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October 30, 2018
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Brainstorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Phase 3 Trial to Be Fully Enrolled by Mid-2019…

Based on our probability adjusted DCF model that takes into account potential future revenues from NurOwn® in ALS, BCLI is valued at $15/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (10/30/18)	$3.19
Valuation	**$15.00**

OUTLOOK

On October 29, 2018, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the third quarter of 2018 and provided a business update. Enrollment in the company's ongoing Phase 3 trial of NurOwn® in amyotrophic lateral sclerosis (ALS) is continuing, with the pace of enrollment having picked up with an additional cell manufacturing site now active. We anticipate the trial being fully enrolled by mid-2019 and topline data to be reported in the first half of 2020. Recently, the Data Safety and Monitoring Board (DSMB) reviewed safety data for the first 31 patients treated in the trial and did not find any significant safety concerns and recommended the trial continue as planned. Lastly, the company indicated it conducted a successful pre-IND meeting with the FDA regarding a new indication for NurOwn® and we anticipate an IND being filed before the end of 2018.

SUMMARY DATA

52-Week High	**$5.19**
52-Week Low	**$2.96**
One-Year Return (%)	**-26.47**
Beta	**2.01**
Average Daily Volume (sh)	**60,337**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$67**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**12**
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	**-6.7**
P/E using 2019 Estimate	**-8.2**

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)
2017	0 A	0 A	0 A	0 A	0 A
2018	0 A	0 A	0 A	0 E	0 E
2019					0 E
2020					0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.10 A	-$0.06 A	-$0.13 A	$0.01 A	-$0.27 A
2018	-$0.12 A	-$0.16 A	-$0.15 A	-$0.18 E	-$0.61 E
2019					-$0.69 E
2020					-$0.89 E

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WHAT'S NEW

Business Update

Enrollment in Phase 3 Study Continuing

BrainStorm Cell Therapeutics, Inc. (BCLI) is continuing to enroll patients in the Phase 3 clinical trial of NurOwn® (NCT03280056) for the treatment of amyotrophic lateral sclerosis (ALS). 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, thus there are a large group of patients that could potentially be included in the trial.

The company 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.

During the third quarter conference call, management indicated that there are now double the number of patients enrolled in the trial than there were when the Data Safety Monitoring Board (DSMB) interim safety analysis took place. We estimate that the trial will be fully enrolled by the middle of 2019 and that topline results will be available in the first half of 2020.

Positive Interim Safety Analysis for Phase 3 Trial

In August 2018, BrainStorm announced a positive interim safety analysis by the DSMB for the Phase 3 trial of NurOwn® in ALS. There were no significant safety issues and the DSMB recommended that the trial continue as planned. This is an important milestone for the company as it is the first trial to use repeated injections of NurOwn®, thus it is reassuring to see that there have been no safety issues thus far with repeated injections.

Financial Update

On October 29, 2018, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the third quarter of 2018 and provided a business update. As expected, the company did not report any revenues for the quarter. The company recorded R&D expenses for the third quarter of 2017 and 2018 net of research and development grants from the Israel Innovation Authority (IIA, formerly the Office of the Chief Scientist) and the California Institute for Regenerative Medicine (CIRM). R&D expenses for the third quarter of 2018 were $1.98 million compared with $1.17 million for the third quarter of 2017. Excluding the funds received from the IIA and CIRM grants, R&D expenses were $4.07 million in the third quarter of 2018 compared to $1.55 million for the third quarter of 2017. The increase in expenses was primarily due to increased costs associated with the ongoing Phase 3 clinical trial. G&A expenses for the third quarter of 2018 were $1.3 million compared to $1.2 million in the third quarter of 2017. The increase was primarily due to increased PR activity partially offset by a decrease in consultants, rent, and other costs.

The company recorded a net loss in the third quarter of 2018 of $3.2 million, or $0.15 per share, compared to a net loss of $2.4 million, or $0.13 per share, in the third quarter of 2017. BrainStorm currently has approximately $10.9 million in cash, cash equivalents, and short-term deposits. When factoring in the remaining approximately $7 million in committed cash from CIRM and approximately $1 million from the IIA, the company's cash total is approximately

$19 million. This amount of capital is sufficient to fully fund the Phase 3 ALS trial and an additional indication for NurOwn®, for which we expect an IND to be filed before the end of 2018.

As of October 25, 2018, the company had approximately 20.7 million shares of common stock outstanding. In addition, there were approximately 0.9 million options and 5.9 million warrants for a fully diluted share count of approximately 27.5 million.

Conclusion

We believe that BrainStorm's current valuation represents a compelling opportunity for investors given the current sub-$100 million market cap. The company has previously reported positive Phase 2 data, the Phase 3 trial is fully funded, and the company has sufficient capital to advance an additional indication for NurOwn® into the clinic, with an IND filing anticipated before the end of 2018. We're also encouraged by the positive DSMB outcome that showed no additional safety concerns from multiple injections of NurOwn®. The company continues to strengthen its senior management team, including the recent addition of Mr. Arturo Araya as Chief Commercial Officer, as he previously headed Novartis' Cell and Gene Therapy Unit. Overall, we are highly encouraged by the progress being made by BrainStorm and we see no reason for the recent pullback in the share price. Given the lack of effective therapies for ALS patients, we believe a successful Phase 3 trial (and assuming no new safety concerns) could lead NurOwn® to peak sales of $1 billion, and based on our probability adjusted discounted cash flow analysis our current valuation is $15.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2017 A	Q1 A	Q2 A	Q3 A	Q4 E	2018 E	2019 E	2020 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	$1.0	$1.0	$1.5	$2.0	$2.3	$6.7	$10.0	$15.0
% R&D	-	-	-	-		-	-	-
SG&A	$4.0	$1.3	$1.6	$1.3	$1.4	$5.6	$4.5	$4.5
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($5.0)	($2.3)	($3.1)	($3.2)	($3.7)	($12.3)	($14.5)	($19.5)
Net Other Income	$0.0	($0.0)	$0.0	$0.1	($0.0)	$0.0	($0.1)	($0.1)
Pre-Tax Income	($5.0)	($2.3)	($3.1)	($3.2)	($3.7)	($12.3)	($14.6)	($19.6)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($5.0)	($2.3)	($3.1)	($3.2)	($3.7)	($12.3)	($14.6)	($19.6)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.26)**	**($0.12)**	**($0.16)**	**($0.15)**	**($0.18)**	**($0.61)**	**($0.69)**	**($0.89)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	18.8	19.0	19.5	20.7	20.7	20.0	21.0	22.0

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

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