Zacks Small-Cap Research
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# BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

## *BCLI: FDA Grants Adcom 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 $20.00/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

| | |
|---|---|
| Current Price (03/27/23) | $1.55 |
| **Valuation** | **$20.00** |

## OUTLOOK

On March 27, 2023, BrainStorm Cell Therapeutics, Inc. (BCLI) announced that the U.S. Food and Drug Administration (FDA) has granted the company an Advisory Committee (AdCom) meeting for NurOwn. This news comes following the Type A meeting conducted between the FDA and BrainStorm in early January 2023. Since an active BLA needs to be on file with the FDA before an AdCom can be scheduled, BrainStorm utilized the FDA's File Over Protest procedure and has filed an amendment to the BLA that responds to most of the outstanding questions the FDA had posed. A date for the AdCom has not been set. This news represents a huge turn of events for the company, as we believe an AdCom will allow the totality of the data to be presented and we are confident in a positive outcome.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$4.42** |
| **52-Week Low** | **$1.37** |
| **One-Year Return (%)** | **-54.14** |
| **Beta** | **-0.44** |
| **Average Daily Volume (sh)** | **161,373** |
| **Shares Outstanding (mil)** | **37** |
| **Market Capitalization ($mil)** | **$57** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **11** |
| **Insider Ownership (%)** | **10** |
| **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) |
|---|---|---|---|---|---|
| 2021 | 0 A | 0 A | 0 A | 0 A | 0 A |
| 2022 | 0 A | 0 A | 0 A | 0 E | 0 E |
| 2023 | | | | | 0 E |
| 2024 | | | | | 0 E |

**Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2021 | -$0.19 A | -$0.36 A | -$0.15 A | $0.02 A | -$0.67 A |
| 2022 | -$0.15 A | -$0.20 A | -$0.19 A | -$0.18 E | -$0.72 E |
| 2023 | | | | | -$0.60 E |
| 2024 | | | | | -$0.70 E |

## WHAT'S NEW

**Business Update**

*AdCom Granted for NurOwn®*

On March 27, 2023, BrainStorm Cell Therapeutics, Inc. (BCLI) announced that the U.S. Food and Drug Administration (FDA) has granted an Advisory Committee (AdCom) meeting to discuss the company's Biologics License Application (BLA) for NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS). A date for the Adcom has not been announced yet.

This news follows the company's Type A meeting with the FDA in early January 2023 to discuss the refusal to file letter (RTF) that the company received in November 2022. The RTF letter made the BLA inactive and the FDA offered multiple options for BrainStorm to pursue to re-activate the BLA. One of those was to follow the File Over Protest procedure with the FDA, which the company did. Alternatively, the FDA would have allowed for the company to withdraw the BLA and then re-file, however that process likely would have taken 4-6 months. BrainStorm has always been interested in finding the fastest route to approval as the ALS community has a real sense of urgency for getting access to new therapies. Thus, BrainStorm requested that the Center for Biologics Evaluate and Research (CBER) utilize the FDA's File Over Protest procedure and the company has filed an amendment to the BLA that responds to most of the outstanding questions the FDA had posed. Another advantage of filing the formal protest is that the countdown to the PDUFA date begins from when BrainStorm first submitted the BLA. We anticipate an announcement for the PDUFA date to be made soon as well.

The news announced today is exactly the outcome the company has been working toward, and it is now up to BrainStorm to win the support of the Advisory Committee, which we are confident will occur. We believe the political environment is quite favorable regarding access to new therapies for patients with terminal illnesses such as ALS, particularly for therapies that have a strong safety and tolerability record. Thus, given the totality of the data that BrainStorm has accumulated for NurOwn, we are confident in a positive outcome for the AdCom and eventual approval of the drug.

*Tofersen AdCom*

Recently, an Adcom meeting was held for Biogen and Ionis' tofersen, which is being developed as a therapy for ALS caused by mutations in the SOD1 gene. There are many parallels between the clinical experience for tofersen and NurOwn. Just like NurOwn, tofersen failed to reach the primary endpoint in a Phase 3 clinical trial. However, the drug did show a benefit in a subgroup of patients who started tofersen treatment earlier. In addition, just as with NurOwn, biomarker data showed that tofersen treatment reduced plasma neurofilament light chain (NfL) concentration.

The Adcom for tofersen was held March 22, 2023. During the meeting, the committee voted unanimously yes (9 yes to 0 no) for consideration of a potential accelerated approval for tofersen on the question, "Is the available evidence sufficient to conclude that a reduction in plasma neurofilament light chain (NfL) concentration in tofersen-treated patients is reasonably likely to predict clinical benefit of tofersen for treatment of patients with SOD1-ALS?" We believe this shows that ALS experts understand the importance of biomarkers in evaluating new therapies. The fact that the committee was supportive of biomarker data being used as a proxy for potential clinical benefit is an encouraging sign given that NurOwn was also shown to have a positive effect on various biomarkers, including NfL, while not achieving the primary endpoint in a Phase 3 study.

