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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Public Support for NurOwn® from Prominent ALS Specialists…

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 $20.00/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (09/26/23)	$0.43
Valuation	**$20.00**

OUTLOOK

On September 25, 2023, the U.S. FDA released the briefing documents for the upcoming Advisory Committee (AdCom) meeting regarding BrainStorm Cell Therapeutics, Inc. (BCLI) BLA for NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS). The briefing documents give the FDA's opinion on the BLA, and as expected the agency emphasized the fact that the Phase 3 clinical trial of NurOwn did not reach statistical significance. However, at the AdCom meeting, BrainStorm's team will be given the opportunity to present and we continue to expect a professional and persuasive presentation that will ultimately result in a positive outcome to the AdCom meeting and eventual approval of NurOwn, which has a PDUFA date of December 8, 2023.

SUMMARY DATA

52-Week High	**$4.42**
52-Week Low	**$0.43**
One-Year Return (%)	**-89.72**
Beta	**-0.51**
Average Daily Volume (sh)	**596,662**
Shares Outstanding (mil)	**45**
Market Capitalization ($mil)	**$19**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**21**
Insider Ownership (%)	**10**
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	**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)
2022	0 A	0 A	0 A	0 A	0 A
2023	0 A	0 A	0 E	0 E	0 E
2024					20 E
2025					258 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	-$0.14 E	-$0.15 E	-$0.70 E
2023					-$0.54 E
2024					$2.51 E

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WHAT'S NEW

Business Update

Public Support for NurOwn on Public Docket

The U.S. government establishes a public docket for anyone to comment on upcoming regulatory decisions, and the FDA docket for the NurOwn AdCom received >1,700 comments. Comments received prior to the AdCom will be provided to the committee, while comments received after the meeting will be taken under consideration by the FDA. Investors can see the comments here.

We have identified a number of positive comments regarding NurOwn from prominent ALS physicians and scientists and included selections from a few of them below:

- Dr. Robert Brown, the Leo P. and Theresa M. LaChance Chair in Medical Research and chair at the Department of Neurology at the UMass Chan Medical School and UMass Memorial Medical Center, was a co-author on two publications describing the Phase 2 and Phase 3 trial outcomes for NurOwn. He has over 40 years of experience studying ALS.

  "Impressively, in both studies intrathecal Nurown cell therapy clearly improved the CSF biomarker profile in the ALS cases. I am not aware of other interventions with such a remarkably broad favorable impact on CSF parameters."

- Dr. Namita Goyal, co-director of the UCI Health ALS Neuromuscular Center, was a site Principal Investigator in the Phase 3 NurOwn trial.

  "I've been involved in scientific discussions with medical colleagues around this data. The floor effect is recognized by neurologists and appears to play a factor in the outcome of this trial. When accounting for the floor effect (by evaluating those participants who are not affected by the floor effect in the ALSFRS-R scale at baseline), there is a difference seen between the participants treated with NurOwn versus placebo. In this group, those participants who received NurOwn have >2 points less of a decline in the ALSFRS-R score compared to the placebo group."

- Dr. Stanley H. Appel, director of the Ann Kimball & John W. Johnson Center for Cellular Therapeutics, Professor of Neurology at Weill Cornell Medical College, and the Peggy and Gary Edwards Distinguished Chair for the Treatment and Research of ALS at the Houston Methodist Research Institute.

  "…we are very supportive of the widespread value of cell therapy and the specific safety of the Nurown therapy. Furthermore, Nurown cell therapy suppressed CSF pro-inflammatory constituents and reduced CSF NfL from baseline to week 20 compared to placebo. All such data suggests that Nurown therapy may have value in ALS, and a retrospective analysis suggests that pts with early disease may benefit, as did patients in the study of ederavone, now approved for ALS."

- Dr. Vladimir Klinov, treating physician for a patient in the Phase 3 NurOwn trial.

