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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Waiting for Guidance from FDA on Potential Path Forward for NurOwn® in ALS…

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 $10.00/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (02/05/21)	$7.88
Valuation	**$10.00**

OUTLOOK

On February 4, 2021, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the fourth quarter and full year 2020 and provided a business update. We anticipate the company providing an update on the regulatory pathway for NurOwn® in ALS following receipt of formal feedback from the agency. In addition, topline results from the Phase 2 clinical trial of NurOwn in progressive MS are expected before the end of the first quarter of 2021. The company is also continuing to design a Phase 2 clinical trial of NurOwn in Alzheimer's disease. Lastly, we recently reported on results from a preclinical study of the company's exosome-based platform in a mouse model of ARDS, which could be beneficial for treating those suffering from COVID-19. With $45 million in cash as of January 31, 2021, the company is in a strong financial position to advance each of those lead programs.

SUMMARY DATA

52-Week High	**$17.73**
52-Week Low	**$3.99**
One-Year Return (%)	**94.57**
Beta	**0.22**
Average Daily Volume (sh)	**1,307,972**
Shares Outstanding (mil)	**32**
Market Capitalization ($mil)	**$249**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**22**
Insider Ownership (%)	**22**
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)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 E	0 E	0 E	0 E	0 E
2022					50 E
2023					150 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.29 A	-$0.25 A	-$0.14 A	-$0.39 A	-$1.07 A
2021	-$0.27 E	-$0.25 E	-$0.24 E	-$0.24 E	-$0.99 E
2022					$0.00 E
2023					$1.89 E

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WHAT'S NEW

Business Update

Update on NurOwn® in ALS

BrainStorm Cell Therapeutics, Inc. (BCLI) recently provided a corporate update that included information on NurOwn® and its potential regulatory path for amyotrophic lateral sclerosis (ALS). In November 2020, the company announced topline results from the Phase 3 clinical trial of NurOwn in patients with ALS, which did not reach statistical significance for the primary endpoint, a responder analysis examining the percentage of participants that experienced a 1.25 point per month improvement in the post-treatment Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFRS-R) slope.

However, an analysis of a pre-specified subgroup of patients with ALSFRS-R scores > 35, of which approximately 30% of trial participants were included, showed a clinically meaningful treatment response with NurOwn with 34.6% responders compared to 15.6% of responders in placebo-treated participants (*P*=0.288). In addition, the average change in ALSFRS-R score from baseline to Week 28 for this subgroup was -1.77 for NurOwn-treated participants and -3.78 for placebo-treated participants (*P*=0.198). Both of these results suggest NurOwn is having a clinically meaningful effect for patients. The company is continuing to have discussions with the FDA about a potential regulatory pathway for NurOwn in ALS and we anticipate an update once formal guidance is received from the agency. In addition, the company successfully completed a meeting in December 2020 regarding the Chemistry, Manufacturing and Controls (CMC) plans for registration.

The company also initiated an Expanded Access Program (EAP) in which patients who completed the Phase 3 ALS trial and meet specific eligibility requirements will be eligible to continue receiving NurOwn. The EAP was developed in consultation with the FDA and will initially focus on patients less severely affected by ALS. Treatment will take place at the six clinical trial sites that participated in the Phase 3 trial.

Update on NurOwn® in Progressive MS

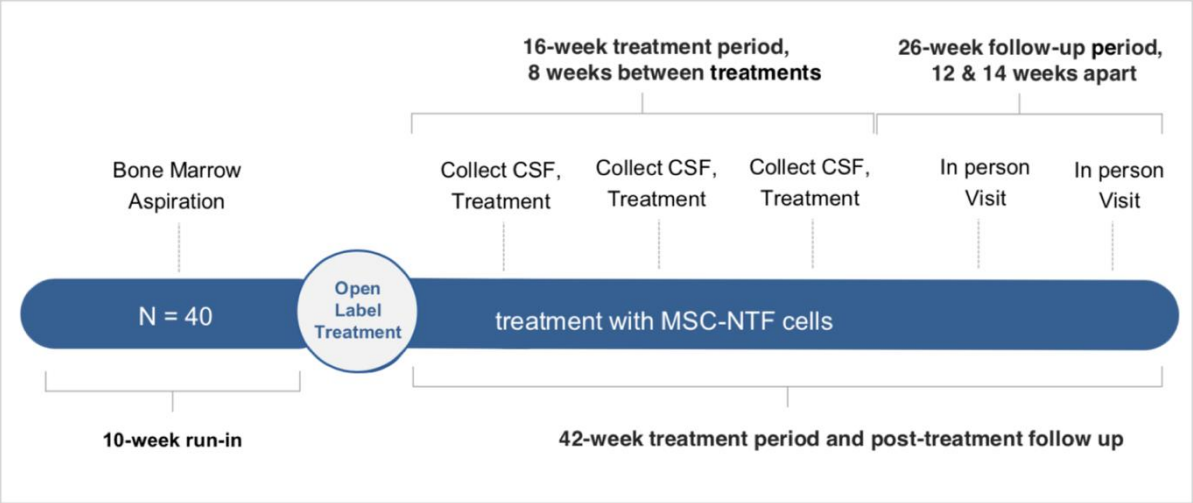
BrainStorm is currently conducting a Phase 2 clinical trial of NurOwn® in patients with progressive multiple sclerosis (MS) (NCT03799718). The trial is an open label, single arm study that is enrolling patients with progressive MS with Expanded Disability Status Scale (EDSS) scores of 3.0 – 6.5. The primary endpoint of the study is the safety and tolerability of three doses of NurOwn® with secondary endpoints examining the timed 25-foot walking speed or 9-hole peg test (both validated MS clinical outcome assessments) along with paired cerebrospinal fluid (CSF) and blood biomarker analysis. The National Multiple Sclerosis Society awarded the company a $0.5 million grant to help fund the study.

