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Brainstorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Phase 3 Trial in ALS Fully Funded; Company to Announced Additional Indications for NurOwn®…

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 (07/24/18)	$4.09
Valuation	**$15.00**

OUTLOOK

On July 23, 2018, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the second quarter of 2018 and provided a business update. The company is continuing to enroll patients in the ongoing Phase 3 study of NurOwn® in amyotrophic lateral sclerosis (ALS). In addition, the company indicated that it will be announcing additional indications for NurOwn® in the coming weeks. This is possible due to a warrant exchange in June 2018 that resulted in gross proceeds of $12.3 million, thus fully funding the Phase 3 ALS trial and allowing the company to advance NurOwn® in additional indications. Lastly, the Data Safety and Monitoring Board (DSMB) will be meeting in the second half of August 2018 to perform an interim safety analysis for the patients that have been treated thus far in the Phase 3 trial.

SUMMARY DATA

52-Week High	**$5.19**
52-Week Low	**$2.96**
One-Year Return (%)	**-15.15**
Beta	**2.07**
Average Daily Volume (sh)	**59,984**
Shares Outstanding (mil)	**20**
Market Capitalization ($mil)	**$83**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**8**
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 2018 Estimate	**-8.3**
P/E using 2019 Estimate	**-8.1**

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)
2017	0 A	0 A	0 A	0 A	0 A
2018	0 A	0 A	0 E	0 E	0 E
2019					0 E
2020					0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.10 A	-$0.06 A	-$0.13 A	$0.01 A	-$0.27 A
2018	-$0.12 A	-$0.16 A	-$0.16 E	-$0.18 E	-$0.62 E
2019					-$0.69 E
2020					-$0.89 E

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WHAT'S NEW

Financial Update

On July 23, 2018, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the second quarter of 2018 and provided a business update. As expected, the company did not report any revenues for the quarter. The company recorded R&D expenses for the second quarter of 2017 and 2018 net of research and development grants from the Israel Innovation Authority (IIA, formerly the Office of the Chief Scientist) and the California Institute for Regenerative Medicine (CIRM). R&D expenses for the second quarter of 2018 were $1.48 million compared with $0.4 million for the second quarter of 2017. Excluding the funds received from the IIA and CIRM grants, R&D expenses were $3.3 million in the second quarter of 2018 compared to $0.9 million for the second quarter of 2017. The increased in expenses was primarily due to increased costs associated with the ongoing Phase 3 clinical trial. G&A expenses for the second quarter of 2018 were $1.6 million compared to $0.6 million in the second quarter of 2017. The increase was primarily due to increased salary and stock-based compensation expenses.

The company recorded a net loss in the second quarter of 2018 of $3.1 million, or $0.16 per share, compared to a net loss of $1.0 million, or $0.05 per share, in the second quarter of 2017. BrainStorm currently has approximately $18.2 million in cash, cash equivalents, and short-term deposits. This is due in part to the exercise of approximately 2.4 million warrants at an amended price of $5 per share generating gross proceeds of approximately $12.3 million. The cash total does not include the remaining approximately $7 million from the CIRM grant and approximately $1 million from the IIA 2018 grant. This amount of capital is sufficient to fully fund the Phase 3 ALS trial and we believe the company will be making an announcement in the next few weeks about additional indications for NurOwn® that will be advanced into the clinic.

As of June 30, 2018, the company had approximately 20.7 million shares of common stock outstanding. In addition, there were approximately 0.9 million options and 5.9 million warrants for a fully diluted share count of approximately 27.5 million.

Business Update

Executive Management Team Strengthened

During the second quarter of 2018, BrainStorm announced the expansion of its executive management team with seasoned veterans that will add valuable experience as the company moves closer to finishing up the Phase 3 trial and potential commercialization stage.

- Susan Ward, PhD has been hired as Head of Clinical Operations. Dr. Ward previously served as Director, Early Clinical Development at Pfizer and has more than 20 years of experience in various leadership positions involving clinical trials, IND-enabling studies, and protocol development.

- Joseph Petroziello has been hired as Vice President of Scientific & Corporate Communications. He previously served as Senior Director/Head of Scientific Communications & Publications at Juno Therapeutics. Mr. Petroziello as over 20 years of medical writing, scientific communication, and drug research experience.

Enrollment in Phase 3 Study Continuing

BrainStorm is continuing to enroll patients in the Phase 3 clinical trial of NurOwn® (NCT03280056) for the treatment of amyotrophic lateral sclerosis (ALS). The trial is taking place at six leading U.S. Medical centers. 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. Cells will be extracted from each patient one time prior to treatment, with all administrations of NurOwn® derived from the same extraction of cells thanks to a cryopreservation process developed for long-term storage of mesenchymal stem cells (MSC). 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”, defined as those who lose at least one point per month in the ALSFRS-R score, thus there are a large group of patients that could potentially be included in the trial.

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. Recently, the company announced that the Connell and O’Reilly Families Cell Manipulation Core Facility at Dana-Farber Cancer Institute will serve as a second manufacturing facility. Dana Farber was previously used as a manufacturing facility of NurOwn® in the Phase 2 trial. In addition to supplying NurOwn® for the ongoing Phase 3 trial, we believe the Dana Farber facility will likely be used to manufacture NurOwn® for any additional clinical indications the company decides to pursue.

DSMB Meeting in August 2018

The first meeting of the Phase 3 Data Safety and Monitoring Board (DSMB) is expected to take place in the second half of August 2018. With some patients having already received multiple doses of NurOwn®, this should give an early indication as to the tolerability of repeat dosing, however we do not anticipate there being any safety issues. The company is also likely to give additional details regarding how many patients have been treated thus far.

Japanese Patent Granted

On July 5, 2018, BrainStorm announced the Japanese Patent Office issued a Decision to Grant notice for Japanese Patent Application 2015-526006 titled “Methods of generating mesenchymal stem cells which secrete neurotrophic factors”. The patent provides protection for NurOwn® in Japan until 2033.

Conclusion

The warrant exercise during the second quarter of 2018 was a smart move by management, as it secured the capital necessary to finish the Phase 3 trial as well as advance additional indications for NurOwn® into the clinic. We look forward to the company providing additional details on these indications in the next few weeks. We also look forward to hearing the outcome of the DSMB meeting in the second half of August 2018, at which time we also anticipate learning additional details about enrollment thus far in the Phase 3 trial. Our probability adjusted discounted cash flow analysis based only on ALS leads to a current valuation of $15.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E	2020 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	$1.0	$1.0	$1.5	$2.0	$2.3	$6.8	$10.0	$15.0
% R&D	-	-	-	-		-	-	-
SG&A	$4.0	$1.3	$1.6	$1.3	$1.4	$5.6	$4.5	$4.5
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($5.0)	($2.3)	($3.1)	($3.3)	($3.7)	($12.4)	($14.5)	($19.5)
Net Other Income	$0.0	($0.0)	$0.0	($0.0)	($0.0)	($0.0)	($0.1)	($0.1)
Pre-Tax Income	($5.0)	($2.3)	($3.1)	($3.3)	($3.7)	($12.4)	($14.6)	($19.6)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($5.0)	($2.3)	($3.1)	($3.3)	($3.7)	($12.4)	($14.6)	($19.6)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.26)**	**($0.12)**	**($0.16)**	**($0.16)**	**($0.18)**	**($0.62)**	**($0.69)**	**($0.89)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	18.8	19.0	19.5	20.7	20.7	20.0	21.0	22.0

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

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