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# BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

## *BCLI: Continuing to Receive Feedback on Next Steps for NurOwn®…*

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 $11.00/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

| | |
|---|---|
| Current Price (04/28/21) | $3.53 |
| **Valuation** | **$11.00** |

## OUTLOOK

On April 26, 2021, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the first quarter of 2021 and provided a business update. The company recently announced positive proof-of-concept data for NurOwn in progressive multiple sclerosis that included consistent improvement across multiple functional measures in comparison to the matched clinical cohort from the CLIMB study. For ALS, we anticipate a publication of NurOwn's Phase 3 results being submitted to a peer-reviewed journal shortly. The company is continuing to meet with consultants and ALS advocates as it weighs its options for next steps in advancing NurOwn.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$17.73** |
| **52-Week Low** | **$3.11** |
| **One-Year Return (%)** | **-41.56** |
| **Beta** | **0.08** |
| **Average Daily Volume (sh)** | **423,329** |
| **Shares Outstanding (mil)** | **36** |
| **Market Capitalization ($mil)** | **$128** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **23** |
| **Insider Ownership (%)** | **22** |
| **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** | **High** |
| **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) |
|---|---|---|---|---|---|
| 2020 | 0 A | 0 A | 0 A | 0 A | 0 A |
| 2021 | 0 A | 0 E | 0 E | 0 E | 0 E |
| 2022 | | | | | 50 E |
| 2023 | | | | | 150 E |

**Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2020 | -$0.29 A | -$0.25 A | -$0.14 A | -$0.39 A | -$1.07 A |
| 2021 | -$0.19 A | -$0.24 E | -$0.24 E | -$0.24 E | -$0.90 E |
| 2022 | | | | | $0.00 E |
| 2023 | | | | | $1.89 E |

## WHAT'S NEW

**Business Update**

*Continuing to Consult on Potential Paths Forward for NurOwn® in ALS*

BrainStorm Cell Therapeutics, Inc. (BCLI) has completed a Phase 3 clinical trial for NurOwn as a treatment for amyotrophic lateral sclerosis (ALS) and in November 2020 announced topline results showing that the trial did not reach statistical significance for the primary endpoint, a responder analysis examining the percentage of participants that experienced a 1.25 point per month improvement in the post-treatment Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFRS-R) slope. However, an analysis of a pre-specified subgroup of patients with ALSFRS-R scores ≥ 35, of which approximately 30% of trial participants were included, showed a clinically meaningful treatment response with NurOwn with 34.6% of responders compared to 15.6% of responders in placebo-treated participants (*P*=0.288).

On February 22, 2021, BrainStorm announced feedback from the FDA following a meeting with senior leadership in which the agency concluded from their initial review of the Phase 3 data that it does not provide the threshold of substantial evidence that the FDA is seeking to support a Biologics License Application (BLA). The FDA also advised that the recommendation does not preclude BrainStorm from proceeding with a BLA submission.

In the near-term, we anticipate the company submitting a publication on the Phase 3 ALS results to a peer-reviewed journal in the near future and presentations at upcoming scientific conferences throughout the year. The company is continuing to meet with regulatory consultants, ALS advocacy groups, physicians, and potential strategic partners to determine the best path forward, which may include an FDA BLA submission, a regulatory submission in other geographies, and/or other regulatory and business options.

*Positive Proof-of-Concept Data for NurOwn in Progressive MS*

On March 24, 2021, BrainStorm Cell Therapeutics, Inc. (BCLI) announced positive proof-of-concept data for NurOwn in patients with progressive multiple sclerosis (MS). The trial achieved the primary endpoint of safety and encouraging results were seen in multiple secondary, functional endpoints.

The Phase 2 trial was a multicenter, open label trial that enrolled 20 patients, with 18 treated and 16 completing the study. Two of the enrolled patients decided against continuing in the trial before dosing began, with one patient withdrawing following dosing due to non-specific symptoms and another due to back/leg pain. Following a 10-week run-in period, patients were dosed with 1-1.25 x $10^6$ MSC-NTF cells three times at 2-month intervals. Patients were followed for 28 weeks following the first treatment. The secondary functional endpoints examined included:

- Timed 25-Foot Walking Speed (T25FW): Scoring is the average of two trials. A patient is directed to walk 25 feet quickly and as safely as possible from one marked end to the other. The patient then walks back the same distance.

- 9-Hole Peg Test (9-HPT): This test is administered by patients taking pegs from a container, one by one, and placing them in holes as quickly as possible. The patient then removes the pegs one by one and puts them back in the container. Both dominant and non-dominant hands are tested.

- Low Contrast Letter Acuity (LCLA): This is similar to a standard eye chart test but instead of black letters on a white background (100% contrast), low contrast levels are used and the number of letters identified is scored.

