Zacks Small-Cap Research

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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Initiates Phase 3 Clinical Trial of NurOwn® 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 (10/17/17)	$4.04
Valuation	**$15.00**

OUTLOOK

On October 16, 2017, BrainStorm Cell Therapeutics, Inc. (BCLI) announced enrollment has commenced in the company's Phase 3 clinical trial of NurOwn® in patients with amyotrophic lateral sclerosis. The randomized, double blind, placebo controlled trial is expected to enroll approximately 200 patients with half receiving three doses of NurOwn® over a six month period and half receiving placebo. We believe that there is a lot of excitement around this trial in the ALS community, thus enrollment should proceed at a steady pace leading to topline data in 2019. This trial is being supported in part by a $16 million grant from the California Institute for Regenerative Medicine (CIRM).

SUMMARY DATA

52-Week High	**$4.94**
52-Week Low	**$2.09**
One-Year Return (%)	**76.42**
Beta	**2.28**
Average Daily Volume (sh)	**49,909**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$76**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**13**
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 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 A	0 A	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)
2016	-$0.10 A	-$0.05 A	-$0.09 A	-$0.03 A	-$0.27 A
2017	-$0.10 A	-$0.06 A	-$0.13 A	-$0.09 E	-$0.37 E
2018					-$0.42 E
2019					-$0.43 E

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WHAT'S NEW

Business Update

Phase 3 Trial Underway

On October 16, 2017, BrainStorm announced that the first patients have been enrolled in the Phase 3 clinical trial of NurOwn® (NCT03280056) for the treatment of amyotrophic lateral sclerosis (ALS). The subjects were enrolled at the Massachusetts General Hospital and UC Irvine Medial Center, which are two of the six leading ALS centers that will take part in the study. The other centers are expected to begin enrolling patients shortly.

The Phase 3 clinical trial is a randomized, double blind, placebo controlled, multi-dose trial that will take place at six leading ALS centers in the U.S. 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®. According to the company, approximately 50-60% of ALS patients could be considered "fast progressors". Management has indicated there is a strong interest in the trial from patients and physicians. Thus, we do not anticipate there being any issues with patient enrollment and we expect topline results in 2019.

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. Worldwide Clinical Trials was selected as the Clinical Research Organization for the Phase 3 trial due to Worldwide's expertise and experience in managing pivotal Phase 3 clinical trials in ALS and neurology.

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

Earlier this year, BrainStorm announced that the company has received a $16 million grant from the California Institute for Regenerative Medicine (CIRM) to help fund the Phase 3 clinical trial of NurOwn®. 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 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.

Edavarone Approval Shows FDA Eagerness to Approve New ALS Treatments

On May 5, 2017, the U.S. Food and Drug Administration (FDA) announced the approval of edaravone for the treatment of amyotrophic lateral sclerosis (ALS). This is the first medication approved for the treatment of ALS since riluzole in 1995. As stated in the press release, the FDA was eager to engage with the drug's developer, Mitsubishi Tanabe Pharmaceuticals Corp., following the approval of the drug in Japan, since there are so few treatment options for ALS patients in the U.S.

We believe the news of edaravone's approval is a positive for BrainStorm. It shows the FDA is willing and eager to work with a company to get an ALS treatment approved in a timely fashion and it shows the type of efficacy data

that the FDA is looking for in an ALS treatment. Lastly, BrainStorm's data for NurOwn® is highly comparable to the edaravone data, which is encouraging given that BrainStorm's data is based on a single dose of NurOwn® while edaravone is required to be infused 64 times.

Edaravone

Edaravone is a potent scavenger of oxygen radicals. While the underlying mechanisms responsible for causing ALS are unknown, it is believed that oxidative stress plays some role in the development of the disease. This is supported by the fact that mutations in superoxide dismutase 1 (SOD1) cause familial ALS. SOD1 is responsible for converting superoxide radicals to oxygen and hydrogen peroxide.

In an ALS mouse model that involves a mutation in SOD1, administration of edaravone resulted in reduced motor decline and preserved motor neurons in the spinal cord. Similar results were seen in a rat model of ALS. Based on these results, edaravone was tested in ALS patients in three different clinical trials.