  "I am writing this letter on behalf of my former patient, Joshua Smith…He was diagnosed with ALS in February 2019…He was placed in phase 3 study for stem cell infusion, Nurown trial. He was given 6 infusions and during that study, he felt much better. The fasciculations nearly completely resolved, muscle stiffness and ambulation was much better as well…I was his treating physician when he was involved in a treatment trial with Nurown, I admit that his quality of life improved significantly…His last treatment was in August 2022. Since then, he has lost his mobility to walk, his strength in his upper extremities have weakened to the point where he cannot raise his arms over his head…I can conclude that when Joshua was in the Nurown trial, the disease progression significantly slowed down and he even had some improvement, and since the infusions were halted he has declined tremendously."

- Dr. Danielle Geraldi-Samara – Neurologist/ALS Specialist

  "I am writing to tell you what I have observed in the day-to-day workings of an ALS clinic…I have seen the full breadth of clinical constellations playing out over time. What I have not seen, though, is anyone with significant functional improvement from a declining baseline; I have not seen patients rise from plateaus. It does not happen in the natural course of ALS. It did happen with the introduction of NurOwn."

These are just a small representation of the positive comments that have been submitted ahead of the AdCom. We believe comments like these are important, particularly from experts in the ALS field, as they give a unique perspective regarding NurOwn that committee members can use to make a fully informed decision about whether the FDA should approve it.

Briefing Documents Released for AdCom on NurOwn

The U.S. Food and Drug Administration (FDA) will convene a meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee (AdCom) to review the Biologics License Application (BLA) for NurOwn® on September 27, 2023. The briefing documents for the meeting were released on September 25, 2023 and they provide an overview of the FDA's opinion of the BLA. As expected, the agency emphasized that the Phase 3 trial for NurOwn did not reach statistical significance. In addition, the agency did not believe that a "floor effect" was demonstrated. However, the briefing documents only give the FDA's opinion of the BLA and at the AdCom meeting BrainStorm's management will be given the opportunity to present their case for why NurOwn should be approved. The company continues to assert that the totality of the evidence shows that NurOwn has a consistent and clinically meaningful treatment effect across a broad range of patients with ALS. We expect this notion to be expanded upon by management during the presentation. There will also be a 60-minute open discussion for the general public to comment, during which time there are sure to be multiple ALS patients testifying. The company, and the ALS patients and advocates who testify, will likely call on the agency for regulatory flexibility in an effort to achieve a positive outcome to the AdCom meeting and eventual approval of NurOwn, which has a PDUFA date of December 8, 2023.

Conclusion

We are eagerly anticipating BrainStorm's presentation, during which time the company will be able to respond to the agency's concerns that were addressed in the briefing documents. When examining all of the positive comments already submitted in support of NurOwn, it is clear that many of those involved in the clinical trials of NurOwn believe that the drug should be approved. We continue to predict a positive outcome for the AdCom and eventual approval of NurOwn on (or before) the PDUFA date of December 8, 2023. Our valuation remains at $20 per share.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
MSC-NTF Stem Cells	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$20**	**$258**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$20**	**$258**
YOY Growth	-					-	-	-
Cost of Goods / Services	$0.0	$0	$0	$0	$0	$0.0	$2.0	$25.0
Product Gross Margin	-	-	-	-	-	-	*90%*	*90%*
R&D	$14.0	$2.9	$5.7	$3.6	$3.9	$16.1	$15.0	$20.0
% R&D	-	-	-	-		-	-	-
SG&A	$10.9	$2.2	$4.9	$2.9	$3.2	$13.2	$30.0	$75.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($24.8)	($5.2)	($10.6)	($6.5)	($7.1)	($29.4)	($27.0)	$138.0
Net Other Income	$0.5	$0.1	($0.2)	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($24.3)	($5.1)	($10.8)	($6.5)	($7.1)	($29.4)	($27.0)	$138.0
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)	($6.5)	($7.1)	($29.4)	($27.0)	$138.0
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.67)**	**($0.14)**	**($0.28)**	**($0.14)**	**($0.15)**	**($0.70)**	**($0.54)**	**$2.51**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	36.5	36.7	38.2	45.0	47.0	41.7	50.0	55.0

