Zacks Small-Cap Research
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November 19, 2020
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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Phase 3 ALS Trial Does Not Meet Primary Endpoint…

Based on our probability adjusted DCF model that takes into account potential future revenues from NurOwn® in ALS, MS, and Alzheimer's, BCLI is valued at $10.00/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (11/19/20)	$3.99
Valuation	**$10.00**

OUTLOOK

On November 17, 2020, BrainStorm Cell Therapeutics, Inc. (BCLI) announced topline data from the company's Phase 3 clinical trial of NurOwn® in patients with amyotrophic lateral sclerosis (ALS). The results showed that the primary endpoint of the percentage of participants who experienced a 1.25 points per month improvement in the ALSFRS-R slope was not statistically significant. A pre-specified subgroup of patients with baseline ALSFRS-R scores > 35 showed a clinically meaningful treatment response. The company will be meeting with the FDA to determine a path forward for NurOwn in the treatment of ALS and will provide an update following that meeting.

SUMMARY DATA

52-Week High	**$17.73**
52-Week Low	**$3.69**
One-Year Return (%)	**1.53**
Beta	**0.91**
Average Daily Volume (sh)	**1,590,340**
Shares Outstanding (mil)	**32**
Market Capitalization ($mil)	**$126**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**20**
Insider Ownership (%)	**22**
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	**N/A**
P/E using 2019 Estimate	**N/A**

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)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 A	0 A	0 A	0 E	0 E
2021					0 E
2022					50 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.24 A	-$0.23 A	-$0.25 A	-$0.34 A	-$1.06 A
2019	-$0.29 A	-$0.25 A	-$0.14 A	-$0.24 E	-$0.91 E
2020					-$0.80 E
2021					$0.10 E

WHAT'S NEW

Business Update

Phase 3 ALS Trial Does Not Meet Primary Endpoint

On November 17, 2020, BrainStorm Cell Therapeutics, Inc. (BCLI) announced topline results from the company's Phase 3 clinical trial of NurOwn® in patients with amyotrophic lateral sclerosis (ALS). The trial did not reach statistical significance for the primary endpoint, a responder analysis examining the percentage of participants that experienced a 1.25 point per month improvement in the post-treatment Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFRS-R) slope. The trial was powered based on assumed treatment response rates of 35% for NurOwn and 15% for placebo. The results showed that 34.7% of NurOwn-treated participants and 27.7% of placebo-treated patients achieved the primary endpoint (*P*=0.453). A secondary efficacy endpoint measuring the average change in ALSFRS-R total score from baseline to Week 28 was -5.52 for NurOwn-treated participants and -5.88 for placebo-treated participants (*P*=0.693).

The company also performed an analysis on a pre-specified subgroup of patients with ALSFRS-R scores > 35, of which approximately 30% of trial participants were included. It is important to remember that while only 30% of trial participants had an ALSFRS-R score >35, almost all patients diagnosed with ALS have an ALSFRS-R score >35 at the time of diagnosis. In this subgroup, NurOwn showed a clinically meaningful treatment response with 34.6% responders compared to 15.6% of responders in placebo-treated participants (*P*=0.288). In addition, the average change in ALSFRS-R score from baseline to Week 28 for this subgroup was -1.77 for NurOwn-treated participants and -3.78 for placebo-treated participants (*P*=0.198).

A number of cerebrospinal fluid (CSF) biomarkers were collected during the trial and a statistically significant increase of neurotrophic factors and neuroinflammatory biomarkers were seen in NurOwn-treated participants compared to placebo-treated participants. Pre-specified statistical modeling showed that treatment outcomes with NurOwn could be predicted based on baseline ALS function along with various CSF biomarkers.

We anticipate the company releasing additional details on the trial results at future scientific meetings. From a regulatory standpoint, the company will be meeting with the FDA to present the data to the agency and determine what the path forward is for NurOwn in ALS. We anticipate the company providing an update following receipt of the minutes from that meeting, at which time we hope to gain a better understanding of the regulatory path for NurOwn.

