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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: Preparing to Initiate Phase 3b Trial of NurOwn™ Before End of 2024…

Based on our probability adjusted DCF model that takes into account potential future revenues from NurOwn® in ALS, BCLI is valued at $2.40/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (07/10/24)	$0.34
Valuation	**$2.40**

OUTLOOK

On July 8, 2024, BrainStorm Cell Therapeutics, Inc. (BCLI) conducted a mid-year conference call to provide an update on the status of the company's NurOwn™ program. During the call, the company reiterated that it is committed to conducting a Phase 3b trial of NurOwn in patients with amyotrophic lateral sclerosis (ALS) to support a potential Biologics License Application (BLA) filing. BrainStorm has reached agreement with the FDA on a Special Protocol Assessment (SPA) and the CMC aspects of the upcoming Phase 3b trial. After recently completing a registered direct offering of $4.0 million, the company now has sufficient capital to initiate the Phase 3b trial (although additional financing will be necessary to fully fund the trial), which we anticipate occurring before the end of 2024.

SUMMARY DATA

52-Week High	**$2.00**
52-Week Low	**$0.15**
One-Year Return (%)	**-82.90**
Beta	**0.37**
Average Daily Volume (sh)	**725,422**
Shares Outstanding (mil)	**70**
Market Capitalization ($mil)	**$24**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**14**
Insider Ownership (%)	**5**
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 2024 Estimate	**N/A**
P/E using 2025 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)
2023	0 A	0 A	0 A	0 A	0 A
2024	0 A	0 E	0 E	0 E	0 E
2025					0 E
2026					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.14 A	-$0.28 A	-$0.03 A	$0.01 A	-$0.40 A
2024	-$0.05 A	-$0.04 E	-$0.03 E	-$0.03 E	-$0.14 E
2025					-$0.22 E
2026					-$0.22 E

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WHAT'S NEW

Business Update

Ready to Move Ahead with Phase 3b Trial for NurOwn in ALS

On July 8, 2024, BrainStorm Cell Therapeutics, Inc. (BCLI) conducted a conference call to provide an update on the company's NurOwn™ program. The company is currently preparing for a Phase 3b clinical trial of NurOwn in patients with amyotrophic lateral sclerosis (ALS). We anticipate the trial initiating before the end of 2024. Over the past few months, BrainStorm has made considerable progress in trial preparation, including the following:

- In March 2024, the company presented the proposed design for the Phase 3b trial in a poster at the MDA Clinical and Scientific Conference. The Phase 3b trial will be a two-part, multicenter study that will enroll ALS patients who are earlier in the course of their disease (onset of ALS symptoms, including limb weakness, within the prior 24 months), with all ALSFRS-R items ≥ 2 at screening, and upright slow vital capacity ≥65% of predicted for gender, height, and age. Part A of the trial will have a double blind, placebo controlled period of 24 weeks. Up to approximately 200 patients are expected to be enrolled and randomized 1:1 to receive NurOwn or placebo. There will be a screening period of six to nine weeks, during which time eligible participants will undergo a single bone marrow aspiration to procure the mesenchymal stem cells (MSCs) to produce NurOwn for the duration of the trial. Participants will receive either NurOwn or placebo via three repeated intrathecal injections once every eight weeks. All participants who complete Part A will be eligible to enroll into Part B, an open label extension period of 24 weeks where all participants will receive three repeated injections of NurOwn once every eight weeks. The primary endpoint of the trial will be the change in the Revised Amyotrophic Lateral Sclerosis Functional Rating (ALSFRS-R) total score from baseline to Week 24. Cerebrospinal fluid (CSF) and blood samples will be collected for analysis of biomarkers of neuroinflammation, neurodegeneration, and neuroprotection. An independent Data Monitoring Committee will be established to monitor the safety of trial participants.
- In April 2024, the company announced it had received written agreement from the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) on the design of the Phase 3b trial. The SPA agreement indicates that the FDA concurs with the adequacy and acceptability of specific elements of a protocols overall design to ensure that the trial conducted under the protocol can be considered an adequate and well-controlled study to support marketing approval.
- In June 2024, the company announced it reached alignment with the FDA on the Chemistry, Manufacturing, and Controls (CMC) aspect of the Phase 3b trial. This means that the company has resolved all previous outstanding CMC issues that the FDA. Given the complexities of cell therapy products, reaching alignment with the FDA ahead of the Phase 3b trial is an additional means to lower the regulatory risk for NurOwn.

