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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 Trial Fully Enrolled; Phase 2 Results Published in* Neurology…**

Based on our probability adjusted DCF model that takes into account potential future revenues from NurOwn® in ALS, BCLI is valued at $17/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (11/21/19)	$3.93
Valuation	**$17.00**

OUTLOOK

On October 11, 2019, BrainStorm Cell Therapeutics, Inc. (BCLI) announced that the Phase 3 clinical trial of NurOwn® in patients with amyotrophic lateral sclerosis (ALS) is now fully enrolled. This is a major milestone for the company and comes approximately two years after the trial was initiated. A pre-specified safety analysis completed recently indicated that the trial should continue as planned. We anticipate topline data from the trial in the fourth quarter of 2020.

The company recently published results from the Phase 2 clinical trial of NurOwn® in ALS in the peer-reviewed journal *Neurology*. Accompanying the manuscript was an editorial in which the authors state the Phase 2 trial should serve as a framework for a well-planned and designed study that other investigators can emulate.

SUMMARY DATA

52-Week High	**$4.48**
52-Week Low	**$2.98**
One-Year Return (%)	**20.92**
Beta	**1.22**
Average Daily Volume (sh)	**64,242**
Shares Outstanding (mil)	**23**
Market Capitalization ($mil)	**$89**
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)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 A	0 A	0 A	0 E	0 E
2020					0 E
2021					0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.12 A	-$0.16 A	-$0.15 A	-$0.26 A	-$0.70 A
2019	-$0.24 A	-$0.23 A	-$0.25 A	-$0.21 E	-$0.93 A
2020					-$0.81 E
2021					-$0.78 E

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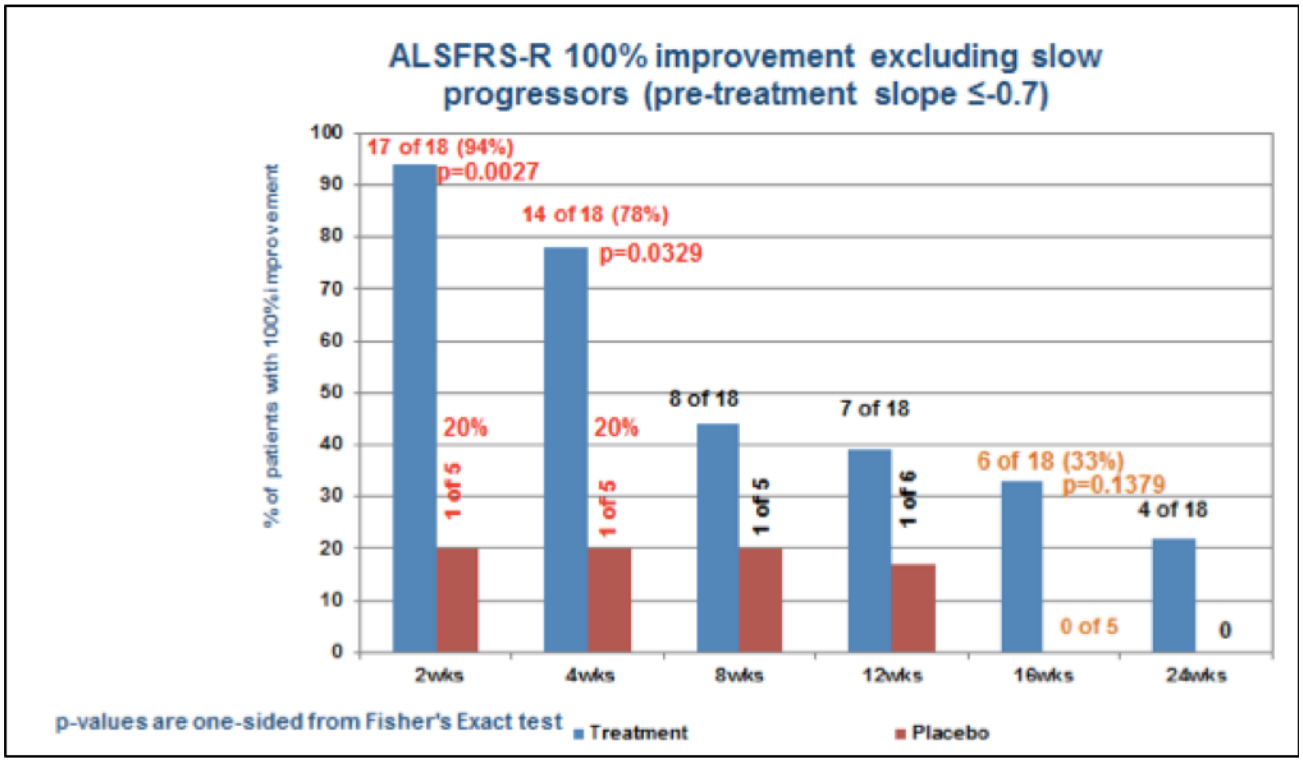
WHAT'S NEW

Business Update

Phase 3 ALS Trial is Fully Enrolled

On October 10, 2019, BrainStorm Cell Therapeutics, Inc. (BCLI) announced that the Phase 3 clinical trial of NurOwn® in patients with amyotrophic lateral sclerosis (ALS) is fully enrolled (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

DSMB Recommends Continuing Phase 3 Trial as Planned

On October 28, 2019, BrainStorm announced that following the second, pre-specified interim safety analysis, the independent Data Safety Monitoring Board (DSMB) found no significant safety concerns after reviewing all of the safety data from the first 106 patients in the study and recommended that the trial should continue with no changes in the protocol. This is another important clinical milestone for the company and an encouraging sign for the trial.

