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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Phase 3 ALS Data Due Soon…

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 $33.00/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (10/15/20)	$15.29
Valuation	**$33.00**

OUTLOOK

On October 15, 2020, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the third quarter of 2020 and provided a business update. The company is set to announce topline results for the Phase 3 clinical trial of NurOwn® in patients with amyotrophic lateral sclerosis (ALS) by the end of November 2020. In preparation for the trial results, the company has been expanding its management team to include a new Head of Market Access and Pricing along with a new Global Head of Regulatory Affairs in preparation for becoming a commercial stage organization. In addition, the company's Phase 2 trial of NurOwn in patients with multiple sclerosis is ongoing and we anticipate dosing being completed by the end of 2020.

SUMMARY DATA

52-Week High	**$17.73**
52-Week Low	**$3.62**
One-Year Return (%)	**292.05**
Beta	**0.83**
Average Daily Volume (sh)	**473,756**
Shares Outstanding (mil)	**32**
Market Capitalization ($mil)	**$483**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**20**
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	**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)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 A	0 A	0 A	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	-$0.25 A	-$0.14 A	-$0.24 E	-$0.91 E
2020					-$0.80 E
2021					$0.10 E

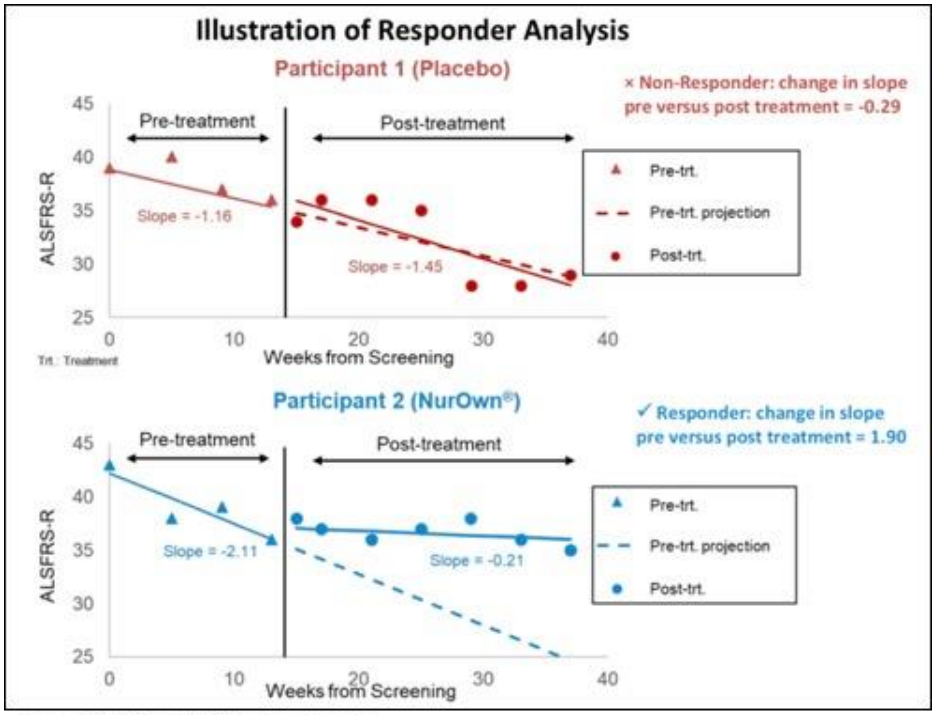
WHAT'S NEW

Business Update

Topline Data from Phase 3 ALS Trial Before End of November 2020

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 now anticipate topline results before the end of November 2020.

The following image provides an illustration of the responder analysis. Each participants ALSFRS-R data is fit with a linear regression model for the pre-treatment period (12 weeks) and the post-treatment period (28 weeks). This provides an estimate of disease progression over time. A responder is defined as a participant with a ≥1.25 points/month improvement in ALSFRS-R post-treatment slope compared to the pre-treatment slope. The graphs shown are for illustration purposes only and do not represent actual data from the trial.



Source: BrainStorm Cell Therapeutics, Inc.