**Conclusion**

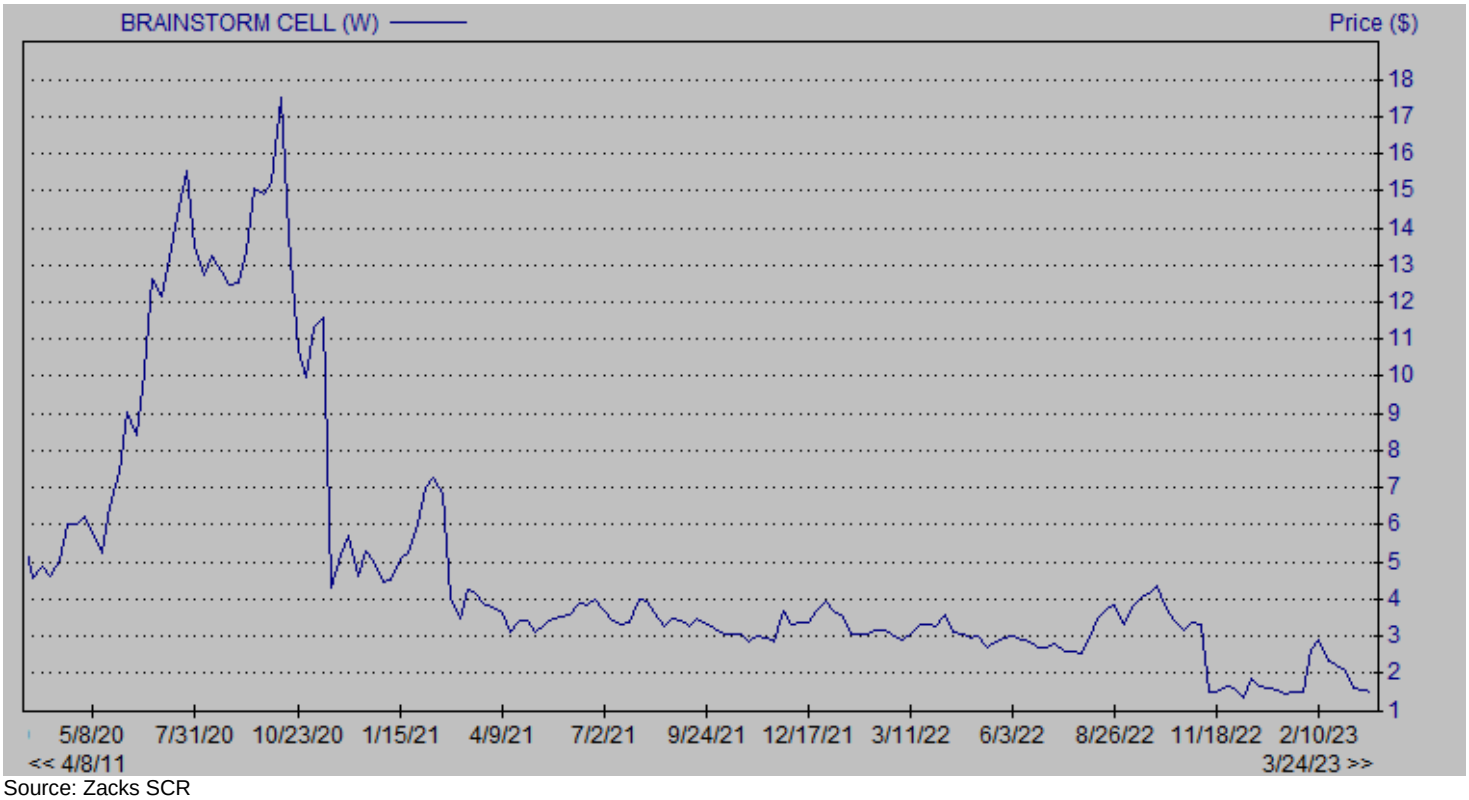
The FDA's decision to grant an AdCom for NurOwn is indicative of the agency's flexibility regarding therapies for terminal illnesses such as ALS, particularly when there are so few treatment options available to patients. We have the utmost confidence in BrainStorm's management team as they prepare to present their case for NurOwn's approval, and we believe the results of tofersen's AdCom provides further support that a positive outcome for NurOwn is possible. In regards to valuation, we now believe that BrainStorm should be valued in a similar manner as Amylyx was prior to its two AdCom meetings. We have increased the probability of approval for NurOwn to 70%, which has increased our valuation to $20 per share.

## PROJECTED FINANCIALS

| Brainstorm Cell Therapeutics | 2021 A | Q1 A | Q2 A | Q3 A | Q4 E | 2022 E | 2023 E | 2024 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 | $15.2 | $2.6 | $5.1 | $3.8 | $4.0 | $15.5 | $17.0 | $20.0 |
| *% R&D* | - | - | - | - | | - | - | - |
| SG&A | $9.3 | $2.9 | $2.5 | $3.1 | $2.5 | $10.9 | $10.0 | $12.0 |
| *% SG&A* | - | - | - | - | - | - | - | - |
| Operating Income | ($24.5) | ($5.5) | ($7.6) | ($6.8) | ($6.5) | ($26.4) | ($27.0) | ($32.0) |
| Net Other Income | $0.4 | $0.1 | $0.1 | $0.0 | $0.0 | $0.3 | $0.0 | $0.0 |
| Pre-Tax Income | ($24.2) | ($5.4) | ($7.5) | ($6.8) | ($6.5) | ($26.2) | ($27.0) | ($32.0) |
| Taxes | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| Net Income | ($24.2) | ($5.4) | ($7.5) | ($6.8) | ($6.5) | ($26.2) | ($27.0) | ($32.0) |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($0.67)** | **($0.15)** | **($0.20)** | **($0.19)** | **($0.18)** | **($0.72)** | **($0.60)** | **($0.70)** |
| *YOY Growth* | - | - | - | - | - | - | - | - |
| Wt. Avg Shares Outstanding | 36.2 | 36.4 | 36.5 | 36.5 | 36.6 | 36.5 | 45.0 | 46.0 |

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

## HISTORICAL STOCK PRICE




Source: Zacks SCR

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