On December 18, 2020, the company announced that all dosing has been completed for all patients, with the focus now shifting to completing all remaining clinical trial assessments and biomarker analyses. We anticipate topline results being reported by the end of the first quarter of 2021.

Update on NurOwn® in Alzheimer's Disease

BrainStorm is currently designing a Phase 2 clinical trial of NurOwn in patients with Alzheimer's disease (AD). The trial is expected to enroll approximately 40 patients with prodromal to mild AD. It will be taking place at medical centers in France and the Netherlands. To be eligible for the trial, patients must have been diagnosed with prodromal to mild dementia at least six months prior to enrollment. In addition, patients must score between 20-30 on the Mini-Mental State Exam (MMSE) and have a Clinical Dementia Rating (CDR) global score of 0.5-1.0. The MMSE is a series of questions that are designed to assess a patient's mental skills, with the maximum score being 30 points and a score of 20-24 suggesting mild dementia. The CDR is a scale used to characterize six domains of cognitive and functional performance with a score of 0.5 suggesting very mild dementia and a score of 1.0 suggesting mild dementia.

The primary objective of the trial is to assess the safety and tolerability of three intrathecal injections of NurOwn® in AD patients. Following bone marrow aspiration during a 10-week run-in period, patients will be treated three times with NurOwn®, with eight weeks between treatments. Follow-up visits will occur 12 and 26 weeks following the final injection of NurOwn® for a total trial length of 52 weeks. The following figure gives an overview of the trial design.



Source: BrainStorm Cell Therapeutics, Inc.

Financial Update

On February 4, 2020, BrainStorm announced financial results for 2020. As anticipated, the company did not report any revenues during 2020. Net R&D expenses for 2020 were $22.3 million compared to $17.2 million in 2019. The increase was due to increased payroll costs, stock-based compensation, a decrease in funds received from the treatment of patients under the hospital exemption regulatory pathway, and a decrease in funds received from the Israel Innovation Authority (IIA) and the California Institute for Regenerative Medicine (CIRM). Excluding participation from the IIA and CIRM, R&D expenses decreased by $0.1 million from $24.7 million in 2019 to $24.6 million in 2020. G&A expenses increased to $9.4 million compared to $5.8 million in 2019. The increase was primarily due to increased payroll cost, stock-based compensation, and consultant costs.

The company exited 2020 with approximately $41.9 million in cash, cash equivalents, and short-term deposits. Since December 31, 2020, BrainStorm has raised approximately $3.1 million and as of January 31, 2021 the company had approximately $45 million in cash. As of February 4, 2021, the company had approximately 35.7 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of 40.8 million.

Conclusion

We anxiously await the company's update regarding the regulatory pathway for NurOwn in ALS and the next steps in that process. In addition, we look forward to results from the Phase 2 clinical trial of NurOwn in progressive MS, which should be reported by the end of the first quarter of 2021. We have advanced our DCF model ahead a year, however with the additional shares issued recently our valuation remains at $10 per share.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2020 A	Q1 E	Q2 E	Q3 E	Q4 E	2021 E	2022 E	2023 E
MSC-NTF Stem Cells	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$50**	**$150**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$50**	**$150**
YOY Growth	-					-	-	-
Cost of Goods / Services	$0.0	$0	$0	$0	$0	$0.0	$5.0	$15.0
Product Gross Margin	-	-	-	-	-	-	*90.0%*	*90.0%*
R&D	$22.3	$6.0	$6.0	$6.0	$6.0	$24.0	$30.0	$33.0
% R&D	-	-	-	-		-	-	-
SG&A	$9.4	$2.8	$2.8	$2.9	$3.0	$11.5	$15.0	$17.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($31.7)	($8.8)	($8.8)	($8.9)	($9.0)	($35.5)	$0.0	$85.0
Net Other Income	($0.1)	$0.0	$0.0	$0.0	$0.0	$0.1	$0.0	$0.0
Pre-Tax Income	($31.8)	($8.8)	($8.8)	($8.9)	($9.0)	($35.4)	$0.0	$85.0
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($31.8)	($8.8)	($8.8)	($8.9)	($9.0)	($35.4)	$0.0	$85.0
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.07)**	**($0.27)**	**($0.25)**	**($0.24)**	**($0.24)**	**($0.99)**	**$0.00**	**$1.89**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	29.8	33.0	35.5	37.0	38.0	35.9	40.0	45.0

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

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