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 now fully enrolled and we anticipate dosing to be completed for all patients by the end of 2020. While the company had previously considered performing an interim analysis, since topline data would be available soon after an interim analysis could be performed the company has decided against performing an interim analysis and will instead report topline data for all 20 patients when it becomes available.

Expansion of Management Team

During the third quarter of 2020, BrainStorm announced the hiring of two additional members of the management team as the company moves toward becoming a commercial stage entity.

- On September, 2, 2020, BrainStorm announced the appointment of Anthony Waclawski, PhD as Executive Vice President, Global Head of Regulatory Affairs. Dr. Waclawski has over 35 years of multinational pharmaceutical experience in the FDA regulatory approval process, including most recently as Vice President and Head, Regulatory and Pharmaceutical Sciences at Bristol-Myers Squibb. His experience is across multiple therapeutic areas and geographies that includes executing successful global regulatory strategies.

- On September 29, 2020, BrainStorm announced the appointment of William White as Senior Vice President, Head of Market Access and Pricing. Mr. White has over 25 years of experience leading successful product commercializations, including most recently with Avexis (now Novartis Gene Therapy) as Vice President of Patient and Market Access. He also held leadership positions in managed care and patient access at Insys Therapeutics and Lundbeck.

Financial Update

On October 15, 2020, BrainStorm announced financial results for the third quarter of 2020. As anticipated, the company did not report any revenues during the third quarter of 2020. Net R&D expenses for the third quarter of 2020 were $1.9 million, compared to $4.0 million for the third quarter of 2019. The decrease was primarily due to decreased costs related to the Phase 3 and Phase 2 clinical trials and increased participation of the Israel Innovation Authority (IIA) and California Institute for Regenerative Medicine (CIRM) under various grant awards. Excluding participation from the IIA and CIRM, R&D expenses were $4.0 million in the third quarter of 2020 compared to $5.6 million in the third quarter of 2019. G&A expenses for the third quarter of 2020 were $2.6 million compared to $1.5 million for the third quarter of 2019. The increase was primarily due to increased payroll, PR, consultant, and stock-based costs.

The company exited the third quarter of 2020 with approximately $28.8 million in cash, cash equivalents, and short-term investments. Subsequent to the end of the quarter, the company raised gross proceeds of approximately $5.1 million through the amended ATM facility originally entered into in March 2020 and amended on September 25, 2020. From September 25, 2020 through Oct. 14, 2020, the company sold 294,723 shares at an average price of $17.21 per share and as of October 14, 2020 the company has approximately $33.1 million in cash, cash equivalents, and short term deposits.

As of September 31, 2020, the company had approximately 31.6 million shares outstanding and, when factoring in warrants and stock options, a fully diluted share count of approximately 37.1 million.