- Symbol Digit Modality Test (SDMT): Using a reference key, a test subject has 90 seconds to pair specific numbers with given geometric figures. It is a simple substitution task that normal adults can easily perform and can be utilized to detect changes in cognitive functioning over time.

- 12-item Multiple Sclerosis Walking Scale (MSWS-12): This is a self-reported measure of the impact of MS on a patient's walking ability.

Baseline characteristics for study participants showed that the mean age was 47, 56% were female, and the mean

baseline Expanded Disability Status Scale (EDSS) score was 5.4. The results of the trial were compared to a matched clinical cohort of 48 patients from the Comprehensive Longitudinal Investigations in MS at the Brigham & Woman's Hospital (CLIMB Study) (Gauthier *et al*., 2006).

Highlights from the topline results of secondary functional outcomes include:

- 14% and 13% of NurOwn-treated patients showed a 25% improvement in T25FW and 9-HPT, respectively, compared to 0% from the matched cohort from the CLIMB registry.

- 38% of NurOwn-treated patients showed a ≥10-point improvement in the MSWS-12 (CLIMB cohort not analyzed for this outcome).

- 47% of NurOwn-treated patients showed a ≥8-letter improvement in the LCLA (CLIMB cohort not analyzed for this outcome).

- 67% of NurOwn-treated patients showed a ≥3-point improvement in the SDMT (BrainStorm is waiting on the results for SDMT for the CLIMB cohort).

- On average, there was a 10% improvement in T25FW and a 4.8% improvement on the 9-HPT for NurOwn-treated patients, compared to a 1.8% and 1.4% worsening, respectively, in the matched control group from the CLIMB registry.

Previous trials of MS drugs have noted an association between loss of vision, as measured by the LCLA, and diminished quality of life (Chahin *et al*., 2015), thus the improvements in vision seen in almost half the patients treated with NurOwn are particularly noteworthy.

We anticipate the company presenting the full data set at an upcoming scientific conference and publishing the results in a peer reviewed journal article later this year. Additional analyses that the company has not yet completed include detailed cerebrospinal fluid (CSF) and blood biomarker analyses along with MRI analyses (brain lesions, brain volume, etc.).

**Financial Update**

On April 26, 2021, BrainStorm announced financial results for the first quarter of 2021. As anticipated, the company did not report any revenues during the first quarter of 2021. Net R&D expenses for the first quarter of 2021 were $4.3 million, compared to $6.0 million during the first quarter of 2020. The decrease was primarily due to lower clinical trial costs and stock-based compensation. Excluding participation from the Israeli Innovation Authority (IIA) and proceeds received under the hospital exemption regulatory pathway, R&D expenses were $4.8 million in the first quarter of 2021 compared to $7.1 million in the first quarter of 2020. G&A expenses for the first quarter of 2021 were $2.6 million compared to $2.4 million for the first quarter of 2020. The increase was primarily due to increased compensation and consultant expenses.

The company exited the first quarter of 2021 with approximately $40 million in cash, cash equivalents, and short-term deposits. In addition, BrainStorm has approximately $16 million available in untapped ATM capacity. As of April 23, 2021, BrainStorm had approximately 36.3 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 43.3 million.

