Zacks Small-Cap Research

May 17, 2016
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: Preparing for Multi-dose Phase 2 Trial of NurOwn™ in ALS; Data From Single-dose ALS Trial in the U.S. in mid-2016…***

Based on our probability adjusted DCF model that takes into account potential future revenues from NurOwn™ in ALS, BCLI is valued at $10/share. This model is highly dependent upon continued clinical success of NurOwn™ and will be adjusted accordingly based upon future clinical results.

| | |
|---|---|
| Current Price (05/17/16) | $2.28 |
| **Valuation** | **$10.00** |

## OUTLOOK

On May 10, 2016, BrainStorm Cell Therapeutics, Inc. announced financial results for the first quarter of 2015. The company reported a net loss of $1.8 million and ended the quarter with approximately $12.9 million in cash and short-term deposits, which should be enough to fund operations for at least the next 12 months.

BrainStorm announced that results from the ongoing Phase 2 clinical trial of NurOwn™ in patients with amyotrophic lateral sclerosis (ALS) will be reported in mid-2016. In addition, the company will be conducting a multi-dose trial of NurOwn™ in ALS patients that we anticipate beginning later in 2016, following approval from the Ministry of Health in Israel.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$4.02** |
| **52-Week Low** | **$1.90** |
| **One-Year Return (%)** | **-38.53** |
| **Beta** | **1.24** |
| **Average Daily Volume (sh)** | **49,414** |
| **Shares Outstanding (mil)** | **19** |
| **Market Capitalization ($mil)** | **$42** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **10** |
| **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) |
|---|---|---|---|---|---|
| 2015 | 0 A | 0 A | 0 A | 0 A | 0 A |
| 2016 | 0 A | 0 E | 0 E | 0 E | 0 E |
| 2017 | | | | | 0 E |
| 2018 | | | | | 0 E |

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

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2015 | -$0.12 A | -$0.12 A | -$0.14 A | -$0.08 A | -$0.46 A |
| 2016 | -$0.10 A | -$0.10 E | -$0.10 E | -$0.09 E | -$0.38 E |
| 2017 | | | | | -$0.41 E |
| 2018 | | | | | -$0.46 E |

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

## WHAT'S NEW

**Financial Update**

On May 10, 2016, BrainStorm Cell Therapeutics (BCLI) announced financial results for the first quarter of 2016. As expected, the company reported no revenues for the quarter. Net loss for the first quarter of 2016 was $1.8 million, or $0.10 per share, and was comprised of $1.0 million of R&D expenses and $0.8 million of G&A expenses. The company exited the first quarter of 2016 with cash and short-term investments of $12.9 million. We estimate that this is sufficient to fund operations for at least the next 12 months.

As of May 6, 2016 the company had approximately 18.7 million shares outstanding. In addition, there were 1.0 million stock options and 6.4 million warrants for a fully diluted share count of 26.1 million. The warrants have a wide range of exercise prices, however the 3.86 million warrants issued in connection with the raise in January 2015 have an exercise price of $6.50, an expiration date of June 2018, and could potentially bring in gross proceeds of $25 million to the company.

On May 12, 2016, BrainStorm announced the receipt of a new grant of approximately $1.47 million from Israel's Office of the Chief Scientist (OCS). This is the ninth year that OCS has supported BrainStorm with grant money, which is indicative of the confidence OCS has in the company's technology. BrainStorm will pay mid-single digit royalties to the OCS based o sales of NurOwn™ up to a total of the cumulative amount of OCS grants received plus accumulated interest.

**Business Update**

*NurOwn™ Phase 2 Clinical Trial Data to be Reported in Mid-2016*

BrainStorm is developing adult stem cells therapies for the treatment of a range of neurodegenerative diseases, including ALS, Autism, Multiple Sclerosis (MS), and Parkinson's disease (PD). The company has a proprietary process called NurOwn™ that harvests and propagates autologous Mesenchymal Stem Cells (MSC) and then induces their differentiation into neurotrophic factor (NTF) secreting cells, called MSC-NTF. The cells are then returned to the patient at or near the target area for treatment. Because these cells are autologous, there is virtually no risk of rejection or tumor formation.

