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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Phase 3 ALS Results in 4Q20…

Based on our probability adjusted DCF model that takes into account potential future revenues from NurOwn® in ALS, BCLI is valued at $17.50/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (02/20/20)	$5.96
Valuation	**$17.50**

OUTLOOK

BrainStorm Cell Therapeutics, Inc. (BCLI) is currently conducting a Phase 3 clinical trial of NurOwn® in patients with amyotrophic lateral sclerosis (ALS). The trial is fully enrolled and we anticipate topline results in the fourth quarter of 2020.

The company recently conducted a meeting with the FDA at which the agency confirmed the ongoing Phase 3 trial is collecting relevant data for the assessment of NurOwn® efficacy and that they are committed to working with BrainStorm to identify a regulatory path forward.

The company recently released financial results for 2019 and disclosed that the current cash balance is $11.1 million as a result of raising approximately $18.6 million thus far from the ATM agreement, which the company utilized following an increase in the stock price.

SUMMARY DATA

52-Week High	**$6.33**
52-Week Low	**$3.54**
One-Year Return (%)	**54.81**
Beta	**1.34**
Average Daily Volume (sh)	**704,912**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$156**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
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	**Average**
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)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 E	0 E	0 E	0 E	0 E
2021					0 E
2022					50 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.24 A	-$0.23 A	-$0.25 A	-$0.34 A	-$1.06 A
2019	-$0.22 E	-$0.23 E	-$0.24 E	-$0.25 E	-$0.94 E
2020					-$0.80 E
2021					$0.10 E

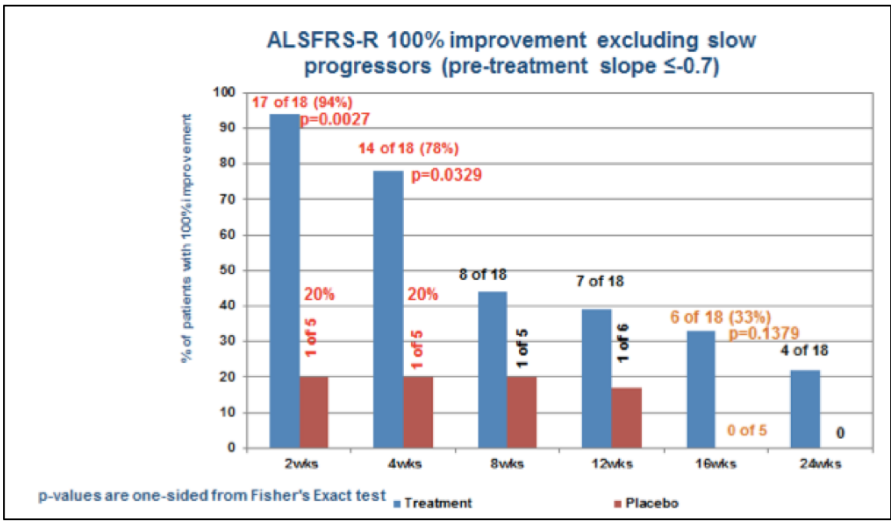
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Business Update

Topline Data from Phase 3 ALS Trial Expected in 4Q20

BrainStorm Cell Therapeutics, Inc. (BCLI) is currently conducting a Phase 3 clinical trial of NurOwn® in patients with amyotrophic lateral sclerosis (ALS) (NCT03280056). A total of 200 patients were randomized 1:1 to receive NurOwn® or placebo in the randomized, double blind, placebo controlled, multi-dose trial. Cells were extracted once from each patient prior to treatment, with all administrations of NurOwn® derived from the same extraction of cells due to a cryopreservation process the company developed for long-term storage of mesenchymal stem cells (MSC). Just as with the company's prior studies, there was a 3-month run-in period prior to the first treatment with two additional NurOwn® treatments occurring two and four months following the first treatment. The company is focusing the trial on faster-progressing ALS patients since those patients demonstrated superior outcomes in the Phase 2 trial of NurOwn®. The primary outcome of the trial is the ALSFRS-R score responder analysis and we anticipate topline results in the fourth quarter of 2020.

The decision to focus the study on faster-progressing patients was based in part on an examination of those patients that experienced 100% improvement in ALSFRS-R change in slope follow treatment in the Phase 2 clinical trial. A 100% improvement means that a patient had to have either stable disease or an improvement in ALSFRS-R score. The following graph shows the results from the Phase 2 trial for patients who had steadily progressing disease (defined as a decrease in ALSFRS-R slope of ≥-0.7 points/month) and then saw their progression either stabilize or improve following treatment. One month post treatment, 78% (14/18) of NurOwn® treated patients showed either stabilization or improvement compared to only 20% (1/5) of placebo-treated patients. Even out to 16 weeks, 33% (6/18) of NurOwn® treated patients continued to be stable compared to 0% of the placebo-treated patients. As a reminder, the Phase 2 trial was only one injection of NurOwn®, thus we believe these results could at least be replicated, if not improved upon, in the Phase 3 trial in which multiple doses of NurOwn® are being administered.