Edaravone Clinical Trials

Edaravone was originally tested in a Phase 2 clinical trial involving 20 ALS patients. The study was an open-label comparison study that evaluated patients before and after treatment with edaravone. Results showed a statistically significant difference in the change in ALS function rating scale revised (ALSFRS-R) before treatment (4.7 points) compared to during the treatment period (2.3 points; *P*=0.036).

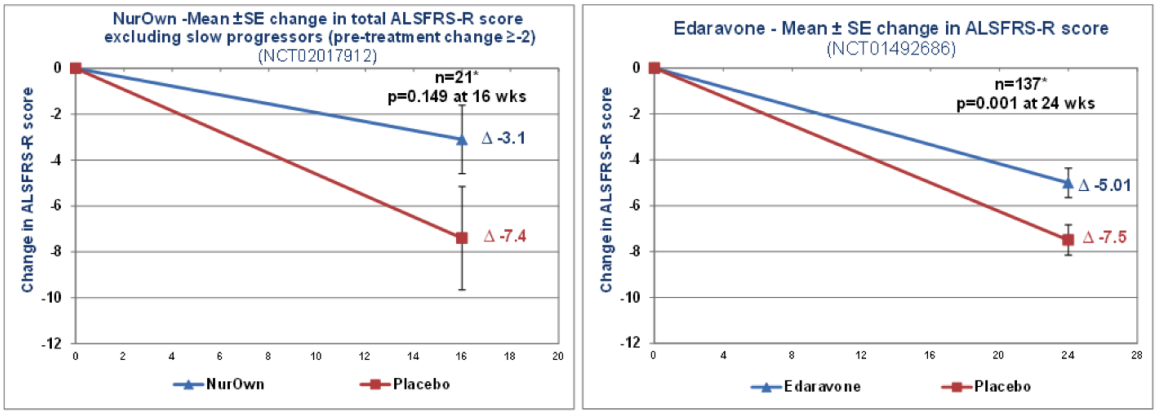
The first Phase 3 clinical trial of edaravone was conducted in 205 patients randomized to receive edaravone (n=101) or placebo (n=104) (Abe *et al*., 2014). Treatment consisted of i.v. infusions given over 60 min for the first 14 days of cycle 1 (followed by 14 days off drug), and then 10 of the first 14 days during cycles two through six, with 14 days off drug following treatment in each cycle. The primary endpoint was the change in ALSFRS-R during the 24-week treatment period. Results showed that the change in ALSFRS-R scores were -5.70 and -6.35 in the edaravone and placebo groups, respectively, which did not represent a statistically significant different (*P*=0.411). No serious adverse events were reported and the level and frequency of adverse events were similar between the two treatment groups. A post-hoc analysis suggested that edaravone could be efficacious in a restricted subgroup that includes recently diagnosed patients with milder disease symptoms.

Based on the post-hoc analysis, a second Phase 3 clinical trial was conducted that was restricted to patients with a disease duration of <2 years and independent activity of daily living (Tanaka *et al*., 2015). A total of 134 patients were randomized to receive edaravone (n=68) or placebo (n=66) for six months, with treatment given the same as in the first Phase 3 clinical trial. The change in ALSFRS-R score from baseline at six months was -5.01 in the edaravone group and -7.50 in the placebo group (*P*=0.001). Once again, adverse events were similar between the edaravone and the placebo groups.

The results of the two Phase 3 trials of edaravone show that the drug is efficacious in ALS patients, however due to the small effect size its use may be limited to patients who are newly diagnosed and who have mild symptoms. The drug will be sold under the name Radicava by MT Pharma America, a subsidiary of Mitsubishi Tanabe Pharmaceuticals, and will cost approximately $145,000 per year.

Edaravone vs. NurOwn®

The approval of edaravaone helps to give an idea of what type of results the FDA is looking for in order to gain approval as an ALS treatment. Thus, we feel it is worth comparing the results seen in the pivotal trial of edaravone to those seen with NurOwn®. The following graph shows a comparison between edaravone 24-week data and NurOwn® 16-week data, showing that the two treatments are quite comparable.



Source: BrainStorm Cell Therapeutics, Inc.

