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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: 170 Patients Enrolled in Phase 3 ALS Trial…

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 (08/16/19)	$3.58
Valuation	**$17.00**

OUTLOOK

On August 13, 2019, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the second quarter of 2019 and provided a business update. The company has enrolled 170 out of a planned 200 patients in the ongoing Phase 3 clinical trial of NurOwn® in amyotrophic lateral sclerosis (ALS). We anticipate enrollment being completed in late Sep. or early October 2019. Topline results will then be available approximately 11-12 months following completion of enrollment. The company has opened two additional clinical trial sites for the Phase 2 trial of NurOwn® in patients with multiple sclerosis. We anticipate topline results from that study in the second half of 2020.

SUMMARY DATA

52-Week High	**$4.48**
52-Week Low	**$2.98**
One-Year Return (%)	**-3.75**
Beta	**1.20**
Average Daily Volume (sh)	**274,535**
Shares Outstanding (mil)	**23**
Market Capitalization ($mil)	**$81**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**11**
Insider Ownership (%)	**23**
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 E	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	-$0.21 E	-$0.21 E	-$0.89 E
2020					-$0.81 E
2021					-$0.78 E

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WHAT'S NEW

Business Update

Patient Enrollment in Phase 3 ALS Trial to Conclude Soon

BrainStorm Cell Therapeutics, Inc. (BCLI) is continuing to enroll patients in the Phase 3 clinical trial of NurOwn® (NCT03280056) for the treatment of ALS. Thus far, 170 patients have been enrolled in the trial and we anticipate enrollment concluding in late September or early October 2019. We estimate that topline results will be available approximately 11-12 months following enrollment of the final patient.

The trial is taking place at six leading U.S. Medical centers. It is a randomized, double blind, placebo controlled, multi-dose trial that is expected to enroll approximately 200 patients randomized 1:1 to NurOwn® or placebo. Cells will be extracted from each patient one time prior to treatment, with all administrations of NurOwn® derived from the same extraction of cells thanks to a cryopreservation process developed for long-term storage of mesenchymal stem cells (MSC). As in previous studies, there will be 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 primary outcome of the study is the ALSFRS-R score responder analysis.

The company is focusing the trial on faster-progressing ALS patients since these patients demonstrated superior outcomes in the Phase 2 trial of NurOwn®. According to the company, approximately 50-60% of ALS patients could be considered "fast progressors", defined as those who lose at least one point per month in the ALSFRS-R score during the pretreatment run-in period, thus there is a large group of patients that could potentially be included in the trial.

BrainStorm has contracted with City of Hope's Center for Biomedicine and Genetics to produce clinical supplies of NurOwn® for all of the centers participating in the Phase 3 trial. The company previously announced that the Connell and O'Reilly Families Cell Manipulation Core Facility at Dana-Farber Cancer Institute will serve as a second manufacturing facility. Dana Farber was previously used as a manufacturing facility of NurOwn® in the Phase 2 trial. In addition to supplying NurOwn® for the ongoing Phase 3 trial, we believe the Dana Farber facility will likely be used to manufacture NurOwn® for any additional clinical indications the company decides to pursue.

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, seven patients have been enrolled in the trial, with a target of 20 patients to be enrolled in total. The company recently announced two additional clinical trial sites have opened at the Stanford University School of Medicine and the Keck School of Medicine at the University of Southern California. We anticipate enrollment being completed by the end of 2019 and topline results being reported in mid-2020.

Financial Update

On August 13, 2019, BrainStorm announced financial results for the second quarter of 2019. Net R&D expenses for the second quarter of 2019 were $3.6 million compared to $1.5 million for the second quarter of 2018. The increase was mainly due to increased costs associated with the Phase 3 ALS trial. Those amounts included grants from both the Israel Innovation Authority (IIA) and the California Institute for Regenerative Medicine (CIRM), which were recorded as offsets to R&D expenses. Without accounting for the IIA and CIRM grants, R&D expenses were $6.5 million in the second quarter of 2019 compared to $3.2 million in the second quarter of 2018. G&A expenses in the second quarter of 2019 were $1.3 million compared to $1.6 million in the second quarter of 2018. The decrease was primarily due to decreased payroll and stock-based compensation expenses.

As of June 30, 2019, BrainStorm had approximately $2.7 million in cash, cash equivalents, and short-term

investments. This does not include the remaining commitments from the CIRM grant (approximately $3 million) or the IIA grant (approximately $1 million). Subsequent to the end of the quarter, BrainStorm entered into a warrant exchange with certain holders of warrants whereby the company raised gross proceeds of approximately $3.3 million through the exercise of 842,000 warrants at an amended exercise price of $3.90 per share. In exchange, those warrant holders were issued warrants to purchase 842,000 shares at an exercise price of $7.00 per share with an expiration date of Dec. 31, 2021. The company's cash, cash equivalents, and short-term investments as of August 6, 2019 totaled $4.5 million.

Conclusion

We are glad to see that enrollment is steadily increasing in the Phase 3 ALS trial and we look forward to the announcement that the final patient has been enrolled, most likely in late September or early October 2019. We estimate that topline results for that trial will be available approximately 11-12 months after the final patient enrolls. In addition, the company should finish enrollment in the Phase 2 MS trial before the end of 2019 and announce topline results in mid-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 E	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	$3.5	$3.5	$14.0	$15.0	$15.0
% R&D	-	-	-	-		-	-	-
SG&A	$5.8	$1.5	$1.3	$1.3	$1.4	$5.4	$4.5	$4.5
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($14.1)	($4.9)	($4.9)	($4.8)	($4.9)	($19.4)	($19.5)	($19.5)
Net Other Income	$0.1	($0.1)	($0.0)	$0.0	$0.0	($0.1)	($0.1)	($0.1)
Pre-Tax Income	($13.9)	($5.0)	($4.9)	($4.7)	($4.9)	($19.5)	($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)	($4.7)	($4.9)	($19.5)	($19.6)	($19.6)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.70)**	**($0.24)**	**($0.23)**	**($0.21)**	**($0.21)**	**($0.89)**	**($0.81)**	**($0.78)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	20.0	20.9	21.7	22.5	22.7	22.0	24.0	25.0

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

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