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

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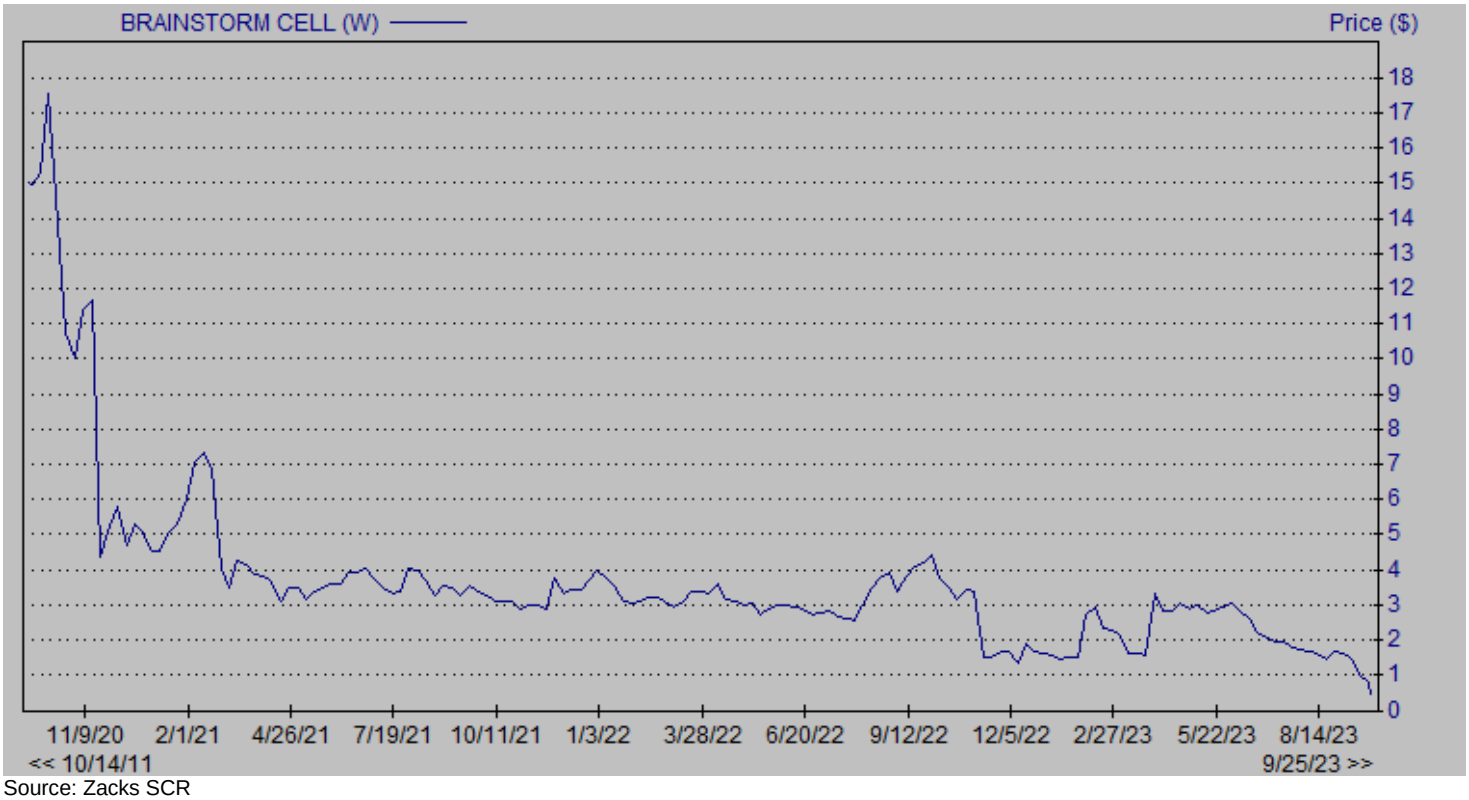

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