Source: BrainStorm Cell Therapeutics

Meeting with FDA Regarding Potential Regulatory Pathway for NurOwn®

On February 11, 2020, BrainStorm announced that the company held a high level meeting that was attended by senior leadership of the Center for Biologics Evaluation and Research (CBER) from the U.S. FDA at which the agency confirmed that the ongoing Phase 3 clinical trial of NurOwn® is collecting relevant data that will be vital to evaluating its clinical efficacy. In addition, the FDA indicated that they will look at the "totality of the evidence" when determining whether to approve NurOwn®. Lastly, the agency stated their commitment to working with BrainStorm to identify a regulatory path forward for NurOwn®, which may include an expedited statistical review of the Phase 3 data. The FDA has various options at their disposal to do a statistical analysis more quickly and they indicated that those options will be available to BrainStorm.

We are encouraged by the outcome of this meeting as it indicates that the FDA understands the urgent medical need for ALS patients and the agency is willing to work with BrainStorm to get NurOwn® through the regulatory pathway as expeditiously as possible.

Update on Hospital Exemption Program in Israel

The Hospital Exemption (HE) program in Israel allows the treatment of up to 13 ALS patients with NurOwn® using a pathway that was pioneered by the European Medicines Agency. It is a similar situation to accelerated approval, however the approval is to a specific medical facility, which in this case is the Tel Aviv Sourasky Medical Center (Ichilov Hospital). Thus far, eleven ALS patients have been treated with NurOwn® through this program. The company is currently examining interim clinical results, which may be published in the Spring of 2020. In addition, we believe this data may be part of the "totality of the evidence" that the FDA has indicated it will use to determine whether to approve NurOwn®.

Update on Phase 2 Progressive Multiple Sclerosis Trial

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.

The trial is currently more than half enrolled. The company has yet to determine whether an interim analysis will take place, which would include an examination of both clinical and biomarker data. We anticipate topline results being reported in the fourth quarter of 2020.

Financial Update

On February 18, 2020, BrainStorm announced financial results for 2019. As anticipated, the company did not report any revenues during 2019. Net R&D expenses for 2019 were $17.2 million compared to $8.3 million for 2018. The increase was primarily due to increased costs associated with the ongoing Phase 3 clinical trial of NurOwn® and a decrease in participation of the Israel Innovation Authority (IIA) and the California Institute for Regenerative Medicine (CIRM). The increase was partially offset by approximately $2.4 million received in connection with the treatment of patients under the HE program. Excluding participation from the IIA and CIRM, R&D expenses were $24.7 million in 2019 compared to $16.3 million in 2018. G&A expenses for 2019 and 2018 were both $5.8 million. Net loss for 2019 was $23.2 million, or $1.06 per share, compared to a net loss of $13.9 million, or $0.70 per share, in 2018.

The company exited 2019 with $0.6 million in cash and cash equivalents. However, as of Feb. 11, 2020 the company had approximately $11.1 million in cash due to the use of the At the Market (ATM) facility that was enacted in 2019. BrainStorm has raised approximately $18.6 million from that facility thus far at an average price of $4.75 per share. In addition, the company has approximately $3.4 million remaining from the IIA and CRIM grants. As of February 14, 2020, the company had approximately 26.2 million shares outstanding and when factoring in warrants and stock options a fully diluted share count of approximately 32.0 million.

Conclusion

We are anxiously awaiting the results of the Phase 3 clinical trial of NurOwn® in the fourth quarter of 2020 and we are very encouraged by the FDA's seeming commitment to working with BrainStorm to identify a regulatory path forward for NurOwn®. In addition, we were glad to hear that the MS trial is over half enrolled and we look forward to results from that study in the fourth quarter of 2020 as well. We estimate that if successful NurOwn® could attain peak sales of $500 million in MS, while in ALS we believe sales of $1 billion are possible. Our valuation for BrainStorm increased slightly after moving our DCF model ahead a year, partially offset by the increase in shares outstanding, to $17.50 per share.

