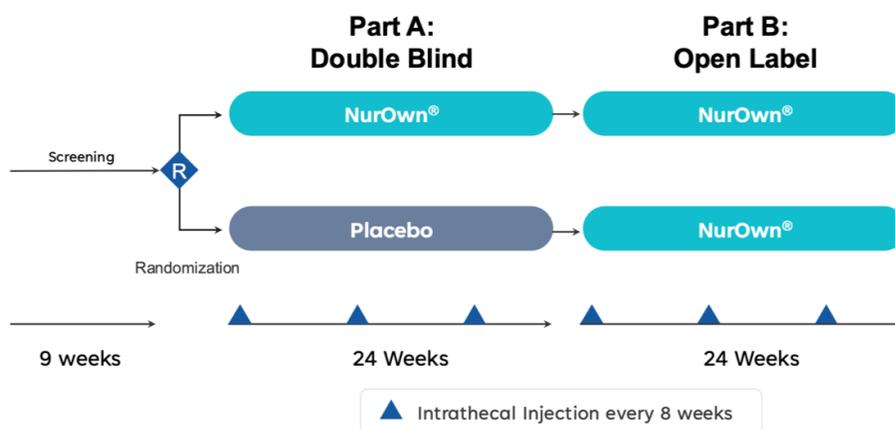
WHAT'S NEW

Business Update

Focused on Advancing NurOwn into Phase 3b ENDURANCE Trial

BrainStorm Cell Therapeutics, Inc. (BCLI) is continuing preparations for the Phase 3b ENDURANCE trial of NurOwn® for the treatment of patients with amyotrophic lateral sclerosis (ALS). In May 2025, the company received regulatory clearance from the U.S. Food and Drug Administration (FDA) to conduct the trial following the filing of 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 ENDURANCE trial are available at clinicaltrials.gov ([NCT06973629](https://clinicaltrials.gov/ct2/show/study/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 regards to manufacturing of NurOwn, 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. In addition, 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 Phase 3b trial. The partnership with Minaris strengthens BrainStorm's U.S. manufacturing capabilities and compliments the agreement with Pluri Inc. in Israel.

Awaiting Word from FDA on Citizen's Petition

In July 2025, a Citizen's Petition was filed with the U.S. FDA in which the petitioners, a group consisting mostly of amyotrophic lateral sclerosis (ALS) patients who have previously received NurOwn treatment, are requesting 1) that the agency invite BrainStorm to re-submit its BLA for NurOwn, and 2) request that the FDA exert its "regulatory flexibility" and grant Accelerated Approval or new Conditional Approval of NurOwn for the treatment of ALS with a Phase 4 confirmatory study with requirement of patients' participation in a biorepository with a natural history and exposome database. The full 300+ page petition has been assigned Docket ID FDA-2025-P-2109 and can be accessed [here](#). For an analysis of the petition, we invite investors to read our previous [report](#). We continue to await a response from the FDA regarding the petition.

Financial Update

On August 14, 2025, BrainStorm announced financial results for the second quarter of 2025. As anticipated, the company did not report any revenues for the second quarter of 2025. Net R&D expenses for the second quarter of 2025 were \$1.1 million, compared to \$0.9 million for the second quarter of 2024. The increase was primarily due to increased payroll expenses, stock-based compensation, and clinical activities suppliers. G&A expenses for the second quarter of 2025 were \$1.5 million compared to \$2.1 million for the second quarter of 2024. The decrease was primarily due to lower payroll, PR activities, rent costs, depreciation, and consultants costs.

The company exited the second quarter of 2025 with approximately \$1.0 million in cash, cash equivalents, and restricted cash. A financing in July 2025 did not go through due to the uncertainty created by the filing of the Citizen's Petition. Due to this, BrainStorm also became ineligible for non-dilutive funding it had applied for, which required a committed, secondary source of funding. Thus, BrainStorm will re-apply for the non-dilutive funding after it is able to secure additional financing. Unfortunately, due to the inability to close the financing the company was unable to maintain the listing requirements for the Nasdaq, and on July 18, 2025 the stock began trading on the OTCQB. As of August 11, 2025, BrainStorm had approximately 10.4 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 13.9 million.

