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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: The Countdown to Phase 3 ALS Data Begins…

Based on our probability adjusted DCF model that takes into account potential future revenues from NurOwn® in ALS and MS, 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 (05/08/20)	$5.91
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 quickly responded to the challenges presented by the ongoing coronavirus pandemic, and because of this we currently don't anticipate any delays in reporting topline results from the ALS trial. The pandemic has affected enrollment in the Phase 2 trial in progressive multiple sclerosis (MS), due to clinical sites being closed, but the company is hopeful that those sites will open in the near future and patient enrollment and treatment can resume. We anticipate an interim analysis being performed following treatment of the first 50% of patients.

SUMMARY DATA

52-Week High	**$8.88**
52-Week Low	**$3.54**
One-Year Return (%)	**47.01**
Beta	**1.03**
Average Daily Volume (sh)	**429,548**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$155**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
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 A	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	-$0.29 A	-$0.21 E	-$0.22 E	-$0.25 E	-$0.96 E
2020					-$0.80 E
2021					$0.10 E

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WHAT'S NEW

Business Update

Phase 3 ALS Topline Data 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.

Due to the company's proactive response to the ongoing coronavirus pandemic, we don't anticipate any delays in reporting the topline results in the fourth quarter of 2020. For example, the clinical trial sites quickly implemented the option to collect ALS outcomes over the phone to ensure patient safety and preclude hospital visits. Actions such as that were in line with guidelines published by the FDA and will help ensure that all the necessary data for the trial is collected in a safe and timely manner.

New Facility to Support NurOwn Manufacture for EU

On May 7, 2020, BrainStorm announced a lease agreement with the Tel Aviv Sourasky Medical Center to produce NurOwn®, which will allow the company to increase its manufacturing capability for the European Union (EU) and Israel. The company made this move in anticipation of the demand that will be likely when NurOwn® is approved in the EU.

In support of expanding the company's global footprint into the EU, the company announced an agreement with a senior, leading European Medicines Agency (EMA) regulatory consultant who will advise the company in advance of approaching the EMA regarding the regulatory pathway for NurOwn® in the EU.

Abstract Presented at AAN 2020

On May 4, 2020, BrainStorm announced the publication of an abstract describing new data supporting the immunomodulatory effects of NurOwn® on B and T cell function (Aricha *et al*., 2020). The abstract was originally planned to be presented at the recently cancelled 2020 American Academy of Neurology (AAN) annual meeting. The project involved co-culturing bone-marrow derived mesenchymal stem cells (MSC) that secrete neurotrophic factors (NTFs) from healthy donors with human peripheral blood mononuclear cells (PBMC) or isolated B cells. MSC-NTF cells inhibited interferon (IFN)-g and tumor necrosis factor (TNF)-a secretion and CD4+/CD8+ T cell proliferation along with inducing CD4+CD25+FoxP3+ regulatory T cells (which help to downregulate the immune response). In addition, MSC-NTF cells induced the secretion of interleukin (IL)-10, which is important as IL-10 is a known anti-inflammatory cytokine and its overexpression in microglia cells was shown to significantly delay disease onset in a mouse model of ALS (Gravel *et al*., 2016) and B cells of patients with MS show diminished IL-10 secretion (Duddy *et al*., 2004). These results provide novel insights into the mechanism of action of MSC-NTF cells in treating ALS and MS and their role in modulating neuroinflammation.

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). Due to the ongoing coronavirus epidemic, treatments for the first 13 patients have not completed, due in part to Israel not allowing foreign visitors into the country, thus some of the non-Israeli citizens receiving treatment have not been able to complete their treatment protocols. The company had planned on releasing a detailed analysis of the data for these patients, however this may not be possible if delays would mean publishing

the data too close to release of the Phase 3 ALS data. While the company may not be able to publicly share the data from the HE program, it will be shared with the FDA as the agency has indicated it will evaluate the "totality of the evidence" to determine whether to approve NurOwn®. Lastly, the program has been cleared to treat an additional 13 patients once the initial 13 patients have received all treatments.

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.

Due to the ongoing coronavirus pandemic enrollment has been delayed due to access restrictions being put in place, with those restrictions expected to be lifted in May 2020. The company has yet to determine when an interim analysis will take place, which will include an examination of both clinical and biomarker data, but it is anticipated once 50% of participants have been treated.

Financial Update

On May 7, 2020, BrainStorm announced financial results for the first quarter of 2020. As anticipated, the company did not report any revenues during the first quarter of 2020. Net R&D expenses for the first quarter of 2020 were $5.9 million, compared to $3.5 million for the first quarter of 2019. The increase was primarily due to increased expenses associated with the ongoing clinical trials, an increase in stock-based compensation, and a decrease in support from the Israel Innovation Authority (IIA) and California Institute for Regenerative Medicine (CIRM). Excluding participation from the IIA and CIRM, R&D expenses were $7.1 million in the first quarter of 2020, compared to $5.2 million in the first quarter of 2019. G&A expenses for the first quarter of 2020 were $2.4 million, compared to $1.5 million in the first quarter of 2019. The increase was primarily due to increased payroll and stock-based compensation.

The company exited the first quarter of 2020 with approximately $17.5 million in cash, cash equivalents, and short-term investments. During the first quarter of 2020, the company raised approximately $17.9 million from a $20 million At the Market (ATM) facility that was enacted in 2019 and under this facility a total of approximately 4.14 million shares of stock were sold at an average price of $4.83. In March 2020, the company entered into a new $50 million ATM facility and through the end of the first quarter of 2020 the company sold 336,487 shares of common stock at an average price of $5.23 raising gross proceeds of $1.76 million.

