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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Preparing for AdCom on September 27, 2023…

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 (08/18/23)	$1.49
Valuation	**$20.00**

OUTLOOK

On August 14, 2023, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the second quarter of 2023 and provided a business update. The company is focusing all its efforts on preparing for the Advisory Committee (AdCom) meeting that is scheduled for September 27, 2023. We anticipate that the briefing documents for the AdCom will be published 48 hours prior to the meeting. The PDUFA action date is targeted to occur by December 8, 2023.

The company recently presented new biomarker data from the Phase 3 trial of NurOwn at the 2023 Gordon Research Conference. The data show that NurOwn significantly elevated markets of neuroprotection and lowered markers of neuroinflammation and neurodegeneration, particularly NfL. The ALS literature suggests decreases in NfL are reasonably likely to predict clinical benefit in ALS.

SUMMARY DATA

52-Week High	**$4.42**
52-Week Low	**$1.37**
One-Year Return (%)	**-60.42**
Beta	**-0.53**
Average Daily Volume (sh)	**208,026**
Shares Outstanding (mil)	**45**
Market Capitalization ($mil)	**$67**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**25**
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	**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 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

Preparing for Advisory Committee Meeting on September 27, 2023

In June 2023, BrainStorm Cell Therapeutics, Inc. (BCLI) announced that 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. In addition, the FDA assigned a Prescription Drug User Fee Act (PDUFA) action date targeted to occur by December 8, 2023.

The company's immediate top priority is preparing for the AdCom as well as complete preparations for commercial launch of NurOwn, if approved. BrainStorm has been working with outside consultants to ensure it prepares a powerful and persuasive presentation and is fully prepared for the questions that the FDA is likely to raise.

The briefing documents for the meeting will be posted approximately 48 hours prior to the meeting and at that time we will learn what questions will be posed to the committee to vote on. We have the utmost confidence in BrainStorm's senior management and believe it will win the support of the Advisory Committee to secure a positive vote for NurOwn. We believe the political environment is quite favorable regarding access to new therapies for patients with terminal illnesses such as ALS, particularly for therapies that have a strong safety and tolerability record. Thus, given the totality of the data that BrainStorm has accumulated for NurOwn, we are confident in a positive outcome for the AdCom and eventual approval of the drug.

The FDA has established a docket for public comment on the AdCom (docket number FDA-2023-N-2608). Comments can be submitted by anyone (https://www.regulations.gov/document/FDA-2023-N-2608-0001/comment) and those received before September 20, 2023 will be provided to the Advisory Committee. As of August 17, 2023, there have been 125 comments submitted, the vast majority of which are strongly in support of NurOwn being approved.

Presentation on Biomarker Data at Gordon Research Conference

In July 2023, BrainStorm announced new biomarker data from the Phase 3 trial of NurOwn was presented at the 2023 ALS and Related Motor Neuron Diseases Gordon Research Conference. A copy of the poster can be accessed here. The study examined biomarkers that were pre-specified in the Phase 3 trial: 16 pro-inflammatory/anti-inflammatory, eight neurodegeneration, and nine neuroprotection biomarkers. Cerebrospinal fluid was collected from trial participants at seven time points.

Statistical modeling identified three biomarkers that predict clinical outcomes observed with NurOwn treatment, including change in Galectin-1 and baseline biomarkers neurofilament light (NfL) and LAP/TGFβ1. NfL has previously been shown to be prognostic of ALS disease progression (Gaiani *et al*., 2017). After accounting for baseline disease covariates, NurOwn-treated participants had reduced NfL values from baseline to Week 20 compared to placebo ($P<0.05$). In addition, NfL baseline values were predictive of ALS disease progression, which confirms results from other ALS trials. Lastly, using a natural disease progression model showed a relationship between reductions in NfL from baseline due to NurOwn treatment and ALSFRS-R change from baseline. The correlation between NfL level at Week 20 and ALSFRS-R at Week 28, after adjusting for the predicted changes due to natural disease progression, was r=-0.365, $P=0.087$.

The results presented by BrainStorm show the importance of examining biomarker data, particularly NfL, which is a predictor of disease progression. Reductions in NfL that result from NurOwn treatment are associated with better clinical outcomes in ALS.

Financial Update

On August 14, 2023, BrainStorm announced financial results for the second quarter of 2023. As anticipated, the company did not report any revenues during the second quarter of 2023. Net R&D expenses for the second quarter of 2023 were $2.8 million, compared to $5.1 million during the second quarter of 2022. The decrease was primarily due to decreased costs related to the Phase 3 and Phase 2 clinical trials and decreased payroll expense, travel, materials, depreciation, and other activities. G&A expenses for the second quarter of 2023 were $2.7 million

compared to $2.5 million for the second quarter of 2022. The increase was primarily due to increased payroll and consultant costs.

