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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Receives a Refusal to File Letter from the FDA for NurOwn® BLA…

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 $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 (11/17/22)	$1.68
Valuation	**$9.00**

OUTLOOK

On November 10, 2022, BrainStorm Cell Therapeutics, Inc. (BCLI) announced that the company received a refusal to file letter from the U.S. Food and Drug Administration (FDA) regarding the Biologics License Application (BLA) for NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS). The FDA indicated that the company could request a Type A meeting to discuss the BLA filing. BrainStorm has 30 days from the receipt of the refusal to file letter to request a Type A meeting and the FDA then has 30 days to schedule the meeting. The company is focused on getting to an Advisory Committee meeting with the FDA so that the totality of the data regarding NurOwn can be discussed in an open forum.

SUMMARY DATA

52-Week High	**$4.42**
52-Week Low	**$1.52**
One-Year Return (%)	**-48.31**
Beta	**-0.30**
Average Daily Volume (sh)	**319,448**
Shares Outstanding (mil)	**36**
Market Capitalization ($mil)	**$61**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**11**
Insider Ownership (%)	**21**
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)
2021	0 A	0 A	0 A	0 A	0 A
2022	0 A	0 A	0 A	0 E	0 E
2023					0 E
2024					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.19 A	-$0.36 A	-$0.15 A	$0.02 A	-$0.67 A
2022	-$0.15 A	-$0.20 A	-$0.19 A	-$0.18 E	-$0.72 E
2023					-$0.60 E
2024					-$0.70 E

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WHAT'S NEW

Business Update

Refusal to File Letter Received for NurOwn® BLA

On November 10, 2022, BrainStorm Cell Therapeutics, Inc. (BCLI) announced the receipt of a refusal to file letter from the U.S. Food and Drug Administration (FDA) for the Biologics License Application (BLA) for NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS). The company indicated that there were two issues with the BLA: the clinical and statistics section, in which the FDA stated that it still seeks substantial evidence of efficacy as shown through a statistically significant treatment effect in the primary endpoint, and the chemistry manufacturing and controls (CMC), which the company believes can be easily corrected.

The refusal to file letter is disappointing, however it is by no means a dead end. The FDA indicated that BrainStorm can request a Type A meeting, which the company has 30 days to do following receipt of the refusal to file letter. The FDA then has 30 days in which to set a date for the meeting. BrainStorm's main objective at this point is to get to an Advisory Committee meeting such that the totality of the data regarding NurOwn can be discussed in an open forum. Thus, we believe the company will emphasize this point in its meeting with the FDA as they work with the agency to figure out a regulatory path forward for NurOwn in ALS.

New Sensitivity Analyses from Phase 3 ALS Trial Presented at 21st Annual NEALS Meeting

On November 7, 2022, BrainStorm announced the presentation of a poster with new analyses from the Phase 3 ALS trial at the 21st Annual NEALS Meeting. The presentation focused on the limitations in the ALSFRS-R scale and discussed two orthogonal approaches designed to account for its inability to accurately assess disease progression in patients with advanced ALS.

The mean ALSFRS-R score of participants in the Phase 3 ALS trial was 30.9 (± 6.3), and included a number of participants with individual ALSFRS-R item scores of zero at baseline. This meant that further deterioration could not be measured on those items and results in a slowing of ALS decline due to a "floor effect" of the ALSFRS-R that can result in misclassification of the primary endpoint.

To better understand the true effect of NurOwn compared to placebo, two post-hoc sensitivity analyses were used to identify and remove participants from analyses that were most likely impacted by the floor effect. The two methods were: 1) Total Score Threshold (TST), which removed participants with ALSFRS-R score ≤ 25; and 2) Item Level Threshold (ITL), which removed participants with a baseline score of 0 or 1 in at least 5 of 6 of the ALSFRS-R Fine and Gross Motor scale items. The TST and ITL removed 23% (n=44) and 16% (n=30) of trial participants from analyses, respectively. Both the TST and ITL sensitivity analyses showed that participants treated with NurOwn had a higher rate of clinical response and less function loss across 28 weeks compared to placebo.

New Biomarker Analyses from Phase 3 ALS Trial Presented at 5th Annual ALS One Research Symposium

In October 2022, BrainStorm announced the presentation of new biomarker data at the 5th Annual ALS One Research Symposium. The company examined the effects of NurOwn and placebo on cerebrospinal fluid (CSF) biomarkers across pathways of neuroinflammation, neurodegeneration, and neuroprotection. Overall, NurOwn was shown to decrease biomarkers associated with neuroinflammation and neurodegeneration, and increase neuroprotective biomarkers over 20 weeks.

The new analyses examined the change in biomarkers for patients with ALSFRS-R score of > 25 and ≤ 25. Both subgroups showed decreases in neuroinflammatory and neurodegenerative biomarkers and increases in neuroprotective biomarkers in NurOwn-treated participants compared to placebo. This indicates that NurOwn had similar biological effects on ALS participants regardless of how advanced the disease was at baseline.

Financial Update

On November 14, 2022, BrainStorm announced financial results for the third quarter of 2022. As anticipated, the company did not report any revenues during the third quarter of 2022. Net R&D expenses for the third quarter of 2022 were $3.8 million, compared to $3.6 million during the third quarter of 2021. The increase was primarily due to

an increase in costs associated with payroll, material costs, and depreciation. Excluding participation from the Israeli Innovation Authority (IIA) and other grants, R&D expenses were $4.0 million in the third quarter of 2022 compared to $3.6 million in the third quarter of 2021. G&A expenses for the third quarter of 2022 were $3.1 million compared to $1.7 million for the third quarter of 2021. The increase was primarily due to an increase in payroll and stock-based compensation.