As of May 4, 2020, the company had approximately 29.4 million shares outstanding and when factoring in warrants and stock options a fully diluted share count of approximately 35.7 million.

Conclusion

We are glad to hear that there is not currently expected to be a delay in reporting the topline data from the Phase 3 trial of NurOwn® in ALS, which we continue to anticipate in the fourth quarter of 2020. While the stock has had a decent run from its recent lows in March 2020, we still view it as substantially undervalued based on forecasted sales in ALS of >$1 billion and approximately $500 million in MS. Our current valuation is $17.50 per share.

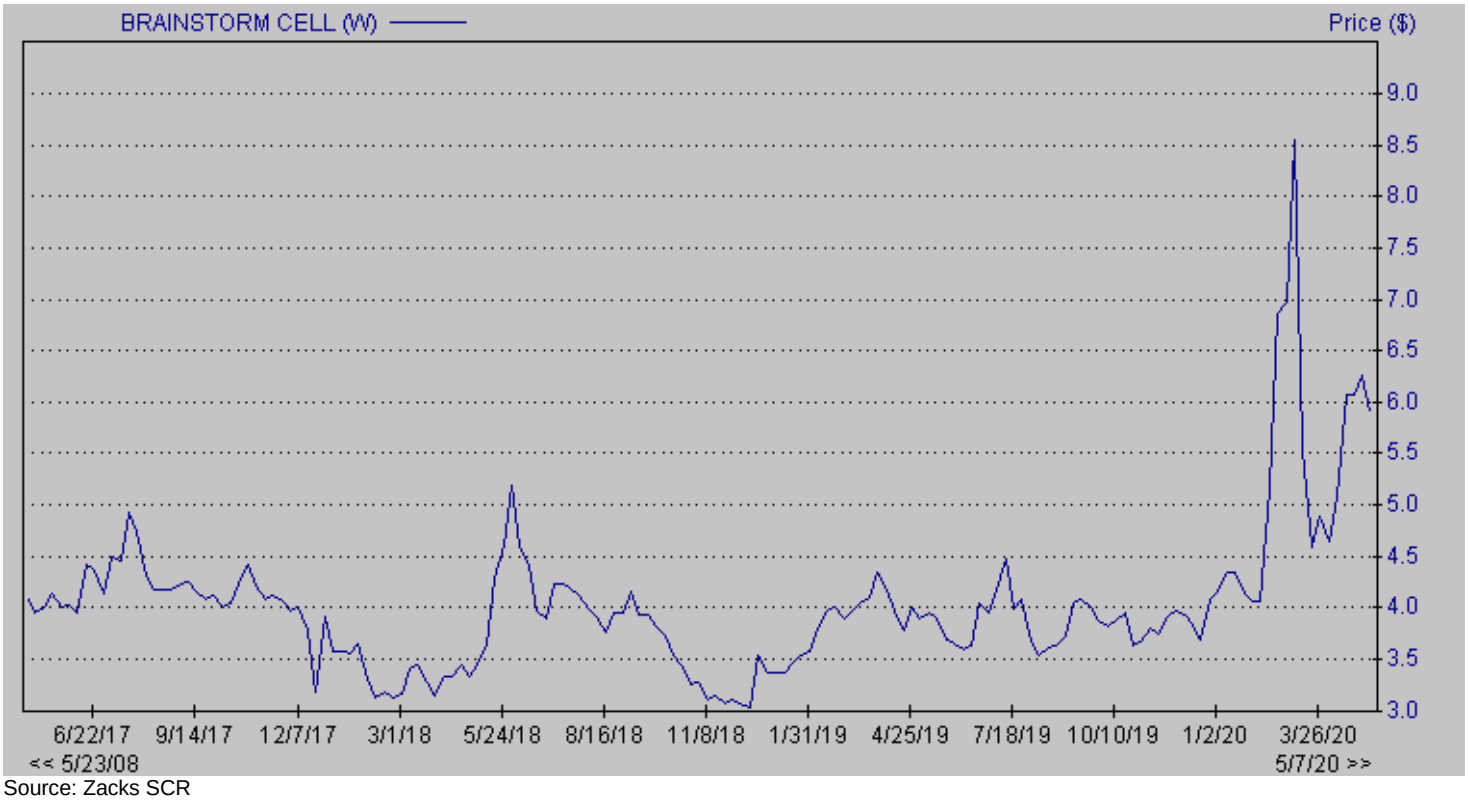
PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2019 A	Q1 A	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	$5.9	$4.5	$5.0	$6.0	$21.4	$20.0	$20.0
% R&D	-	-	-	-		-	-	-
SG&A	$5.8	$2.4	$1.6	$1.6	$1.6	$7.2	$6.5	$19.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($23.0)	($8.3)	($6.1)	($6.6)	($7.6)	($28.6)	($26.5)	$3.5
Net Other Income	($0.3)	$0.2	$0.0	$0.0	$0.0	$0.2	$0.0	$0.0
Pre-Tax Income	($23.3)	($8.1)	($6.1)	($6.6)	($7.6)	($28.4)	($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)	($8.1)	($6.1)	($6.6)	($7.6)	($28.4)	($26.5)	$3.5
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.06)**	**($0.29)**	**($0.21)**	**($0.22)**	**($0.25)**	**($0.96)**	**($0.80)**	**$0.10**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	21.9	28.4	29.5	30.0	30.0	29.5	33.0	35.0

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

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