Conclusion

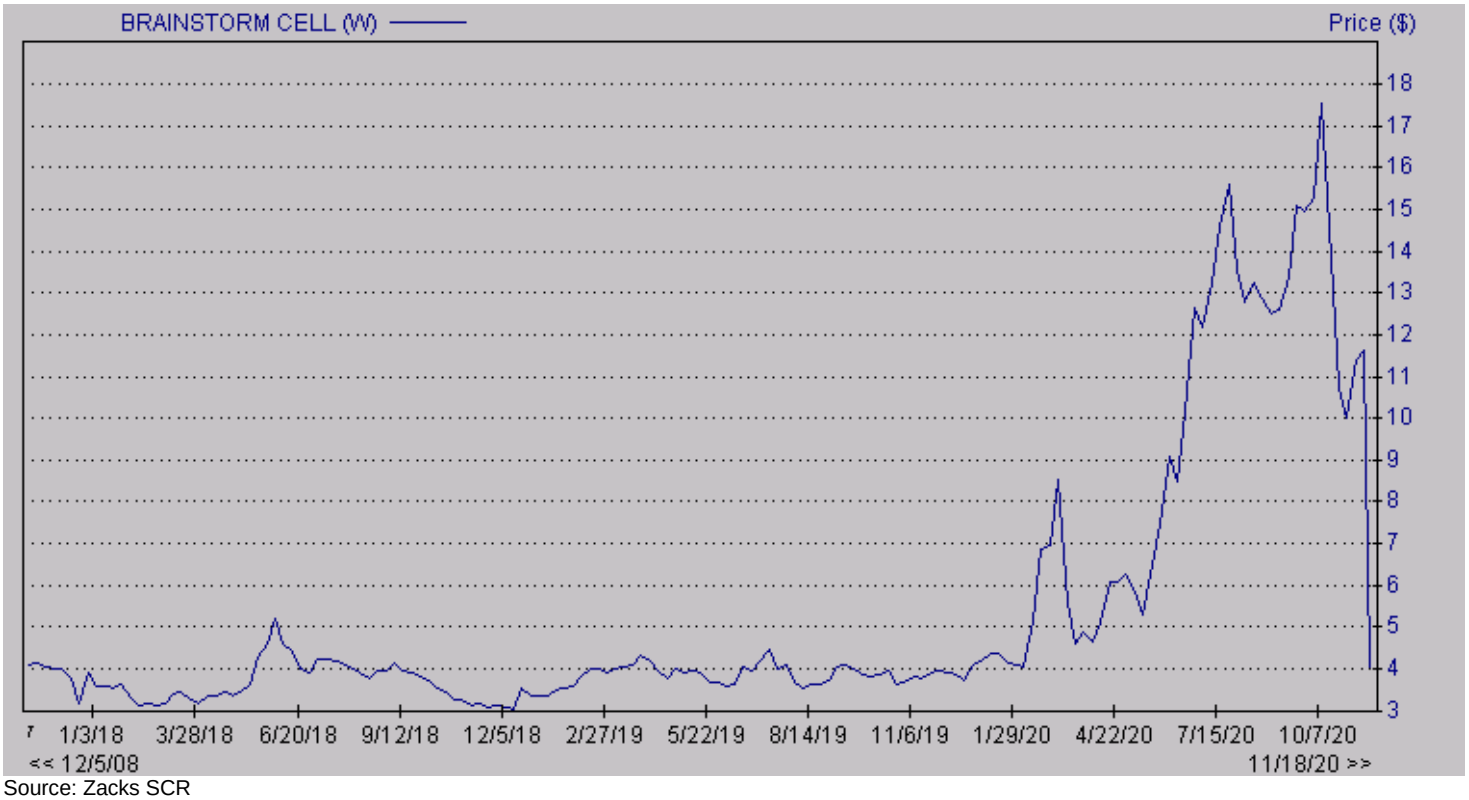
We are disappointed by the results from the Phase 3 ALS trial for NurOwn and had hoped for a better outcome for patients and their families as there are no effective treatment options for ALS available at this point. It is unfortunate that the trial did not meet the primary endpoint, however at this point we don't believe that all hope is lost as the company reported a clinically meaningful response in participants with ALSFRS-R scores > 35 at baseline. Having said that, given the uncertainty surrounding NurOwn and the lack of clarity regarding a path forward until the company meets with the FDA, we have decreased our probability of approval to 10%, which has significantly decreased our valuation to $10 per share.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2019 A	Q1 A	Q2 A	Q3 A	Q4 E	2020 E	2021 E	2022 E
MSC-NTF Stem Cells	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$50**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$50**
YOY Growth	-					-	-	-
Cost of Goods / Services	$0.0	$0	$0	$0	$0	$0.0	$0.0	$7.5
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$17.2	$5.9	$5.7	$1.9	$6.0	$19.5	$20.0	$20.0
% R&D	-	-	-	-		-	-	-
SG&A	$5.8	$2.4	$1.7	$2.6	$1.6	$8.3	$6.5	$19.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($23.0)	($8.3)	($7.4)	($4.5)	($7.6)	($27.8)	($26.5)	$3.5
Net Other Income	($0.3)	$0.2	$0.0	$0.0	$0.0	$0.2	$0.0	$0.0
Pre-Tax Income	($23.3)	($8.1)	($7.4)	($4.5)	($7.6)	($27.6)	($26.5)	$3.5
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($23.3)	($8.1)	($7.4)	($4.5)	($7.6)	($27.6)	($26.5)	$3.5
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.06)**	**($0.29)**	**($0.25)**	**($0.14)**	**($0.24)**	**($0.91)**	**($0.80)**	**$0.10**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	21.9	28.4	29.3	31.2	32.0	30.2	33.0	35.0

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

HISTORICAL STOCK PRICE



Source: Zacks SCR

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