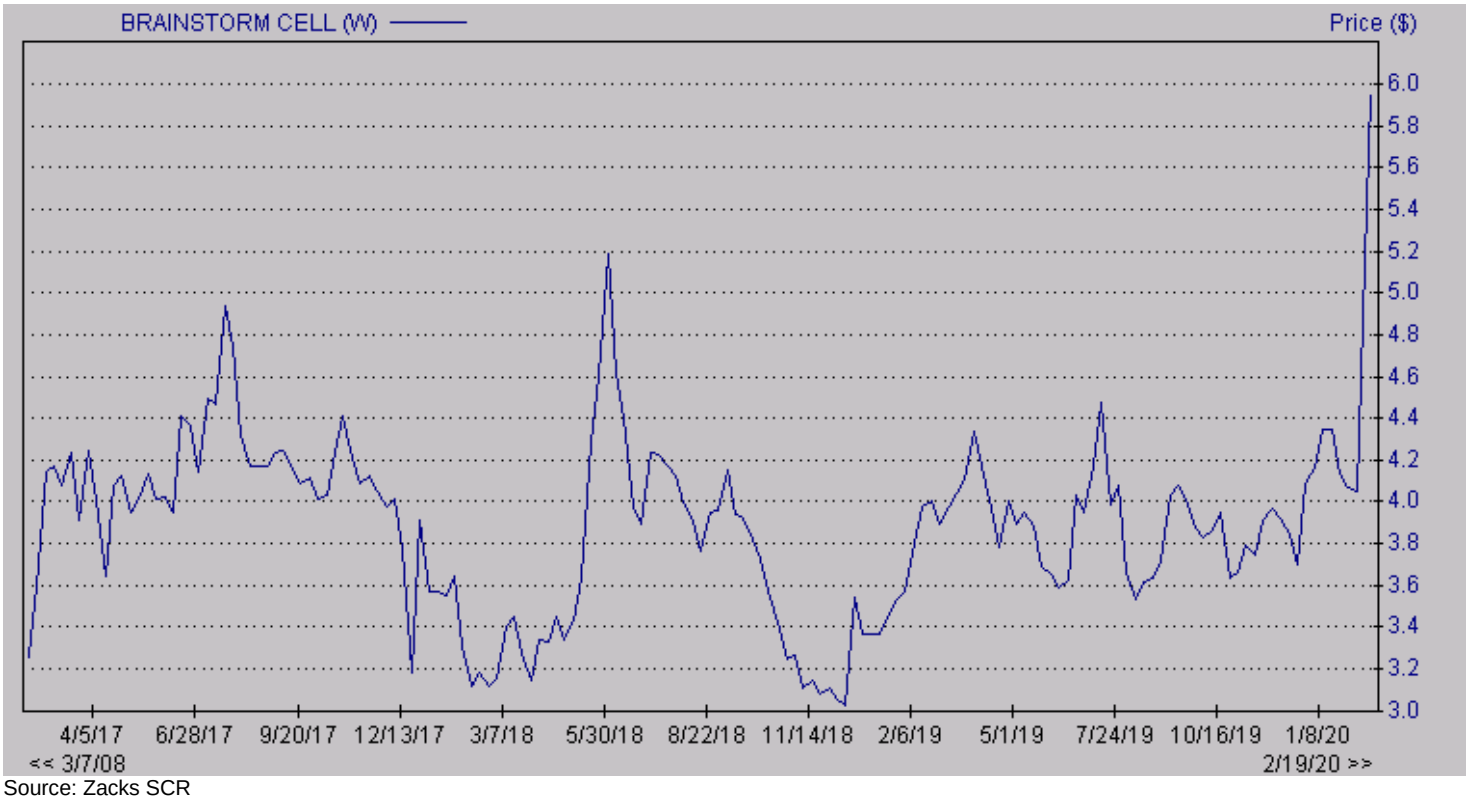
PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2019 A	Q1 E	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 E
MSC-NTF Stem Cells	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$50**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$50**
YOY Growth	-					-	-	-
Cost of Goods / Services	$0.0	$0	$0	$0	$0	$0.0	$0.0	$7.5
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$17.2	$4.0	$4.5	$5.0	$6.0	$19.5	$20.0	$20.0
% R&D	-	-	-	-		-	-	-
SG&A	$5.8	$1.5	$1.6	$1.6	$1.6	$6.3	$6.5	$19.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($23.0)	($5.5)	($6.1)	($6.6)	($7.6)	($25.8)	($26.5)	$3.5
Net Other Income	($0.3)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($23.3)	($5.5)	($6.1)	($6.6)	($7.6)	($25.8)	($26.5)	$3.5
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($23.3)	($5.5)	($6.1)	($6.6)	($7.6)	($25.8)	($26.5)	$3.5
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.06)**	**($0.22)**	**($0.23)**	**($0.24)**	**($0.25)**	**($0.94)**	**($0.80)**	**$0.10**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	21.9	25.0	26.5	28.0	30.0	27.4	33.0	35.0

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

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