Zacks Small-Cap Research

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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Receives GMP Certification for NurOwn® Manufacturing Facility; Ready to Seek Approval Under Hospital Exemption in Israel…

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 (01/04/18)	$3.77
Valuation	**$15.00**

OUTLOOK

On January 3, 2018, BrainStorm Cell Therapeutics, Inc. (BCLI) announced it was granted Good Manufacturing Practice (GMP) approval from the Israel Ministry of Health for its contract manufacturing facility. The approval was necessary in order for the company to apply for the use of NurOwn® in ALS patients in Israel for a fee under the Hospital Exemption regulation. We believe NurOwn® could be approved under the Hospital Exemption by mid-2018.

The Phase 3 clinical trial of NurOwn® continues with strong interest from patients. We are anticipating an interim safety analysis in mid-2018 and topline data in 2019.

SUMMARY DATA

52-Week High	**$4.94**
52-Week Low	**$2.52**
One-Year Return (%)	**49.60**
Beta	**2.21**
Average Daily Volume (sh)	**153,867**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$71**
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	**N/A**
P/E using 2017 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)
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

GMP Certification Approved for NurOwn® Manufacturing Facility in Israel

On January 3, 2018, BrainStorm Cell Therapeutics, Inc. (BCLI) announced that the Israel Ministry of Health has granted Good Manufacturing Practice (GMP) certification for the contract manufacturing facility in Israel. The certification was necessary in order for the company to apply for approval under the new Hospital Exemption regulation. The GMP certification is also recognized as equivalent to the EU GMP, thus BrainStorm could eventually seek approval under any expedited approval protocols in EU countries, although we believe this would not occur for an extended period of time.

The Hospital Exemption is a recently approved regulatory pathway in Israel that allows for companies to partner with medical centers in Israel to allow for patients to receive benefit from custom-made, innovative, treatments where there is a critical unmet need and an absence of valid therapeutic alternatives. The company estimates that approximately 50 to 60 patients could potentially be treated at a time, with a team of neurologists deciding who will get treatment priority based on review of the patients' medical files.

Earlier in 2017, BrainStorm signed a Memorandum of Understanding (MOU) with The Medical Research, Infrastructure, and Health Services Fund of the Tel Aviv Sourasky Medical Center (Ichilov Hospital) which establishes the terms by which BrainStorm and Tel Aviv Sourasky Medical Center would submit an application to the Israel Ministry of Health to allow patient access to NurOwn®. We believe the application will be submitted in the first quarter of 2018.

Phase 3 Trial of NurOwn® Continues

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). 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. The primary outcome of the study is the ALSFRS-R score responder analysis. The study is being supported by $18 million in non-dilutive funding, which consists of a $16 million grant from the California Institute for Regenerative Medicine (CIRM) and a $2.1 million grant from the Israel Innovation Authority. There should be an interim safety analysis performed in mid-2018 with topline data reported in 2019.

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.

Edavarone Approval Shows FDA Eagerness to Approve New ALS Treatments

Earlier in 2017, the U.S. Food and Drug Administration (FDA) announced the approval of edaravone for the treatment of ALS. This is the first medication approved for the treatment of ALS since riluzole in 1995. We believe the news of edaravone's approval is a positive for BrainStorm in that it shows the type of efficacy data that the FDA is looking for in an ALS treatment and BrainStorm's data for NurOwn® is highly comparable to the edaravone data.

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. Following some weakness in the stock toward the end of 2017, it has bounced back somewhat, however we believe it is still greatly undervalued as our 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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