The company exited the third quarter of 2022 with approximately $7.4 million in cash, cash equivalents, and short-term deposits. As of November 14, 2022, BrainStorm had approximately 36.5 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 40.1 million.

Conclusion

It's unfortunate that BrainStorm received a refusal to file letter from the FDA for the NurOwn BLA for the treatment of ALS. We look forward to updates from the company regarding the Type A meeting with the FDA and continue to be cautiously optimistic that the company and the agency will be able to come to an agreement for a regulatory path forward for NurOwn in ALS. Due to the receipt of the refusal to file letter we have decreased the probability of approval for NurOwn in ALS to 33% and increased the future dilution for capital raises. This has decreased our valuation to $9.00 per share.

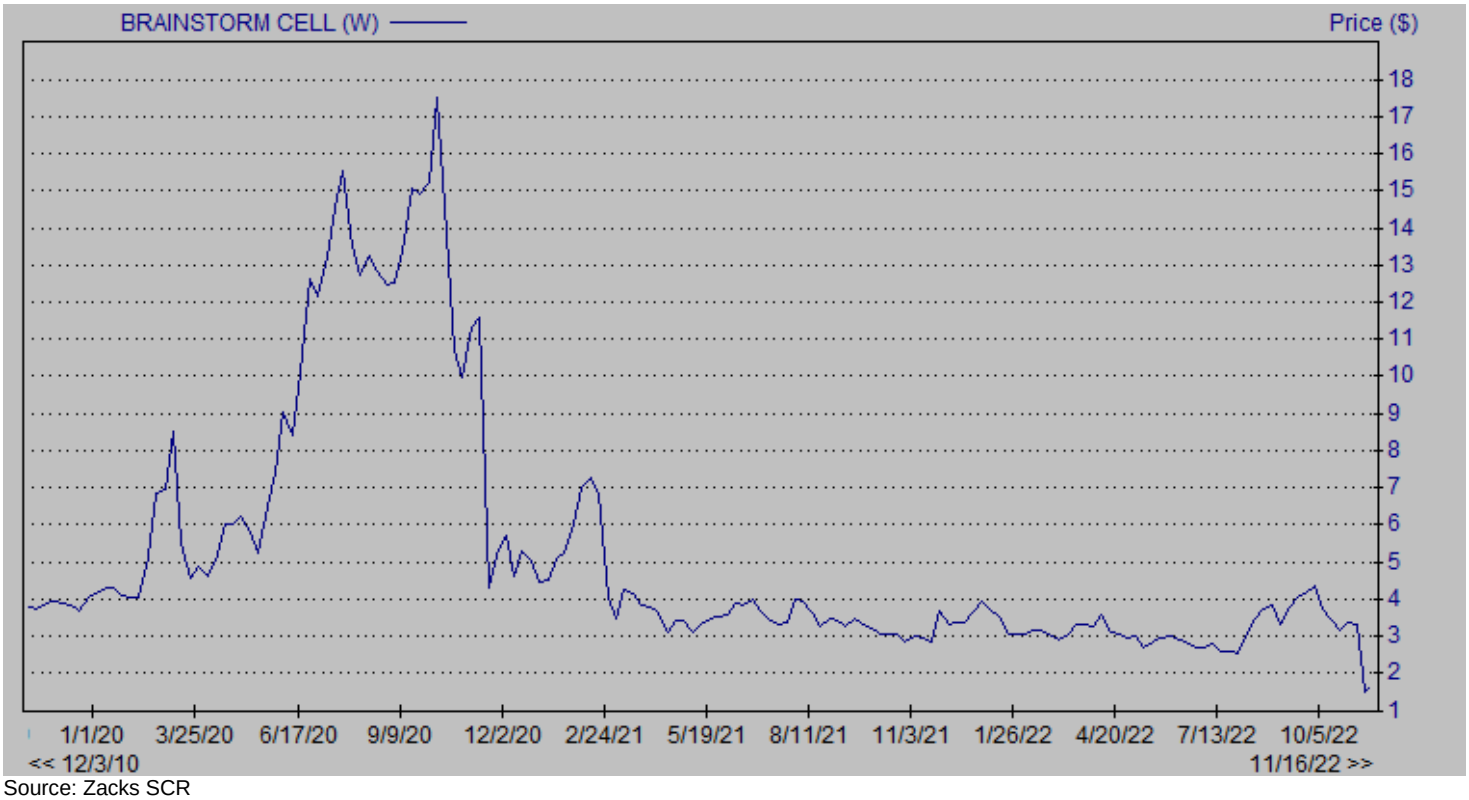
PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 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	$15.2	$2.6	$5.1	$3.8	$4.0	$15.5	$17.0	$20.0
% R&D	-	-	-	-		-	-	-
SG&A	$9.3	$2.9	$2.5	$3.1	$2.5	$10.9	$10.0	$12.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($24.5)	($5.5)	($7.6)	($6.8)	($6.5)	($26.4)	($27.0)	($32.0)
Net Other Income	$0.4	$0.1	$0.1	$0.0	$0.0	$0.3	$0.0	$0.0
Pre-Tax Income	($24.2)	($5.4)	($7.5)	($6.8)	($6.5)	($26.2)	($27.0)	($32.0)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($24.2)	($5.4)	($7.5)	($6.8)	($6.5)	($26.2)	($27.0)	($32.0)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.67)**	**($0.15)**	**($0.20)**	**($0.19)**	**($0.18)**	**($0.72)**	**($0.60)**	**($0.70)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	36.2	36.4	36.5	36.5	36.6	36.5	45.0	46.0

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

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