New Biomarker Data Presented at ALS Drug Development Summit

In May 2024, BrainStorm presented new biomarker data suggesting that ALS patients may benefit from longer-term treatment with NurOwn. The data was presented at the 3rd Annual ALS Drug Development Summit and included outcome data from the Expanded Access Program (EAP) along with data from the Phase 3 trial.

The EAP was conducted over two periods of 28 weeks each, during which participants received three doses of NurOwn each period for a total of six doses. Everyone in the EAP received NurOwn, even those that received placebo during the Phase 3 trial. Thirteen cerebrospinal fluid (CSF) samples were drawn during the Phase 3 trial and the EAP and levels of neurofilament light (NfL) were monitored. Ten trial participants who completed the Phase 3 trial enrolled in the EAP. Eight participants completed EAP Period 1 and six completed EAP Period 2. The participants in the EAP had lower NfL values at Phase 3 baseline as compared to the entire Phase 3 population.

The data from the EAP showed that for participants randomized to NurOwn there was a 4% decrease from baseline in NfL in Phase 3 and a 27% and 36% decrease from baseline at the end of EAP Period 1 and Period 2, respectively. For patients randomized to placebo in the Phase 3 trial and subsequently treated with NurOwn in the EAP, there was a 37% increase in NfL from baseline to the end of the Phase 3 study and following treatment with NurOwn in the EAP the same patients had a 17% increase in NfL from baseline during Period 1 and a 5% decrease from baseline in NfL during Period 2. These results suggest that NurOwn is contributing to a decrease in NfL, with recent published studies showing an association between NfL levels and clinical progression.

New COO Further Reduces CMC Risk

In June 2024, BrainStorm announced the appointment of Hartoun Hartounian, PhD as its new Executive Vice President and Chief Operating Officer. Dr. Hartounian has over 30 years of experience in the biopharmaceutical industry, with a focus on cell and gene therapy. He founded BioCentriq, a CDMO company for cell and gene therapy that focused on all stages of process development and clinical manufacturing, where he served as General Manager from 2015 to 2022 and then as its President, CEO, and a member of the Board of Directors before it was acquired for $73 million by GC Holdings (Korea). Prior to that, Dr. Hartounian was CEO, Co-Founder, and a member of the Board of Directors at DiaVacs, a company specializing in cell therapy for type 1 diabetics. We believe Dr. HartounNNian's vast experience and expertise in cell therapy will be very important for BrainStorm and further decreases the CMC risk as the company advances toward the upcoming Phase 3b trial of NurOwn and its potential commercialization.

Financial Update

In May 2024, BrainStorm announced financial results for the first quarter of 2024. As anticipated, the company did not report any revenues during the first quarter of 2024. Net R&D expenses for the first quarter of 2024 were $1.0 million, compared to $2.9 million during the first quarter of 2023. The decrease was primarily due to decreased costs related to the Phase 3 clinical trial and payroll expenses. G&A expenses for the first quarter of 2024 were $1.5 million compared to $2.3 million for the first quarter of 2023. The decrease was primarily due to lower payroll, rent, and other costs.

The company exited the first quarter of 2024 with approximately $1.0 million in cash, cash equivalents, and short-term deposits. In June 2024, BrainStorm announced a $4.0 million registered direct offering through the sale of approximately 11.1 million shares of common stock at a purchase price of $0.36 per share along with approximatley 16.7 million warrants with an exercise price of $0.3912 per share. We estimate that BrainStorm currently has approximatley 81.2 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 103.7 million.

Conclusion

We are pleased to see the progress that BrainStorm has made over the past few months as the company prepares for the Phase 3b trial of NurOwn in ALS patients. At this point the company just needs to obtain the financing necessary to complete the trial, with the recent $4.0 million raise a step in the right direction. We had already factored in the expected costs of the Phase 3 study into our model, however with market conditions not improving we have made a slight increase into the expected dilution for the next capital raise, which has decreased our valuation slightly to $2.40 per share.

