Zacks Small-Cap Research

May 8, 2017
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: Approval of Edaravone Shows FDA's Eagerness to Approve New Treatments for ALS…

Based on our probability adjusted DCF model that takes into account potential future revenues from NurOwn® in ALS, BCLI is valued at $13/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (05/08/17)	$3.95
Valuation	**$13.00**

OUTLOOK

On May 5, 2017, the U.S. Food and Drug Administration (FDA) approved edaravone for the treatment of amyotrophic lateral sclerosis (ALS). This is the first ALS treatment approved since riluzole in 1995. Edaravone was approved based on a Phase 3 clinical trial conducted in Japan. Results showed that patients treated with edaravone had a mean change at 6 months in the ALSFRS-R of -5.01 compared to -7.50 for those treated with placebo (*P*=0.001).

The approval of edaravone is good news for BrainStorm, as the company's Phase 2 results with NurOwn® are quite comparable to those obtained with edaravone, particularly since they are based on a single treatment, compared with 64 IV treatments of edaravone. In addition, it shows the FDA is eager to approve new treatments for ALS.

SUMMARY DATA

52-Week High	**$4.71**
52-Week Low	**$2.09**
One-Year Return (%)	**82.03**
Beta	**2.28**
Average Daily Volume (sh)	**189,394**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$74**
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 E	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	-$0.04 E	-$0.06 E	-$0.08 E	-$0.09 E	-$0.27 E
2017					-$0.42 E
2018					-$0.43 E

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

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 Phase 2 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 (ref 9). 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 (ref 23). Similar results were seen in a rat model of ALS (ref. 25). Based on these results, edaravone was tested in ALS patients in three different clinical trials.

Edaravone Clinical Trials

Edaravone was originally approved in a Phase 2 clinical trial involving 20 ALS patients (ref 3). 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).

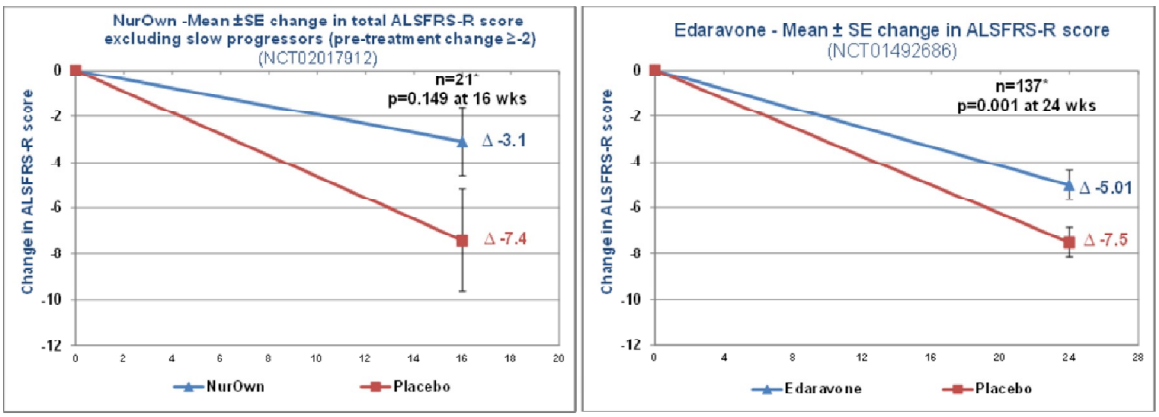
The first Phase 3 clinical trial of edaravone was conducted in 205 patients randomized to receive edaravone (n=101) or placebo (n=104) (Abe *et al*., 2014). Treatment consisted of i.v. infusions given over 60 min for the first 14 days of cycle 1 (followed by 14 days off drug), and then 10 of the first 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 placeo 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 Phase 3 data and NurOwn® 16-week Phase 2 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.
3) The reason that the NurOwn® results did not achieve statistical significance 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. The planned NurOwn® Phase 3 study will be multidose.

Conclusions

The approval of edaravone is exciting news for ALS patients, as it is the first medicine approved for the condition in 22 years. However, 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® results in comparable, if not better, efficacy as edaravone as measured by change in ALSFRS-R score.

We remind investors that BrainStorm will be initiating a multi-dose Phase 3 clinical trial of NurOwn® in ALS patients. It will be a randomized, double blind, placebo controlled, multi-dose trial that will take place at multiple centers in both the U.S. and Israel. We anticipate approximately 150 patients being enrolled in the trial randomized 1:1 to NurOwn® or placebo. 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 trial should initiate in the second quarter of 2017.

BrainStorm is also planning to seek early regulatory approval for NurOwn® in Canada and Israel, and given that results with NurOwn® are similar to those seen with the newly approved edaravone, we are even more confident that early approval will be granted. Based on our probability adjusted discounted cash flow model, we value BrainStrom at $13/share.

PROJECTED FINANCIALS

BrainStorm Cell Therapeutics, Inc.
Income Statement

Brainstorm Cell Therapeutics	2016 A	Q1 E	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	$0.3	$0.5	$0.8	$1.0	$2.6	$5.0	$6.0
% R&D	-	-	-	-	-	-	-	-
SG&A	$2.8	$0.4	$0.6	$0.7	$0.8	$2.5	$4.0	$4.5
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($5.1)	($0.7)	($1.1)	($1.5)	($1.8)	($5.1)	($9.0)	($10.5)
Net Other Income	$0.1	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($5.0)	($0.7)	($1.1)	($1.5)	($1.8)	($5.0)	($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)	($0.7)	($1.1)	($1.5)	($1.8)	($5.0)	($8.9)	($10.4)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.27)**	**($0.04)**	**($0.06)**	**($0.08)**	**($0.09)**	**($0.27)**	**($0.42)**	**($0.43)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Ave 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*

© Copyright 2017, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2017, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.