The company is currently conducting a Phase 2 clinical trial of NurOwn™ for the treatment of ALS in the U.S (NCT02017912). This is a randomized, double blind, placebo controlled trial that will evaluate the safety and efficacy of a single combined IM and IT administration of MSC-NTF cells in early-stage ALS patients. The trial is taking place at three centers in the U.S. (Massachusetts General Hospital (MGH), University of Massachusetts Memorial Hospital, and the Mayo Clinic) and has enrolled 48 patients randomized 3:1 to receive either NurOwn™ cells (n=36) or placebo (n=12).

Just as with prior clinical trial's conducted by the company, there is a three-month run-in, followed by treatment and a six-month follow up. The primary endpoint of the study is safety based on the number of patients with adverse events, with secondary endpoints including the change in the "ALS Functional Rating Scale Revised" (ALSFRS-r) and lung function as measured by vital capacity.

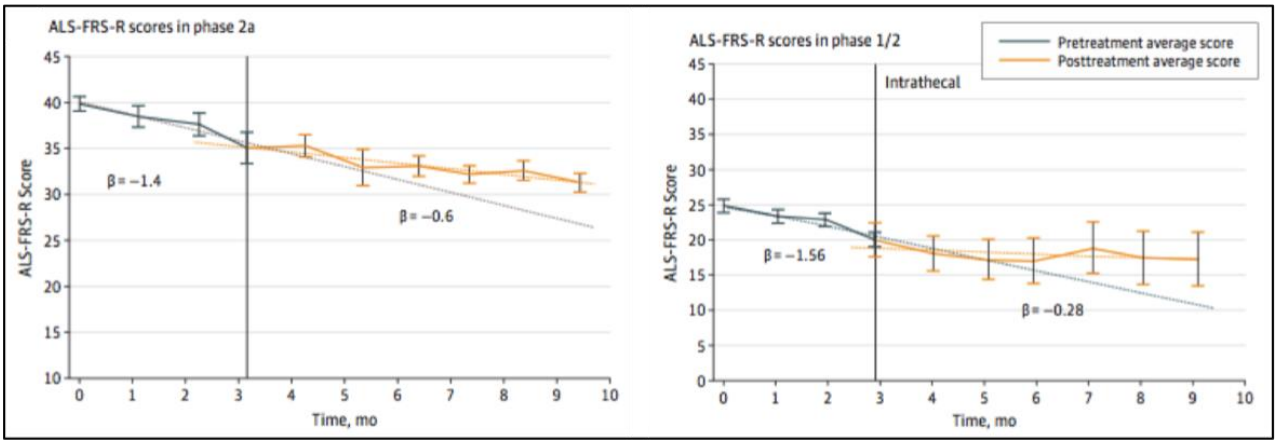
The trial is now fully enrolled and all patients have completed treatment. With a six-month follow up, we are estimating that topline data will be available in mid-2016. An independent Data Safety and Monitoring Board (DSMB) is watching the trial and in February 2015 noted no issues. The DSMB conducted its second pre-planned safety review in November 2015 and again recommended that the study continue as planned with no safety issues noted.