The company exited the second quarter of 2023 with approximately $0.8 million in cash, cash equivalents, and short-term deposits. Subsequent to the end of the quarter, the company entered into a securities purchase agreement with a single institutional investor for the sale of 4.054,055 shares at an offering price of $1.85 per share. In addition, the investor received warrants to purchase up to an aggregate 4,054,055 shares. The warrants have an exercise price of $2.00 per share. Gross proceeds from the offering were approximately $7.5 million. As of August 14, 2023, BrainStorm had approximately 45.0 million common shares outstanding and, when factoring in stock options, warrants, and restricted stock, a fully diluted share count of approximately 50.7 million.

Conclusion

With the AdCom only a little more than a month away, BrainStorm's top priority will be putting together a professional, polished, and persuasive presentation to gain the support of the Advisory Committee and receive a positive outcome for the meeting. We remind investors that the Briefing Documents should become public approximately 48 hours prior to the meeting, and it is at this time that the stock is likely to react one way or the other. From prior experience it is reasonable to assume that the Briefing Documents will likely read negative, however we ask investors not to over-react as the Briefing Documents only give the FDA's view regarding NurOwn. It is on the day of the AdCom that the public will get to hear BrainStorm's presentation, which we have the utmost confidence will be excellent. 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. Having already accounted for an expected financing in our model, our valuation remains at $20 per share.

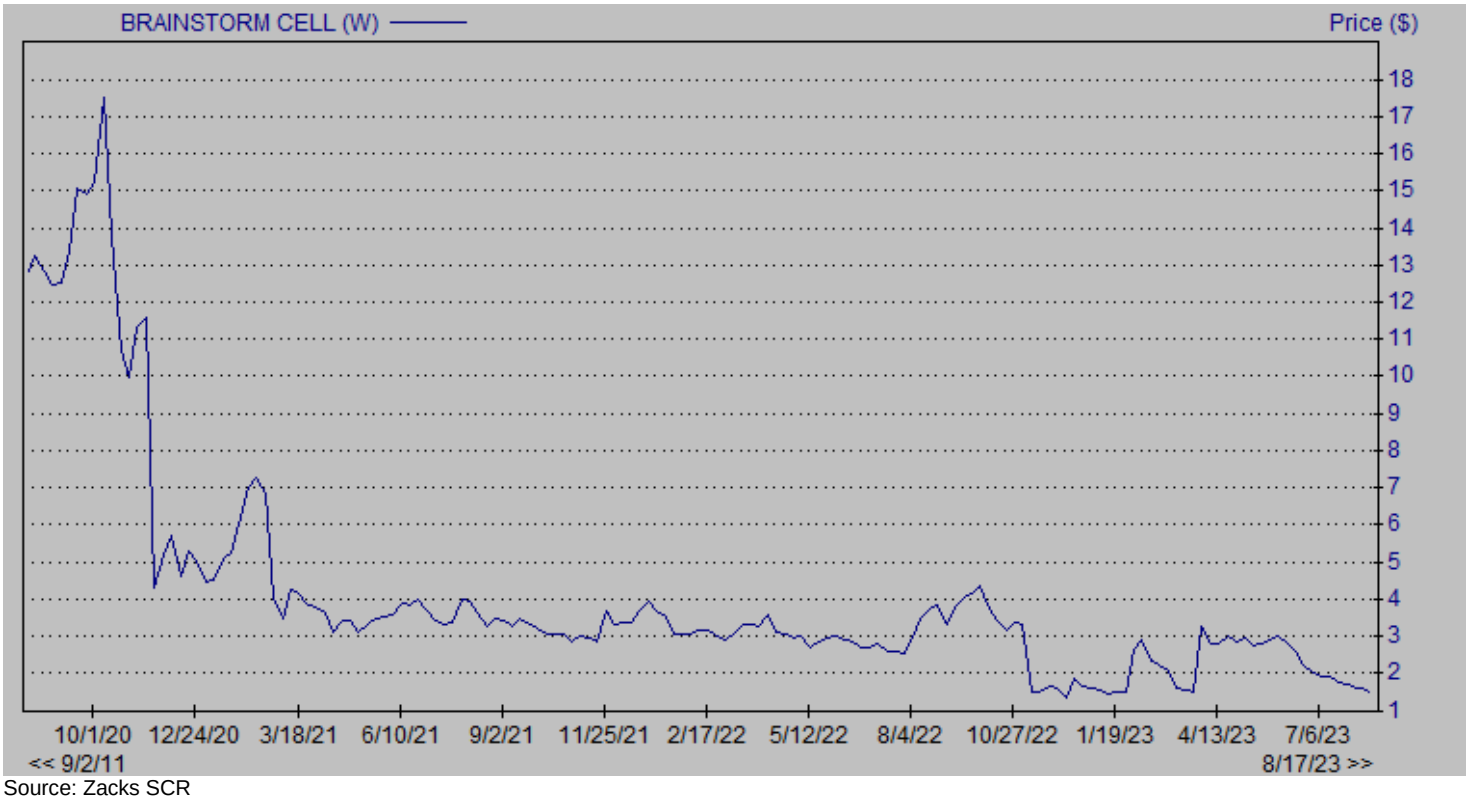
PROJECTED FINANCIALS

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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