Zacks Small-Cap Research
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Brainstorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Positive Interim Safety Analysis for Phase 3 Trial…

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 (08/23/18)	$4.04
Valuation	**$15.00**

OUTLOOK

On August 23, 2018, BrainStorm Cell Therapeutics, Inc. (BCLI) announced positive interim safety analysis for the company's ongoing Phase 3 trial of NurOwn® in amyotrophic lateral sclerosis (ALS). The Data Safety Monitoring Board (DSMB) did not find any significant safety concerns and recommended the trial continue as planned. This is an important milestone for the company as it is the first trial to utilize repeated injections of NurOwn®. Thus far, a total of 82 subjects have been enrolled in the trial with 61 currently active. Many of the study subjects have received two intrathecal injections of NurOwn® while a smaller subset has completed all three injections. We believe a total of 110 of the planned 200 subjects will be enrolled by January 2019 and that enrollment for the study will be complete in mid-2019.

SUMMARY DATA

52-Week High	**$5.19**
52-Week Low	**$2.96**
One-Year Return (%)	**-1.22**
Beta	**2.06**
Average Daily Volume (sh)	**55,975**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$84**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**25**
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	**-8.3**
P/E using 2019 Estimate	**-8.1**

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 E	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	-$0.16 E	-$0.18 E	-$0.62 E
2019					-$0.69 E
2020					-$0.89 E

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Business Update

Positive Interim Safety Analysis for Phase 3 Trial

On August 23, 2018, BrainStorm Cell Therapeutics, Inc. (BCLI) announced a positive interim safety analysis by the Data Safety Monitoring Board (DSMB) for the Phase 3 trial of NurOwn® in amyotrophic lateral sclerosis (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.

Thus far, a total of 82 subjects have been enrolled in the study and 61 of them are currently active. A large number of subjects have received two injections of NurOwn® with a smaller subset having already completed all three injections. At the current pace of enrollment, we believe a total of 110 subjects will be enrolled by January 2019 and that full enrollment of approximately 200 subjects in the study will be completed by mid-2019. With this timeframe, we estimate topline data would be reported in the first half of 2020.

The Phase 3 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. Recently, the company 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.

Conclusion

The positive interim safety analysis for the Phase 3 trial of NurOwn® in ALS is an important milestone for the company as it indicates that there will likely not be any issues with dosing patients' multiple times. For a disease such as ALS, it was always thought that multiple treatments would be necessary, thus it is reassuring to see that repeat administrations of NurOwn® is not associated with any unforeseen safety issues. The trial appears to be enrolling at a good pace, and with enrollment projected to be completed by mid-2019 we estimate that topline data would be reported in the first half of 2020. As a reminder, the company has sufficient capital to complete the trial through the remaining portion of the grants from the California Institute for Regenerative Medicine (CIRM) and the Israel Innovation Authority along with the company's current cash position. Our probability adjusted discounted cash flow analysis based only on the use of NurOwn® in ALS leads to a current valuation of $15.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2017 A	Q1 A	Q2 A	Q3 E	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	$6.8	$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)	($3.3)	($3.7)	($12.4)	($14.5)	($19.5)
Net Other Income	$0.0	($0.0)	$0.0	($0.0)	($0.0)	($0.0)	($0.1)	($0.1)
Pre-Tax Income	($5.0)	($2.3)	($3.1)	($3.3)	($3.7)	($12.4)	($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)	($3.3)	($3.7)	($12.4)	($14.6)	($19.6)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.26)**	**($0.12)**	**($0.16)**	**($0.16)**	**($0.18)**	**($0.62)**	**($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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