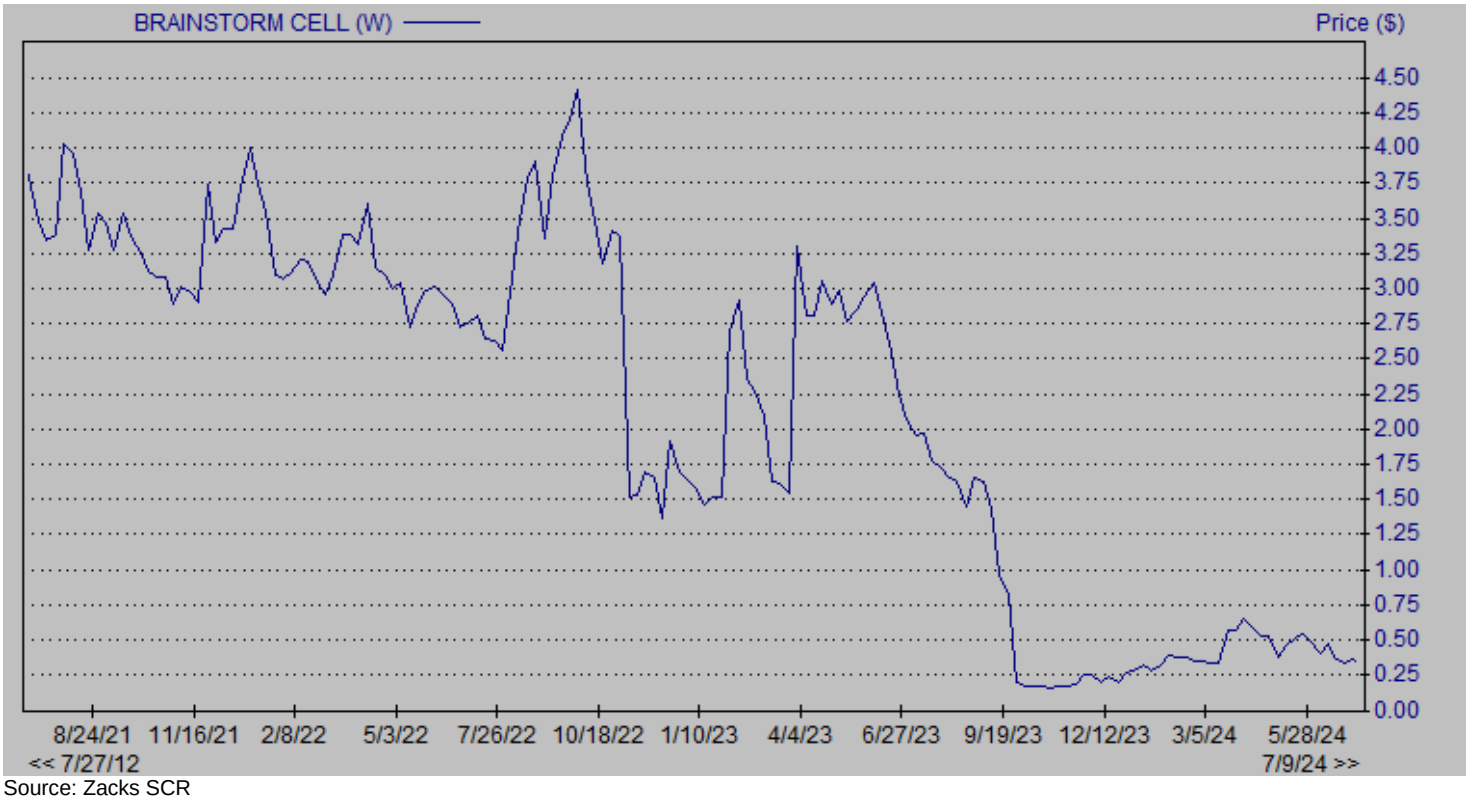
PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2023 A	Q1 A	Q2 E	Q3 E	Q4 E	2024 E	2025 E	2026 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	$10.7	$1.0	$1.1	$1.1	$1.1	$4.3	$13.0	$15.0
% R&D	-	-	-	-		-	-	-
SG&A	$10.7	$1.5	$1.5	$1.5	$1.5	$6.0	$11.0	$11.5
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($21.4)	($2.5)	($2.6)	($2.6)	($2.6)	($10.3)	($24.0)	($26.5)
Net Other Income	$4.2	($0.9)	$0.0	$0.0	$0.0	($0.9)	$0.0	$0.0
Pre-Tax Income	($17.2)	($3.4)	($2.6)	($2.6)	($2.6)	($11.2)	($24.0)	($26.5)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($17.2)	($3.4)	($2.6)	($2.6)	($2.6)	($11.2)	($24.0)	($26.5)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.40)**	**($0.05)**	**($0.04)**	**($0.03)**	**($0.03)**	**($0.14)**	**($0.22)**	**($0.22)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	43.1	64.7	70.0	80.0	95.0	77.4	110.0	120.0

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

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