*NurOwn™ Data in ALS Published in JAMA Neurology*

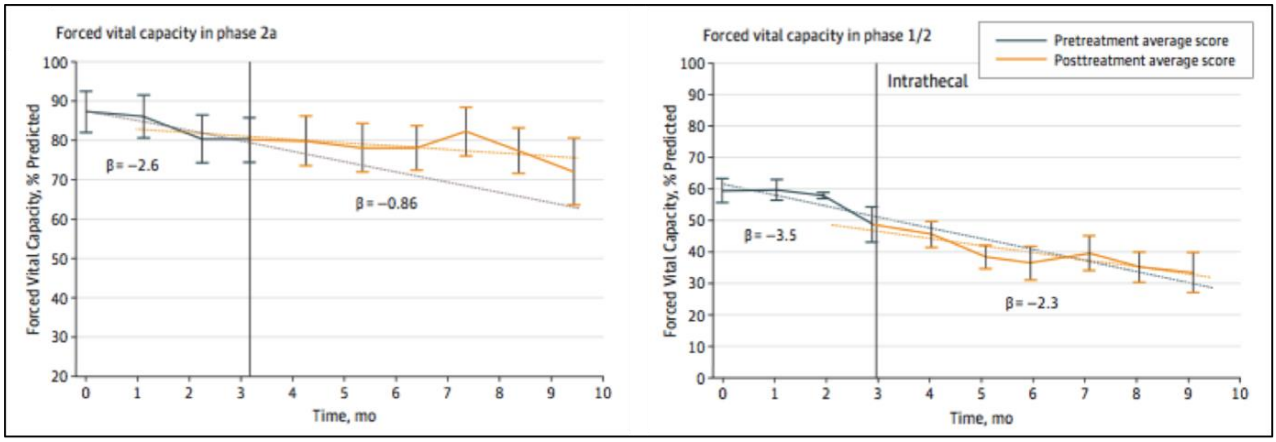
On January 11, 2016, BrainStorm announced the publication of a peer-reviewed paper in the journal *JAMA Neurology* describing results from BrainStorm's Phase 1/2 and Phase 2a clinical trials of NurOwn™ in ALS patients. The paper can be found here. Getting the clinical trial data published in a prestigious journal such as *JAMA Neurology* (Impact Factor = 7.348 in 2015) was a very important milestone for the company.

As a brief reminder, BrainStorm previously conducted a Phase 1/2 and a Phase 2a clinical trial of NurOwn™, both of which took place at Hadassah Medical Center between June 2011 and October 2014. All patients in the trials had a three-month run-in period, were treated with NurOwn™, and then evaluated during a six-month follow-up time. The Phase 1/2 trial consisted of 12 patients (six patients received NurOwn™ intramuscularly [IM] while six patients received NurOwn™ intrathecally [IT]) and the study met its primary endpoints of safety and tolerability, with no treatment-related adverse events reported. The Phase 2a study consisted of 14 patients that received both IM and IT injections of NurOwn™. Topline results from the Phase 2a study were released in January 2015, and the study achieved its primary endpoint of demonstrating that NurOwn™ cells were safe and well tolerated at doses up to 2 million cells per kilogram administered IT and 24 million cells administered IM.

As discussed in the press release announcing the publication, the results from the two clinical trials demonstrated indications of clinically meaningful benefits in those patients that received IT injections of NurOwn™. This was shown by a change in the rate of decline in the ALSFRS-r as well as the forced vial capacity (FVC) in the pretreatment versus posttreatment periods. The results are shown below.




*Adapted from*: Petrou *et al*., 2016




*Adapted from*: Petrou *et al*., 2016

In the paper, BrainStorm indicated that a patient who demonstrated a posttreatment improvement in the slope of at least 25% for either ALSFRS-r or FVC compared to the run-in period was considered a “responder”. The reason that BrainStorm classified these patients as such is based on a 2010 survey of ALS clinicians and researchers that showed all participants in the survey believed a decline of 25% or more in the change in ALSFRS-r was at least somewhat clinically meaningful (Castrillo-Viguera *et al*., 2010). According to this definition, 87% of the patients injected IT with NurOwn™ were considered responders, which is a very encouraging number. These data provide a nice foundation from which to support the company’s planned multi-dose Phase 2 clinical trial, which will get underway later in 2016.