Conclusion

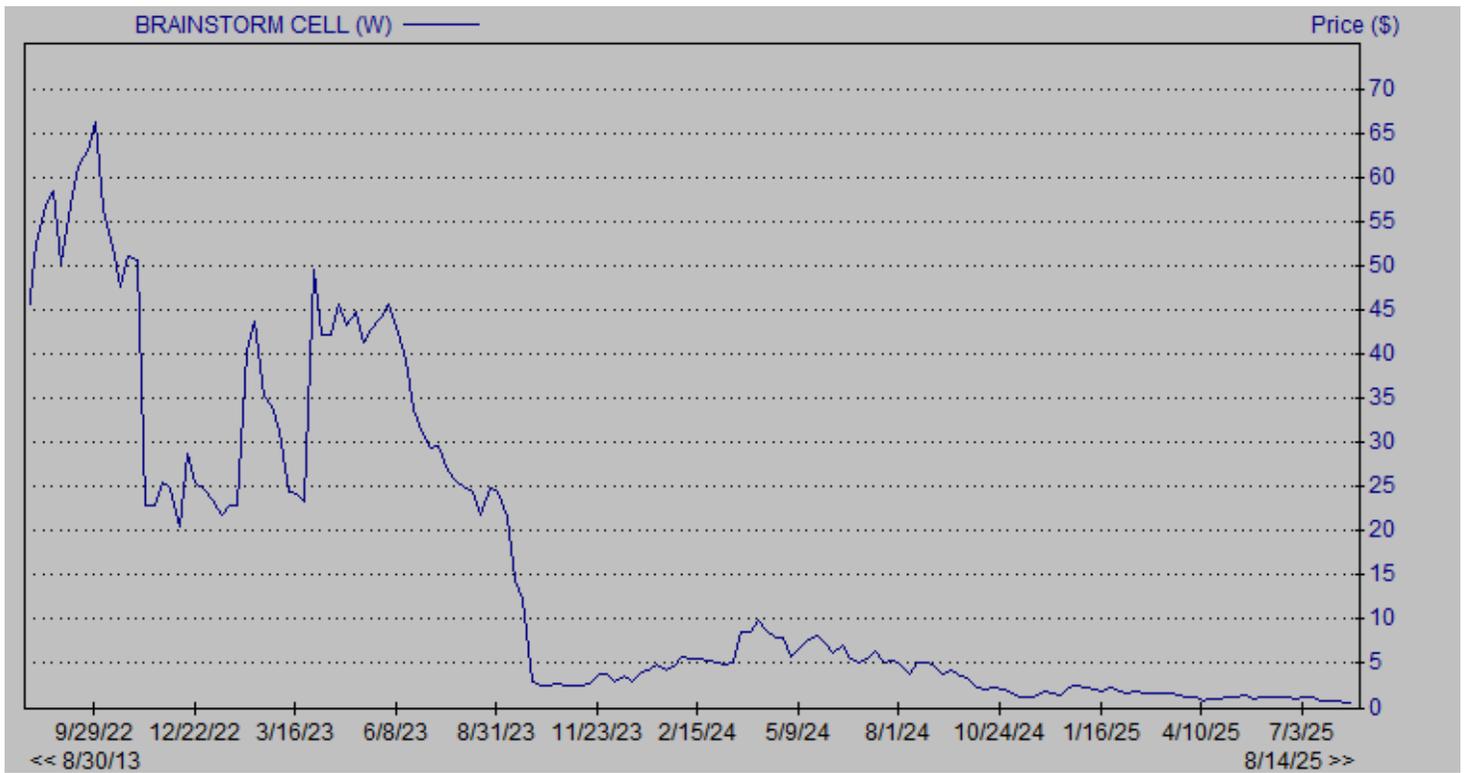
BrainStorm is in a bit of a 'holding pattern' as it awaits word from the FDA regarding the Citizen's Petition. While on the one hand the petition could ultimately turn out to be a golden opportunity for the company, in the meantime it had introduced regulatory uncertainty, which inhibited the company's ability to close a financing in July 2025, and subsequently delayed its ability to obtain the non-dilutive funding it had applied for, which requires co-funding. However, in the meantime the company is continuing to make advancements for the Phase 3b ENDURANCE trial, which the company is fully committed to initiating. The de-listing from the Nasdaq was an unfortunate consequence of the aforementioned events, and while re-listing on the Nasdaq is a high priority, BrainStorm is first and foremost dedicated to initiating the ENDURANCE trial. While we await word on the Citizen's Petition, our valuation remains at \$17 per share.

PROJECTED FINANCIALS

Brainsorm Cell Therapeutics	2024 A	Q1 A	Q2 A	Q3 E	Q4 E	2025 E	2026 E	2027 E
MSC-NTF Stem Cells	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Total Revenues	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Cost of Goods / Services	\$0.0	\$0	\$0	\$0	\$0	\$0.0	\$0.0	\$0.0
<i>Product Gross Margin</i>	-	-	-	-	-	-	-	-
R&D	\$4.7	\$1.3	\$1.1	\$1.5	\$1.5	\$5.4	\$7.0	\$8.0
<i>% R&D</i>	-	-	-	-	-	-	-	-
SG&A	\$7.0	\$1.8	\$1.5	\$2.0	\$2.2	\$7.4	\$8.3	\$8.5
<i>% SG&A</i>	-	-	-	-	-	-	-	-
Operating Income	(\$11.7)	(\$3.1)	(\$2.6)	(\$3.5)	(\$3.7)	(\$12.9)	(\$15.3)	(\$16.5)
Net Other Income	\$0.1	\$0.2	(\$0.3)	\$0.0	\$0.0	(\$0.1)	\$0.0	\$0.0
Pre-Tax Income	(\$11.623)	(\$2.9)	(\$2.9)	(\$3.5)	(\$3.7)	(\$13.0)	(\$15.3)	(\$16.5)
Taxes	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$11.6)	(\$2.9)	(\$2.9)	(\$3.5)	(\$3.7)	(\$13.0)	(\$15.3)	(\$16.5)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$2.31)	(\$0.45)	(\$0.34)	(\$0.35)	(\$0.28)	(\$1.37)	(\$0.85)	(\$0.75)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	5.0	6.3	8.6	10.0	13.0	9.5	18.0	22.0

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

HISTORICAL STOCK PRICE



Source: Zacks SCR

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