A couple of things to keep in mind when comparing the data are:

1) The NurOwn® study was conducted in the U.S., while the edaravone study was conducted in Japan, thus differences in the standard of care could contribute to any differences in the rate of change in ALSFRS-R, on top of the inherent differences that would be expected based on the variability of ALS patient progression.
2) The difference in ALSFRS-R at 16 weeks in NurOwn®-treated "fast progressors" compared to placebo-treated was 4.3 points, while the difference between edaravone-treated and placebo-treated patients at 24 weeks was only 2.5 points. It is reasonable to think that if the NurOwn® study had gone out to 24 weeks the difference between NurOwn® and placebo-treated patients would only increase more.
3) The reason that the NurOwn® results were not significant is because only 21 patients were included in the analysis while the edaravone results included 137 patients.
4) The NurOwn® results are based a single treatment. Edaravone was dosed 64 times, with each dosage consisting of a 1 hour intravenous infusion.

In summary, we believe that data from the Phase 3 trial of NurOwn® that is similar to the data from the Phase 2 trial will very likely lead to FDA approval, especially in light of the data that led to edaravone's approval.

Financial Update

On October 17, 2017, BrainStorm announced financial results for the third quarter of 2017. As expected, the company did not report any revenue. Net loss for the second quarter of 2017 was $2.4 million, or $0.13 per share. R&D expenses were $1.2 million in the third quarter of 2017 compared to $0.8 million in the third quarter of 2016. The increase was due to an increase in payroll and stock based compensation along with increased costs associated with the Phase 3 clinical trial partially offset by funds provided by the Israel Innovation Authority. G&A expenses were $1.2 million in the third quarter of 2017 compared to $0.8 million in the third quarter of 2016. The increase was primarily due to increased payroll costs. The company exited the second quarter of 2017 with cash, cash equivalents, and marketable securities of approximately $10.5 million.

On June 13, 2017, BrainStorm announced it received a grant totaling approximately $2.1 million from the Israel Innovation Authority (IIA, formerly the Office of the Chief Scientist). Thus far, BrainStorm has received approximately $7.5 million in total from the IIA since 2007. The company will be required to pay mid-single digit royalties to the IIA based on sales of NurOwn® up to the total cumulative amount of the IIA grants received plus interest.

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). During the third quarter of 2017, the company received a $5.5 million milestone payment, or approximately 30% of the grant.

As of October 13, 2017, BrainStorm had approximately 18.8 million shares of common stock outstanding. When factoring in the 5.9 million warrants and 0.9 million stock options the fully diluted share count is approximately 25.7 million.

Conclusions

BrainStorm is now officially a “Phase 3 company”! Management has indicated that patient interest in the Phase 3 trial is very strong, thus we believe enrollment will proceed at a good pace and lead to topline data in 2019. We’ll likely be able to provide more precise guidance on when in 2019 the data will be available following future updates on patient enrollment.

The approval of edaravone is exciting news for ALS patients, as it is the first medicine approved for the condition in 22 years. However, we believe it is also good news for BrainStorm and its shareholders, as the company now has some idea of the type of data that the FDA would like to see in order to approve an ALS treatment. As shown in the graph above, one treatment of NurOwn® leads to comparable, if not better, efficacy as edaravone as measured by change in ALSFRS-R score. Thus, similar data from a Phase 3 study, with no new safety signals, would very likely lead to NurOwn’s® approval.

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 BrainStorm 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. We are conservatively modeling for NurOwn™ to cost $100,000 per year and continue to believe that upon approval NurOwn® could generate peak revenues of over $1 billion. Our current valuation is $15 per share.

PROJECTED FINANCIALS

BrainStorm Cell Therapeutics, Inc.
Income Statement

Brainstorm Cell Therapeutics	2016 A	Q1 A	Q2 A	Q3 A	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	$0.4	$1.2	$1.0	$3.5	$5.0	$6.0
% R&D	-	-	-	-	-	-	-	-
SG&A	$2.8	$0.8	$0.6	$1.2	$0.8	$3.5	$4.0	$4.5
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($5.1)	($1.8)	($1.1)	($2.4)	($1.8)	($7.0)	($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)	($1.0)	($2.4)	($1.8)	($7.0)	($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)	($1.0)	($2.4)	($1.8)	($7.0)	($8.9)	($10.4)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.27)**	**($0.10)**	**($0.06)**	**($0.13)**	**($0.09)**	**($0.37)**	**($0.42)**	**($0.43)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	18.7	18.7	18.7	18.8	18.8	18.8	21.0	24.0

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

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