**Multi-dose Trial Set to Get Underway Later in 2016**

On January 11, 2016, BrainStorm announced that the company will be conducting a multi-dose trial of NurOwn™ in ALS patients. The trial will be taking place at Hadassah Medical Center in Israel and will be used to provide guidance for a Phase 3 program for NurOwn™. We anticipate 24 patients to enroll in the trial, although this number may be increased to allow for greater statistical power in the study, who will be treated with three doses of NurOwn™ spaced out every two months to explore the safety and efficacy of multi-dose administration. The company is currently awaiting approval for the trial by the Ministry of Health, and we anticipate that this will occur shortly such that the trial can get underway in the second half of 2016.

**Conclusion**

With the publication of data from the company's initial trials of NurOwn™ in ALS patients, BrainStorm has successfully demonstrated proof-of-concept for NurOwn™ cells for the treatment of ALS. However, it must be kept in mind that these were primarily safety studies and did not contain a control arm. This doesn't necessarily take away from the positive results reported, but means that additional data is necessary before firm conclusions can be drawn about the ability of NurOwn™ treatment to augment the natural progression of ALS. We are looking forward to evaluating the data from the ongoing placebo controlled Phase 2 study, which should give more clarity about the efficacy of NurOwn™.

From a valuation standpoint, we think BrainStorm shares are highly attractive. The company is well capitalized, with $12.9 million cash and cash equivalents as of March 31, 2016. In terms of timeline, top-line data from the Phase 2 trial should be available in mid-2016. The multi-dose Phase 2 trial will likely commence in the second half of 2016. This would likely lead to a Phase 3 trial starting in late 2017. For valuation purposes, we note that Riluzole®, the only FDA approved treatment for ALS, costs $50,000 per year and was shown to only extend survival by two to three months. We believe NurOwn™ has the potential to extend patient survival by much more than that, particularly with multiple doses. Thus, we think $100,000 per treatment is very realistic for NurOwn™. We have built a detailed financial model to forecast potential sales of NurOwn™ in ALS. We believe U.S. penetration could approach 40%, which would put U.S. sales at the $1.6 billion range. With 25% probability of success, we see BrainStorm worth $250 million, or $10 per share.

## PROJECTED FINANCIALS

**BrainStorm Cell Therapeutics, Inc.**
Income Statement

| Brainstorm Cell Therapeutics | 2015 A | Q1 A | Q2 E | Q3 E | Q4 E | 2016 E | 2017 E | 2018 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 |
| *Product Gross Margin* | - | - | - | - | - | - | - | - |
| R&D | $4.9 | $1.0 | $1.0 | $1.1 | $1.0 | $4.1 | $5.5 | $7.0 |
| *% R&D* | - | - | - | - | - | - | - | - |
| SG&A | $3.6 | $0.8 | $0.8 | $0.8 | $0.8 | $3.2 | $3.6 | $4.0 |
| *% SG&A* | - | - | - | - | - | - | - | - |
| Operating Income | ($8.5) | ($1.8) | ($1.8) | ($1.9) | ($1.8) | ($7.3) | ($9.1) | ($11.0) |
| Net Other Income | $0.0 | $0.0 | $0.0 | ($0.0) | ($0.0) | $0.0 | ($0.0) | ($0.0) |
| Pre-Tax Income | ($8.5) | ($1.8) | ($1.8) | ($1.9) | ($1.8) | ($7.3) | ($9.1) | ($11.0) |
| Taxes | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| Net Income | ($8.5) | ($1.8) | ($1.8) | ($1.9) | ($1.8) | ($7.3) | ($9.1) | ($11.0) |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($0.46)** | **($0.10)** | **($0.10)** | **($0.10)** | **($0.09)** | **($0.38)** | **($0.41)** | **($0.46)** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Wt. Ave Shares Outstanding | 18.4 | 18.7 | 18.9 | 19.1 | 19.4 | 19.0 | 22.0 | 24.0 |

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

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

## WEEKLY PRICE CHART




Source: Stockcharts.com

© Copyright 2016, 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.