Zacks Small-Cap Research

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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Receives $16 Million Grant From CIRM to Fund Phase 3 Trial in ALS…

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 (07/24/17)	$4.94
Valuation	**$15.00**

OUTLOOK

On July 21, 2017, BrainStorm Cell Therapeutics, Inc. (BCLI) announced that the California Institute for Regenerative Medicine (CIRM) awarded the company a non-dilutive $16 million grant to help support the Phase 3 clinical trial of NurOwn® in amyotrophic lateral sclerosis (ALS).

The grant is important for two reasons: 1) it removes any funding overhang that had been dragging on the stock as investors were unsure of how the company was going to fund the P3 trial, and 2) it validates NurOwn® and the data obtained thus far from the company's clinical program. We anticipate the Phase 3 trial initiating soon, which will be taking place at six leading institutions in the U.S.

SUMMARY DATA

52-Week High	**$4.94**
52-Week Low	**$2.09**
One-Year Return (%)	**105.83**
Beta	**2.26**
Average Daily Volume (sh)	**138,139**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$93**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**24**
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 2016 Estimate	**-5.8**
P/E using 2017 Estimate	**-5.5**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	0 A	0 A	0 A	0 A	0 A
2017	0 A	0 E	0 E	0 E	0 E
2018					0 E
2019					0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.10 A	-$0.05 A	-$0.09 A	-$0.03 A	-$0.27 A
2016	-$0.10 A	-$0.10 E	-$0.10 E	-$0.09 E	-$0.38 E
2017					-$0.42 E
2018					-$0.43 E

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WHAT'S NEW

Business Update

Awarded $16 Million Grant From CIRM to Help Fund Phase 3 Trial

On July 21, 2017, BrainStorm announced that the company has received a $16 million grant from the California Institute for Regenerative Medicine (CIRM) to help fund the company's upcoming Phase 3 clinical trial of NurOwn® in patients with amyotrophic lateral sclerosis (ALS). CIRM was established in 2004 through Proposition 71: the California Stem Cell Research and Cures Initiative. While CIRM initially concerned itself with supporting scientists who were just entering the stem cell field, the organization has recently launched CIRM 2.0, which aims to make funding available sooner for projects that are likely to bring stem cell therapies to patients with unmet medical needs (e.g., late stage clinical trials).

The grant helps the company in two important ways: 1) it removes the funding overhang that had been dragging on the stock as investors were unsure of how the company was going to fund the upcoming Phase 3 clinical trial, and 2) it validates NurOwn® and provides significant credibility to the data that the company has compiled thus far from the ALS program.

In addition to the grant from CIRM, the company also recently announced a non-dilutive grant from the Israel Innovation Authority (formerly the Office of the Chief Scientist) for $2.1 million to support the development of NurOwn®, thus the company is continuing to successfully obtain capital in a shareholder friendly way.

Phase 3 Study of NurOwn® in ALS Set to Get Underway

BrainStorm has entered the final planning stage for the Phase 3 clinical trial of NurOwn® in patients with ALS, which includes accomplishing the following activities:

- The company recently announced that City of Hope's Center for Biomedicine and Genetics would produce clinical supplies of NurOwn® for all U.S. medical centers involved in the Phase 3 study and that it had initiated training of the cell manufacturing team that will be producing clinical supplies of NurOwn®.

- BrainStorm has selected Worldwide Clinical Trials as its Clinical Research Organization for the Phase 3 trial of NurOwn. Worldwide has extensive expertise and experience in managing pivotal Phase 3 clinical trials, particularly in the field of ALS and neurology.

- The company has signed definitive agreements with Massachusetts General Hospital and California Pacific Medical Center, with Drs. Merit Cudkowicz and Robert G. Miller agreeing to participate as principal investigators.

The planned Phase 3 clinical trial will be a randomized, double blind, placebo controlled, multi-dose trial that will take place at six leading ALS centers in both the U.S. and Israel. We anticipate approximately 200 patients being enrolled in the trial 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. 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®.

Conclusions

The non-dilutive CIRM grant is yet another example of the shareholder friendly way in which BrainStorm is continuing to accumulate capital to fund development of NurOwn®. We believe investors were concerned about how the company was going to fund the Phase 3 trial, which resulted in a drag on the stock price. We estimate the company has sufficient capital to fund operations through 2018, and can now choose to raise additional funds on its terms, which could easily be accomplished through an at-the-market agreement or a warrant exchange, like the company did in 2014. Either way, investors concern with funding the Phase 3 trial should be alleviated by the CIRM grant.

In addition to allaying the fears associated with financing the trial, the CIRM grant should also serve to alleviate any trepidation investors had regarding the integrity of the data BrainStorm has accumulated thus far for NurOwn® in ALS. The CIRM review process includes a highly rigorous evaluation of the clinical data accumulated thus far by a panel of leading scientists, thus awarding a grant is a validation of the technology and clinical data. While this does not guarantee success in the Phase 3 trial, it is highly supportive of the approach BrainStorm is taking and the data up to this point.

Before becoming generic, Riluzole® cost $50,000 per year and was shown to only extend survival of ALS patients by two to three months. The results previously reported by the company indicate that NurOwn® may be able to slow down the progression of ALS, and for some patients it may even lead to disease stabilization. Multiple doses of NurOwn® could increase these effects. As such, we currently model for NurOwn™ to cost $100,000 per year. We continue to believe that upon approval NurOwn® could generate peak revenues of over $1 billion. With additional non-dilutive funding in place we have increased our valuation to $15 per share.

PROJECTED FINANCIALS

BrainStorm Cell Therapeutics, Inc.
Income Statement

Brainstorm Cell Therapeutics	2016 A	Q1 A	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 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	$2.3	$0.9	$1.0	$1.0	$1.0	$3.9	$5.0	$6.0
% R&D	-	-	-	-	-	-	-	-
SG&A	$2.8	$0.8	$0.8	$0.8	$0.8	$3.2	$4.0	$4.5
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($5.1)	($1.8)	($1.8)	($1.8)	($1.8)	($7.2)	($9.0)	($10.5)
Net Other Income	$0.1	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1
Pre-Tax Income	($5.0)	($1.8)	($1.8)	($1.8)	($1.8)	($7.1)	($8.9)	($10.4)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($5.0)	($1.8)	($1.8)	($1.8)	($1.8)	($7.1)	($8.9)	($10.4)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.27)**	**($0.10)**	**($0.10)**	**($0.10)**	**($0.09)**	**($0.38)**	**($0.42)**	**($0.43)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	18.7	18.7	18.7	18.7	18.8	18.7	21.0	24.0

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

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