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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 ALS Data Expected by the End of November 2020…*

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 $33.00/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

| | |
|---|---|
| Current Price (08/07/20) | $13.11 |
| **Valuation** | **$33.00** |

## OUTLOOK

On August 5, 2020, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the second quarter of 2020 and provided a business update. Having successfully completed dosing for all patients in the Phase 3 trial of NurOwn® we now anticipate topline data from that trial before the end of November 2020. The company has also finished enrollment in the Phase 2 trial of NurOwn® in patients with progressive multiple sclerosis (MS) and we anticipate dosing to be completed by the end of 2020. Following the recent rise in the share price, the company raised gross proceeds of approximately $13.6 million from its ATM agreement along with gross proceeds of approximately $6.3 million from warrant exercises.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$15.83** |
| **52-Week Low** | **$3.54** |
| **One-Year Return (%)** | **208.38** |
| **Beta** | **1.19** |
| **Average Daily Volume (sh)** | **779,444** |
| **Shares Outstanding (mil)** | **32** |
| **Market Capitalization ($mil)** | **$383** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **13** |
| **Insider Ownership (%)** | **21** |
| **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 E | 0 E | 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 | -$0.21 E | -$0.22 E | -$0.25 E | -$0.96 E |
| 2020 | | | | | -$0.80 E |
| 2021 | | | | | $0.10 E |

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## WHAT'S NEW

### Business Update

*Topline Data from Phase 3 ALS Trial Before End of November 2020*

BrainStorm Cell Therapeutics, Inc. (BCLI) is currently conducting a Phase 3 clinical trial of NurOwn® in patients with amyotrophic lateral sclerosis (ALS) (NCT03280056). A total of 200 patients were randomized 1:1 to receive NurOwn® or placebo in the randomized, double blind, placebo controlled, multi-dose trial. Cells were extracted once from each patient prior to treatment, with all administrations of NurOwn® derived from the same extraction of cells due to a cryopreservation process the company developed for long-term storage of mesenchymal stem cells (MSC). Just as with the company's prior studies, there was 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 company is focusing the trial on faster-progressing ALS patients since those patients demonstrated superior outcomes in the Phase 2 trial of NurOwn®. The primary outcome of the trial is the ALSFRS-R score responder analysis and we now anticipate topline results before the end of November 2020.

*Update on Phase 2 Progressive Multiple Sclerosis Trial*

BrainStorm is currently conducting a Phase 2 clinical trial of NurOwn® in patients with progressive multiple sclerosis (MS) (NCT03799718). The trial is an open label, single arm study that is enrolling patients with progressive MS with Expanded Disability Status Scale (EDSS) scores of 3.0 – 6.5. The primary endpoint of the study is the safety and tolerability of three doses of NurOwn® with secondary endpoints examining the timed 25-foot walking speed or 9-hole peg test (both validated MS clinical outcome assessments) along with paired cerebrospinal fluid (CSF) and blood biomarker analysis. The National Multiple Sclerosis Society awarded the company a $0.5 million grant to help fund the study.

The trial is now fully enrolled and we anticipate dosing to be completed for all patients by the end of 2020. While the company had previously considered performing an interim analysis, since topline data would be available soon after an interim analysis could be performed the company has decided against performing an interim analysis and will instead report topline data for all 20 patients when it becomes available.

*NurOwn® Derived Exosomes Show Promise in Preclinical ARDS Study*

On July 23, 2020, BrainStorm announced the successful completion of the first milestone in developing an exosome-based platform for the treatment of severe acute respiratory distress syndrome (ARDS) caused by COVID-19. Exosomes are small vesicles (30-150 nm) that are secreted by all cell types. Exosomes from mesenchymal stem cells (MSCs), from which NurOwn® is derived, can penetrate into deep tissues and deliver various bioactive molecules. In addition, they can be delivered both intravenously or intratracheally.

BrainStorm conducted a preclinical study of MSC-derived exosomes in a mouse model of lipopolysaccharide (LPS)-induced ARDS. Treatment with intratracheally administered exosomes resulted in a statistically significant improvement in various lung functions, including functional lung recovery and decreased lung damage, as judged by the lung disease severity score ($P$=0.03). In addition, they led to a reduction in a number of pro-inflammatory cytokines. Lastly, exosomes derived from MSC-NTF cells were superior to exosomes derived from naïve MSC from the same donor.

We anticipate the results being submitted to a peer reviewed journal for publication and the company is currently deciding whether to initiate a clinical trial program in COVID-19 patients with ARDS.

### Financial Update

On August 5, 2020, BrainStorm announced financial results for the second quarter of 2020. As anticipated, the company did not report any revenues during the second quarter of 2020. Net R&D expenses for the second quarter of 2020 were $5.7 million, compared to $3.6 million for the second quarter of 2019. The increase was primarily due to an increase in payroll and stock-based compensation and a decrease in support from the Israel Innovation Authority (IIA) and California Institute for Regenerative Medicine (CIRM) along with a decrease in costs related to the Phase 3 and Phase 2 clinical trials. Excluding participation from the IIA and CIRM, R&D expenses were $6.0

million in the second quarter of 2020, compared to $6.5 million in the second quarter of 2019. G&A expenses for the second quarter of 2020 were $1.7 million, compared to $1.3 million in the second quarter of 2019. The increase was primarily due to increased payroll and stock-based compensation.

The company exited the second quarter of 2020 with approximately $16.2 million in cash, cash equivalents, and short-term investments. Subsequent to the end of the quarter, the company raised gross proceeds of approximately $13.7 million from the $50 million ATM facility entered into in March 2020 through the sale of 945,082 shares at an average price of $14.48 per share. In addition, the company raised gross proceeds of approximately $6.3 million from the exercise of warrants. We estimate that the company currently has approximately $35 million in cash, cash equivalents, and short-term investments.