Conclusion

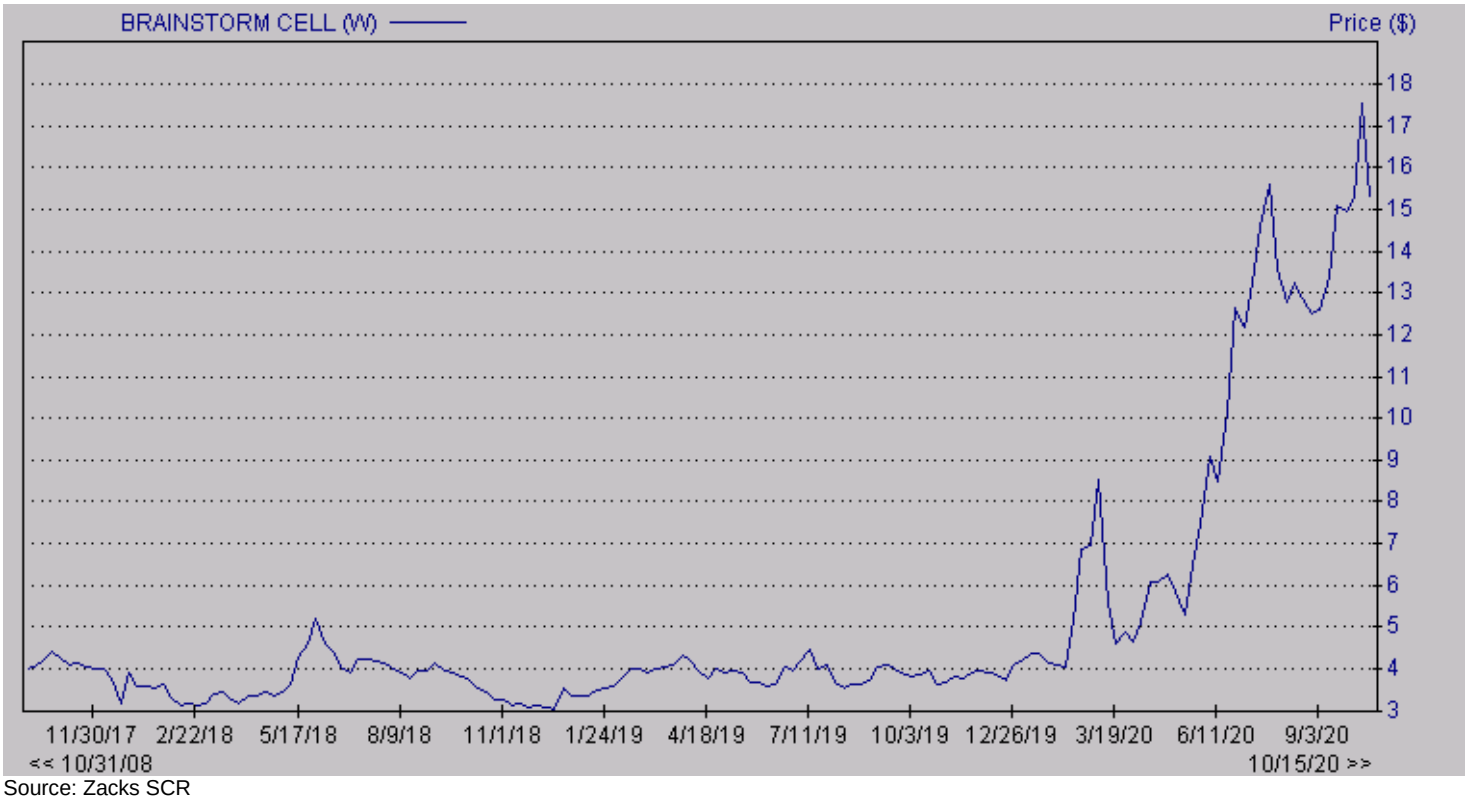
The next expected news from the company is the topline data release for the Phase 3 ALS trial, with those results expected before the end of November 2020. The company has already begun planning for a BLA filing upon positive results from the Phase 3 trial and is considering potential paths to expediting the approval process. In addition, given the recent delay in filing a BLA announced by Iovance Therapeutics (IOVA) for its cell therapy due to an inability to come to an agreement with the FDA on a required potency assay (a requirement for a BLA filing), BrainStorm is aware of the importance of such an assay for NurOwn and will be discussing the specifics of such an assay with the FDA prior to filing a BLA. We are confident the company will have a qualified assay in place in time for a BLA filing such that a delay like Iovance's will not occur. With no changes to our model our valuation remains at $33 per share as we anxiously await the results of the Phase 3 ALS trial.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2019 A	Q1 A	Q2 A	Q3 A	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	$5.7	$1.9	$6.0	$19.5	$20.0	$20.0
% R&D	-	-	-	-		-	-	-
SG&A	$5.8	$2.4	$1.7	$2.6	$1.6	$8.3	$6.5	$19.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($23.0)	($8.3)	($7.4)	($4.5)	($7.6)	($27.8)	($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)	($7.4)	($4.5)	($7.6)	($27.6)	($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)	($7.4)	($4.5)	($7.6)	($27.6)	($26.5)	$3.5
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.06)**	**($0.29)**	**($0.25)**	**($0.14)**	**($0.24)**	**($0.91)**	**($0.80)**	**$0.10**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	21.9	28.4	29.3	31.2	32.0	30.2	33.0	35.0

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

HISTORICAL STOCK PRICE



Source: Zacks SCR

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