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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: Phase 3 Trial in ALS Enrolling Patients...

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 (03/13/18) **\$3.57**
Valuation **\$15.00**

OUTLOOK

On March 8, 2018, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the fourth quarter and full year 2018 and provided a business update. The company has begun enrolling patients in the Phase 3 clinical trial of NurOwn® in patients with amyotrophic lateral sclerosis (ALS). A total of 200 patients are expected to be enrolled in the trial and topline results will be available at the end of 2019. Grants from the California Institute for Regenerative Medicine (CIRM) and Israeli Innovation Authorities are helping to offset the cost of the trial.

SUMMARY DATA

52-Week High **\$4.94**
52-Week Low **\$2.96**
One-Year Return (%) **-12.28**
Beta **1.95**
Average Daily Volume (sh) **41,910**

Shares Outstanding (mil) **19**
Market Capitalization (\$mil) **\$68**
Short Interest Ratio (days) **N/A**
Institutional Ownership (%) **10**
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	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2017	0 A	0 A	0 A	0 A	0 A
2018	0 E	0 E	0 E	0 E	0 E
2019					0 E
2020					0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2017	-\$0.10 A	-\$0.06 A	-\$0.13 A	\$0.01 A	-\$0.27 A
2018	-\$0.14 E	-\$0.15 E	-\$0.17 E	-\$0.19 E	-\$0.66 E
2019					-\$0.73 E
2020					-\$0.89 E

WHAT'S NEW

Business Update

First Patients Enrolled in Phase 3 Trial

BrainStorm Cell Therapeutics, Inc. (BCLI) has enrolled the first 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”. 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 near the end of 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.

Last year, BrainStorm received a \$16 million grant from the California Institute for Regenerative Medicine (CIRM) to help fund the Phase 3 clinical trial of NurOwn®. In addition to the grant from CIRM, the company was also awarded a non-dilutive grant from the Israel Innovation Authority (IIA, formerly the Office of the Chief Scientist) for \$2.1 million to support the development of NurOwn®.

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. 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®. Approval under the Hospital Exemption program would be a potentially transformative event for BrainStorm into a revenue generating company.

Recent Cell Therapy Approvals Give Insight into Potential Price for NurOwn®

Recently approved cell therapies could provide an insight into what BrainStorm may charge for NurOwn®. In late 2017, Novartis received FDA approval for Kymriah™, a CAR-T cell therapy for the treatment of acute lymphoblastic leukemia (ALL) in children and young adults, for which they are charging \$475,000 for a single treatment. Six weeks later, Gilead received approval for Yescarta™, a CAR-T cell therapy for the treatment of B-cell lymphoma that is priced at \$373,000 per patient. While for a different indication, CAR-T and NurOwn® are similar in that they are autologous cell therapies and thus have similar requirements in terms of infrastructure and costs to produce, thus it would not surprise us to see NurOwn® priced similarly to CAR-T therapies. Our model currently calls for NurOwn® to

be priced at \$100,000/year, thus even if it were priced at only one-half the cost of Yescarta™ our model may prove to be very conservative.

Formation of Scientific Advisory Board

On March 12, 2018, BrainStorm [announced](#) the creation of a scientific advisory board (SAB) and the appointment of Jerold Chun, MD, PhD, as the Chair. Dr. Chun is a neuroscience professor at Sanford Burnham Medical Discovery Institute where he leads of team of 25 researchers in the study of genomic mosaicism and lysophospholipid receptor signaling and their relation to Alzheimer's disease, multiple sclerosis, and other brain diseases. The SAB is being formed to help advise management and provide expertise for both the company's ongoing Phase 3 trial in ALS as well as various other development opportunities in other neurodegenerative diseases such as Parkinson's disease, multiple sclerosis, and autism.

Financial Update

On March 8, 2018, BrainStorm announced financial results for the fourth quarter and full year 2017. As expected, the company did not report any revenues for the quarter or the year. The company recorded 2017 and 2016 R&D expenses net of research and development grants from the IIA and CIRM. For 2017, R&D expenses were \$0.98 million net of research and development grants of \$1.4 million from the IIA and \$4.4 million from CIRM compared with \$2.3 million in 2016 that included \$1.2 million in IIA grants. Excluding the IIA and CRIM grants, R&D expenses were \$6.8 million in 2017 and \$3.4 million in 2016. The increase in expenses was primarily due to activities related to the NurOwn® Phase 3 clinical trial. G&A expenses for 2017 and 2016 were \$4.0 million and \$2.8 million, respectively. The increase was primarily due to increased salary and stock-based compensation expenses, investor relations expenses, and travel and rent expenses.

The company recorded a net loss in 2017 of \$5.0 million, or \$0.26 per share, compared to a net loss of \$5.0 million, or \$0.27 per share, in 2016. BrainStorm exited 2017 with approximately \$7.8 million in cash, cash equivalents, and short-term investments, which we anticipate will be sufficient to fund operations for the next 12 months. In addition, the cash total does not include anticipated funds from the rest of the \$16 million CIRM grant. As of Mar. 6, 2018, the company had approximately 19.0 million shares outstanding. In addition, there were 5.9 million options and 0.9 million warrants for a fully diluted share count of 25.9 million.