As of July 31, 2020, the company had approximately 31.5 million shares outstanding and, when factoring in warrants and stock options, a fully diluted share count of approximately 37.0 million.

**Conclusion**

The countdown is on to the topline data release for the Phase 3 ALS trial, with those results expected before the end of November 2020. Even with the great run the stock has had since its recent lows in March 2020, we continue to view the shares as undervalued as we currently forecast peak sales for NurOwn® of >$1 billion in ALS, >$500 million in MS, and >$2 billion in Alzheimer's disease. We recently made a slight change to our model, in which we decreased the discount rate from 17% to 13%, and combined with the recent financing activity has resulted in an increase to our valuation to $33 per share.

## PROJECTED FINANCIALS

| Brainstorm Cell Therapeutics | 2019 A | Q1 A | Q2 A | Q3 E | 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 | $5.0 | $6.0 | $22.6 | $20.0 | $20.0 |
| *% R&D* | - | - | - | - | | - | - | - |
| SG&A | $5.8 | $2.4 | $1.7 | $1.6 | $1.6 | $7.3 | $6.5 | $19.0 |
| *% SG&A* | - | - | - | - | - | - | - | - |
| Operating Income | ($23.0) | ($8.3) | ($7.4) | ($6.6) | ($7.6) | ($29.9) | ($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) | ($6.6) | ($7.6) | ($29.7) | ($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) | ($6.6) | ($7.6) | ($29.7) | ($26.5) | $3.5 |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($1.06)** | **($0.29)** | **($0.25)** | **($0.21)** | **($0.24)** | **($0.98)** | **($0.80)** | **$0.10** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Wt. Avg Shares Outstanding | 21.9 | 28.4 | 29.3 | 31.5 | 32.0 | 30.3 | 33.0 | 35.0 |

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

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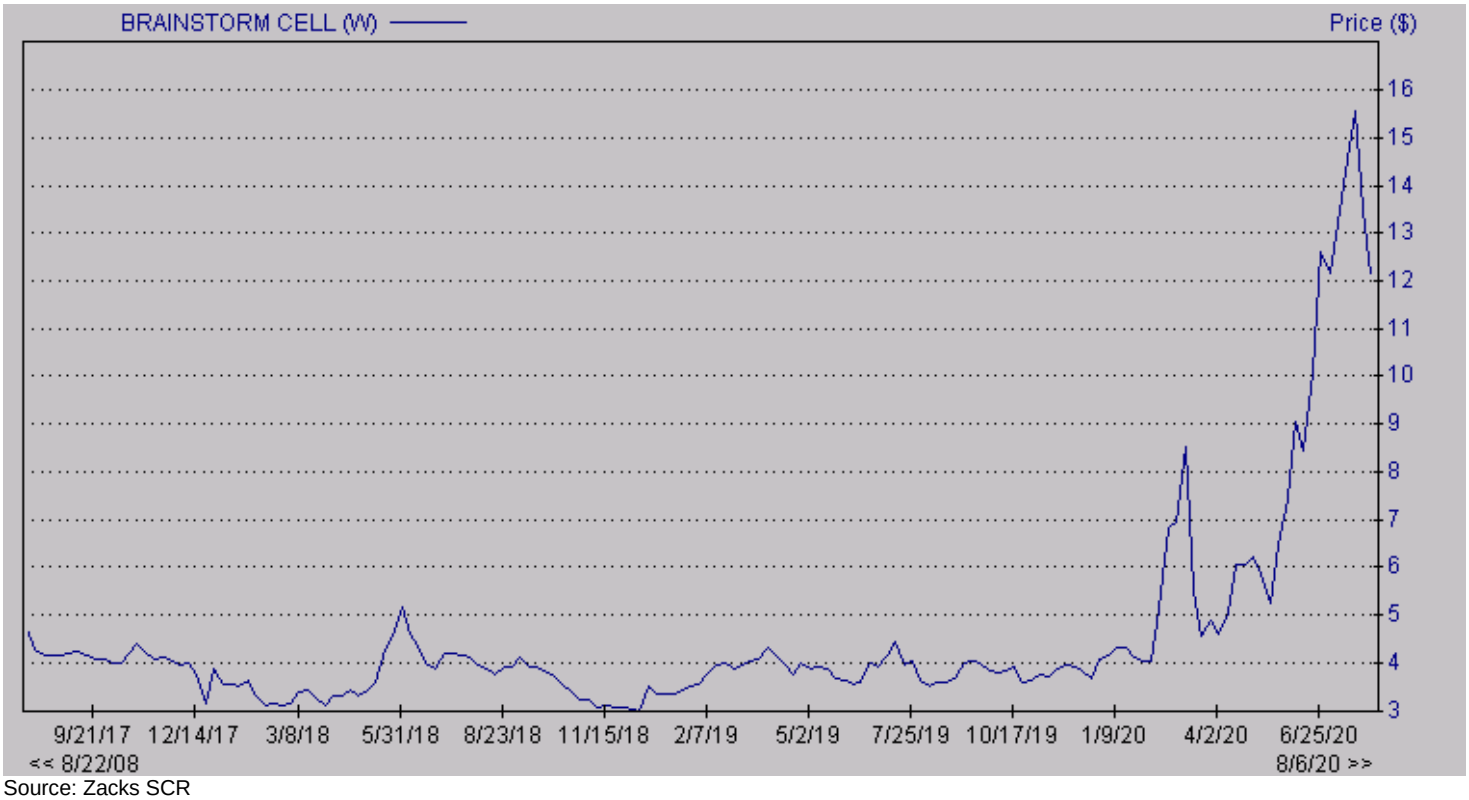
## HISTORICAL STOCK PRICE




Source: Zacks SCR

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