Phase 2 Results Published in Neurology

On November 20, 2019, BrainStorm announced the publication of the Phase 2 results of NurOwn® in the peer-reviewed journal *Neurology* (Berry *et al*., 2019). The Phase 2 trial was a randomized, placebo controlled study that enrolled 48 patients ramdomized 3:1 to receive NurOwn® or placebo. Following a three-month run-in period, participants received one treatment of NurOwn® or placebo and were followed for six months.

Results of the trial showed that NurOwn® was safe and generally well tolerated. In the prespecified 'rapid progressor' subgroup (those that had a decline of >2 points in ALSFRS-R during the 3-month pretreatment period), treatment with NurOwn® resulted in a statistically significant decrease in disease progression at early time points. In addition, a higher percentage of NurOwn®-treated patients experienced ≥1.5 points/month improvement in ALSFRS-R slope at all post-treatment time points, which was statistically significant at four and 12 weeks post-treatment (P=0.004 and 0.046, respectively). Lastly, levels of MCP-1 (a chemokine expressed in the cerebrospinal fluid and indicator of neuroinflammation) were significantly decreased post-transplantation in NurOwn®-treated patients compared to placebo-treated patients. The decrease in levels of MCP-1 correlated with ALSFRS-R slope improvement.

In conjunction with the manuscript, an editorial was published by Drs. Saud Sadiq and Christen Shoesmith discussing the study design and results. Drs. Sadiq and Shoesmith noted that the study showed small hints of efficacy that will need to be replicated in a larger study, and also how Berry *et al*. should be commended for "presenting the framework of a well-planned and designed study…for other investigators to emulate."

Enrollment Continues in 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.

Thus far, eight patients have been enrolled in the trial. All five sites centers are now enrolling patients, with the Cleveland Clinic, Stanford School of Medicine, and the University of Southern California previously announced and we expect an announcement identifying the other two clinical sites in the near future. We anticipate topline results being reported in the fourth quarter of 2020.

Addition to Senior Management Team

In Sep. 2019, BrainStorm announced the appointment of Preetam Shah, PhD, MBA as the company's Chief Financial Officer. Dr. Shah has over 18 years of experience in investment banking and venture capital, healthcare financial consulting, business development, sales and marketing, and scientific research. Previously, Dr. Shah was Director of Healthcare Investment Banking at Barclays Capital Plc., where he was actively involved in closing more than $3.5 billion in M&A and equity transactions along with $20 billion in debt financings for publicly traded companies. He obtained his PhD in Microbiology from the University of Mississippi Medical Center, completed a post-doctoral fellowship in Infectious Diseases at Stanford University School of Medicine, and obtained his MBA in Finance from Wharton School, University of Pennsylvania.

Financial Update

On November 14, 2019, BrainStorm announced financial results for the third quarter of 2019. Net R&D expenses for the third quarter of 2019 were $4 million, compared to $2.0 million for the third quarter of 2018. The increase was mainly due to increased costs associated with the ongoing Phase 3 clinical trial and increased costs associated with payroll and stock-based compensation along with a decrease in participation of the Israel Innovation Authority (IIA) and the California Institute for Regenerative Medicine (CIRM) in 2019. The increase was partially offset by $1.5

million received in connection with treatment of patients under the hospital exemption regulatory pathway. Without accounting for the IIA and CIRM grants or the proceeds from the hospital exemption pathway, R&D expenses were $5.7 million in the third quarter of 2019 compared to $4.1 million in the third quarter of 2018. G&A expenses were $1.5 million in the third quarter of 2019 compared to $1.3 million in the third quarter of 2018. The increase was primarily due to an increase in payroll costs, consultant fees, and stock-based compensation.

As of Sep. 30, 2019, BrainStorm had approximately $2.1 million in cash, cash equivalents, and short-term investments, which does not include the remaining commitments from the CIRM or IIA grants (approximately $3.8 million). On Nov. 14, 2019, the company announced the receipt of $495,330 grant from the National Multiple Sclerosis Society to help offset costs associated with the ongoing Phase 2 clinical trial of NurOwn® in MS.

Conclusion

Completing enrollment in the Phase 3 clinical trial of NurOwn® in ALS patients is a very important milestone for the company and we are eagerly anticipating the topline results from the trial in the fourth quarter of 2020. We also anticipate topline results from the Phase 2 trial of NurOwn® in MS patients in the fourth quarter of 2020, although the company may report interim data in the first half of 2020. 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 is currently $17.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2018 A	Q1 A	Q2 A	Q3 A	Q4 E	2019 E	2020 E	2021 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	$8.3	$3.5	$3.6	$4.0	$3.5	$14.5	$15.0	$15.0
% R&D	-	-	-	-		-	-	-
SG&A	$5.8	$1.5	$1.3	$1.5	$1.4	$5.7	$4.5	$4.5
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($14.1)	($4.9)	($4.9)	($5.6)	($4.9)	($20.2)	($19.5)	($19.5)
Net Other Income	$0.1	($0.1)	($0.0)	$0.1	$0.0	($0.0)	($0.1)	($0.1)
Pre-Tax Income	($13.9)	($5.0)	($4.9)	($5.5)	($4.9)	($20.3)	($19.6)	($19.6)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($13.9)	($5.0)	($4.9)	($5.5)	($4.9)	($20.3)	($19.6)	($19.6)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.70)**	**($0.24)**	**($0.23)**	**($0.25)**	**($0.21)**	**($0.93)**	**($0.81)**	**($0.78)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	20.0	20.9	21.7	22.3	22.7	21.9	24.0	25.0

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

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