**Conclusion**

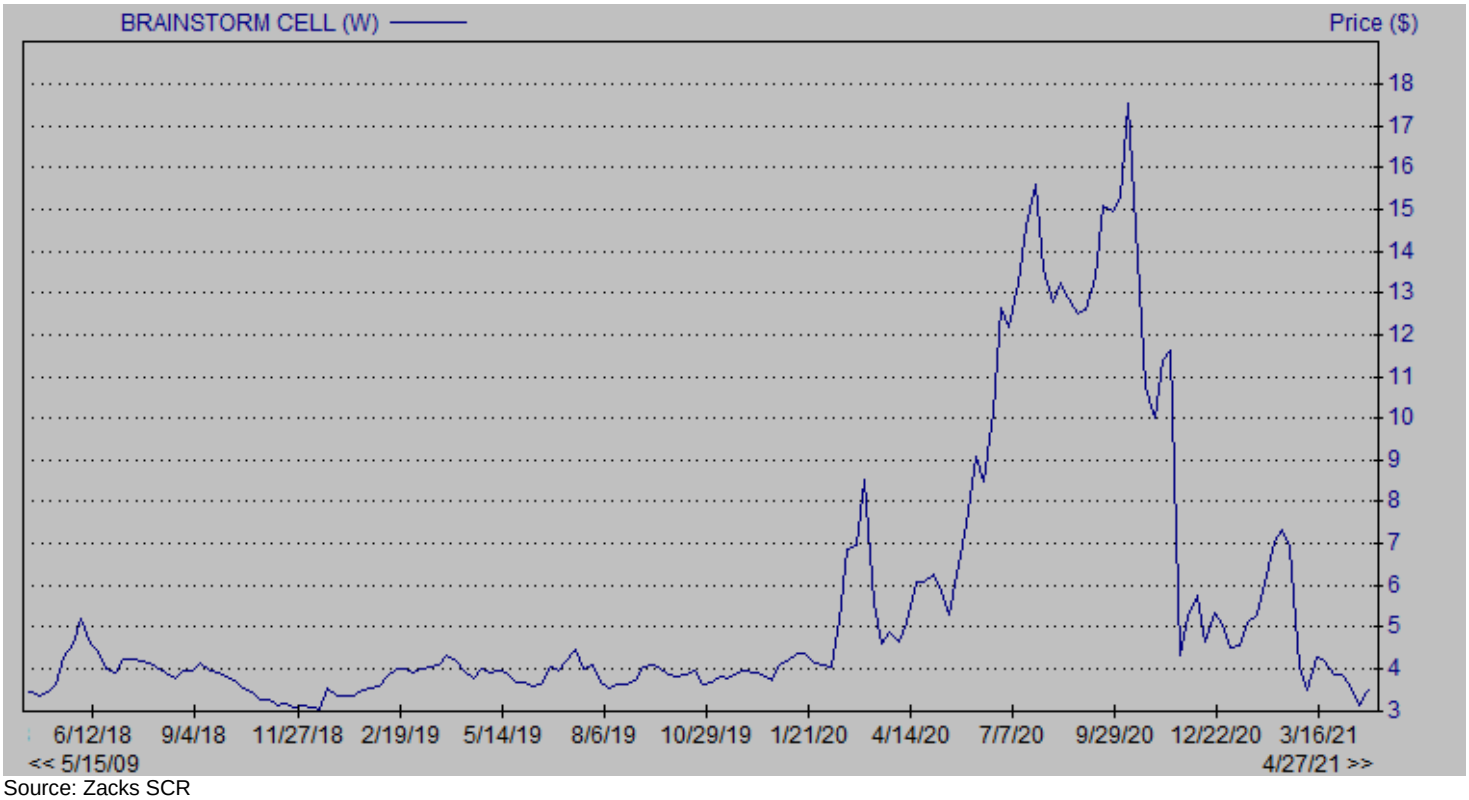
We continue to be in a "wait and see" mode regarding the future of NurOwn in ALS as the company continues to meet with advisors and ALS advocates before deciding the best path forward. We also look forward to the publication of the Phase 3 results so that we can have a look at the totality of the data. The Phase 2 results for NurOwn in progressive MS were encouraging and we look forward to additional details regarding the next step for that program along with the Alzheimer's program later this year. With no changes to our model the valuation remains at $11.

## PROJECTED FINANCIALS

| Brainstorm Cell Therapeutics | 2020 A | Q1 A | Q2 E | Q3 E | Q4 E | 2021 E | 2022 E | 2023 E |
|---|---|---|---|---|---|---|---|---|
| **MSC-NTF Stem Cells** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$50** | **$150** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| **Total Revenues** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$50** | **$150** |
| *YOY Growth* | - | | | | | - | - | - |
| Cost of Goods / Services | $0.0 | $0 | $0 | $0 | $0 | $0.0 | $5.0 | $15.0 |
| *Product Gross Margin* | - | - | - | - | - | - | *90.0%* | *90.0%* |
| R&D | $22.3 | $4.3 | $6.0 | $6.0 | $6.0 | $22.3 | $30.0 | $33.0 |
| *% R&D* | - | - | - | - | | - | - | - |
| SG&A | $9.4 | $2.6 | $2.8 | $2.9 | $3.0 | $11.3 | $15.0 | $17.0 |
| *% SG&A* | - | - | - | - | - | - | - | - |
| Operating Income | ($31.7) | ($6.9) | ($8.8) | ($8.9) | ($9.0) | ($33.6) | $0.0 | $85.0 |
| Net Other Income | ($0.1) | $0.3 | $0.0 | $0.0 | $0.0 | $0.4 | $0.0 | $0.0 |
| Pre-Tax Income | ($31.8) | ($6.7) | ($8.8) | ($8.9) | ($9.0) | ($33.3) | $0.0 | $85.0 |
| Taxes | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| Net Income | ($31.8) | ($6.7) | ($8.8) | ($8.9) | ($9.0) | ($33.3) | $0.0 | $85.0 |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($1.07)** | **($0.19)** | **($0.24)** | **($0.24)** | **($0.24)** | **($0.90)** | **$0.00** | **$1.89** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Wt. Avg Shares Outstanding | 29.8 | 35.8 | 36.5 | 37.0 | 38.0 | 36.8 | 40.0 | 45.0 |

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

## HISTORICAL STOCK PRICE




Source: Zacks SCR

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