Conclusions

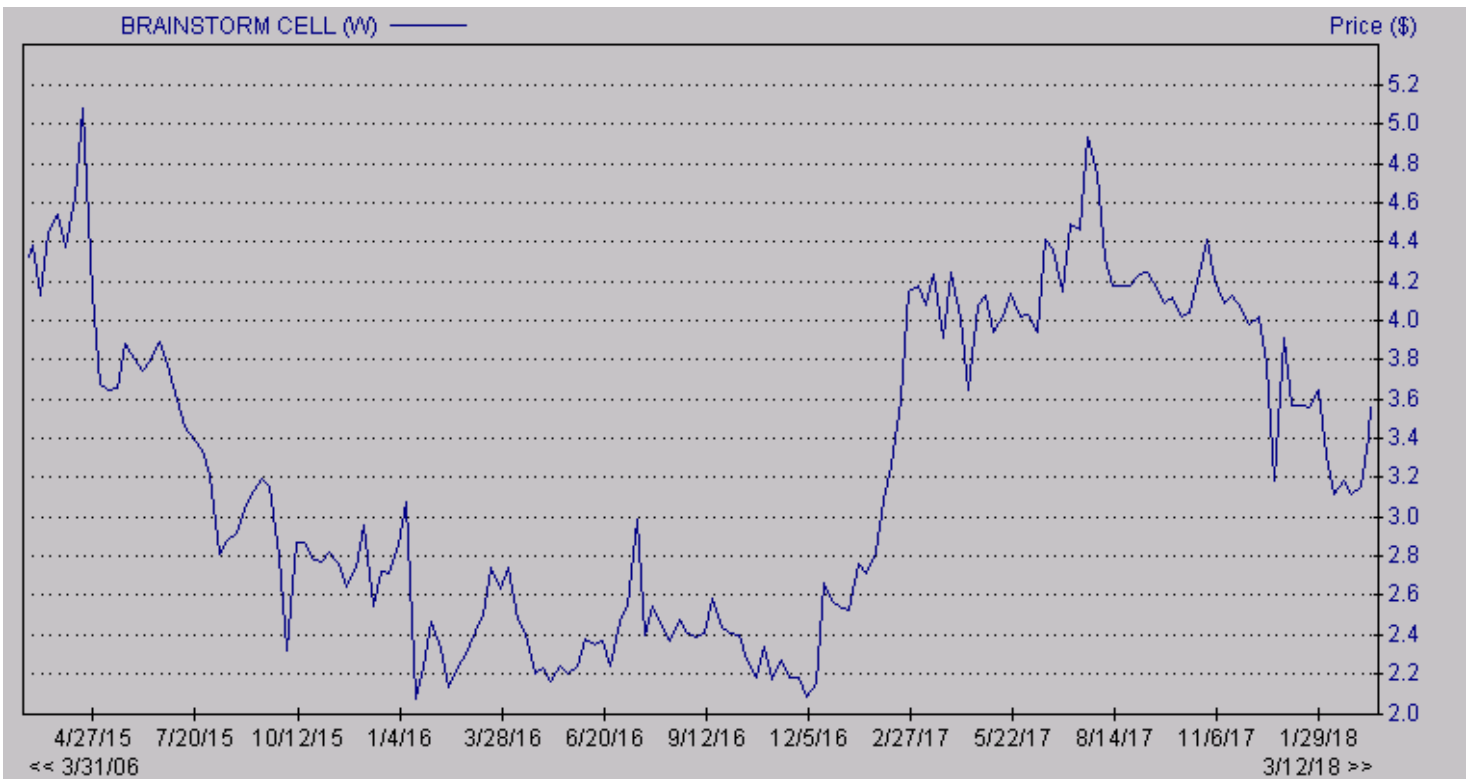
We're glad to see that BrainStorm has begun dosing patients in the Phase 3 study and that the grant money from both CIRM and IIA is helping to offset trial expenses. We anticipate an interim safety analysis for the trial taking place in mid-2018. BrainStorm has been adding expertise to its Board of Directors, most recently with the addition of Anthony Polverino, PhD, who is the Chief Scientific Officer of Kite Pharmaceuticals. His knowledge of cell product manufacturing should prove quite valuable as BrainStorm moves toward commercial operations. On a related note, during the recent conference call management noted that it may be close to providing an update on the Hospital Exemption program in Israel, although we have not included any potential revenues from that program in our model until the company is able to provide additional guidance. Our valuation remains at \$15 per share.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2017 A	Q1 E	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 E
MSC-NTF Stem Cells	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Total Revenues	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Cost of Goods / Services	\$0.0	\$0	\$0	\$0	\$0	\$0.0	\$0.0	\$0.0
<i>Product Gross Margin</i>	-	-	-	-	-	-	-	-
R&D	\$1.0	\$1.5	\$1.7	\$2.0	\$2.3	\$7.5	\$10.0	\$15.0
<i>% R&D</i>	-	-	-	-	-	-	-	-
SG&A	\$4.0	\$1.2	\$1.2	\$1.3	\$1.4	\$5.1	\$4.5	\$4.5
<i>% SG&A</i>	-	-	-	-	-	-	-	-
Operating Income	(\$5.0)	(\$2.7)	(\$2.9)	(\$3.3)	(\$3.7)	(\$12.6)	(\$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)	(\$2.7)	(\$2.9)	(\$3.3)	(\$3.7)	(\$12.6)	(\$14.6)	(\$19.6)
Taxes	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$5.0)	(\$2.7)	(\$2.9)	(\$3.3)	(\$3.7)	(\$12.6)	(\$14.6)	(\$19.6)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$0.26)	(\$0.14)	(\$0.15)	(\$0.17)	(\$0.19)	(\$0.66)	(\$0.73)	(\$0.89)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	18.8	19.1	19.2	19.2	19.3	19.2	20.0	22.0

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

HISTORICAL STOCK PRICE



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