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May 23, 2023
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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Awaiting Adcom Date 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 (05/23/23)	$3.05
Valuation	**$20.00**

OUTLOOK

On May 15, 2023, BrainStorm Cell Therapeutics, Inc. (BCLI) announced financial results for the first quarter of 2023. The U.S. Food and Drug Administration (FDA) recently granted the company an Advisory Committee (AdCom) meeting for NurOwn following a Type A meeting conducted between the FDA and BrainStorm in early January 2023. We anticipate a date for the AdCom meeting as well as a PDUFA date being announced in the coming weeks. The company recently presented at the 2023 ALS Drug Development Summit. The presentation focused on the challenges with the ALSFRS-R endpoint in its current state along with evidence for a floor effect in the NurOwn clinical program along with historical trials. I addition, various strategies were discussed to better analyze a treatment impact on disease progression.

SUMMARY DATA

52-Week High	**$4.42**
52-Week Low	**$1.37**
One-Year Return (%)	**3.39**
Beta	**-0.38**
Average Daily Volume (sh)	**184,049**
Shares Outstanding (mil)	**39**
Market Capitalization ($mil)	**$120**
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)
2022	0 A	0 A	0 A	0 A	0 A
2023	0 A	0 E	0 E	0 E	0 E
2024					20 E
2025					258 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.15 A	-$0.20 A	-$0.19 A	-$0.13 A	-$0.67 A
2022	-$0.14 A	-$0.15 E	-$0.15 E	-$0.17 E	-$0.61 E
2023					-$0.59 E
2024					$2.94 E

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WHAT'S NEW

Business Update

AdCom Granted for NurOwn®

In March 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 using the File Over Protest procedure 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 regarding the AdCom meeting 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.

Presentation at ALS Drug Development Summit Focuses on Floor Effect in ALS Trials

On May 19, 2023, BrainStorm announced it attended the 2023 ALS Drug Development Summit. Stacy Lindborg, the company's co-Chief Executive Officer and Antonio Trejo Diaz, Vice President, Regulatory Affairs, both participated as invited speakers. Dr. Lindborg gave a presentation on the ALSFRS-R and its challenges when used as an endpoint in ALS clinical trials. Highlights from Dr. Lindborg's presentation include:

- Evidence that the floor effect with the ALSFRS-R exists in both the NurOwn clinical program along with historical ALS trials. The FDA acknowledged the floor effect in 2018, which it defines as occurring when the scale of measurement is not able to capture progression at the bottom of the scale, however it was not well known prior to the NurOwn Phase 3 trial and has not been well characterized for the ALSFRS-R.
- Strategies for assessing a treatment impact by accounting for the floor effect of the ALSFRS-R within a trial.
- By reviewing pre-specified and post-hoc analyses, a robust treatment effect can be seen in patients not impacted by the floor effect.
- Implementing new knowledge from studying the floor effect in the ALSFRS-R to better enable future study goals.

Strengthens Leadership Team

In April 2024, BrainStorm announced the appointment of Dr. Kirk Taylor as Executive Vice President and Chief Medical Officer. Dr. Taylor will be responsible for leading the global medical affairs function and launch activities, which includes product launches, post-approval commercialization efforts, and deepening relationships with the medical community. His appointment comes ahead of anticipated growth for the company, as it prepares for the upcoming AdCom and potential approval of NurOwn™.

Dr. Taylor brings more than 26 years of experience in global drug development that includes experience from Phase 1 through post-approval studies. He has been involved in multiple therapeutic areas, including neurology and rare diseases. Previously, Dr. Taylor was at EMD Serano where he served as Senior Vice President, North

American Medical Affairs, and led the medical team's efforts across four therapeutic areas and the launch of three new treatments. Before EMD, he served as Senior Vice President, Medical Affairs Strategy and Operations at Verastem Oncology and was Chief Medical Officer and Chief of Strategy and Late Phase Development at Finch Therapeutics Group. Dr. Taylor holds a BA from Harvard University and a MD from University of New York Downtown Health Sciences University.

Financial Update

On May 15, 2022, BrainStorm announced financial results for the first quarter of 2023. As anticipated, the company did not report any revenues during the first quarter of 2023. Net R&D expenses for the first quarter of 2023 were $2.9 million, compared to $2.6 million during the first quarter of 2022. The increase was primarily due to increase costs related to the expanded access program and commercial preparation expenses partially offset by lower payroll and stock-based compensation expenses and decreased costs related to consultants, depreciation, and travel. G&A expenses for the first quarter of 2023 were $2.2 million compared to $2.9 million for the first quarter of 2022. The decrease was primarily due to lower payroll, stock-based compensation, rent, and other costs.

The company exited the first quarter of 2023 with approximately $2.2 million in cash, cash equivalents, and short-term deposits. As of May 15, 2023, BrainStorm had approximately 39.4 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 40.9 million.

Conclusion

It's encouraging to see BrainStorm's management continue to meet with various members of the ALS community to discuss the ALSFRS-R floor effect and the impact it can have on clinical trial results. The knowledge gained from studying the floor effect will undoubtedly help design better clinical trials in the future and potentially increase the speed at which new drugs are developed. The floor effect will also likely be discussed at the upcoming AdCom, thus increased awareness within the ALS community of its impact in clinical trials is very important.

We eagerly await the announcement of the AdCom and PDUFA date's for NurOwn. We have the utmost confidence in BrainStorm's management team as they prepare to present their case for NurOwn's approval, and the appointment of Dr. Taylor is an important step as the company prepares for the potential commercial approval of NurOwn. We have made no changes to our model, and our valuation remains at $20 per share.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2022 A	Q1 A	Q2 E	Q3 E	Q4 E	2023 E	2024 E	2025 E
MSC-NTF Stem Cells	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$20**	**$258**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$20**	**$258**
YOY Growth	-					-	-	-
Cost of Goods / Services	$0.0	$0	$0	$0	$0	$0.0	$2.0	$25.0
Product Gross Margin	-	-	-	-	-	-	*90%*	*90%*
R&D	$14.0	$2.9	$3.5	$3.6	$3.9	$13.9	$15.0	$20.0
% R&D	-	-	-	-		-	-	-
SG&A	$10.9	$2.2	$2.7	$2.9	$3.2	$11.0	$30.0	$75.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($24.8)	($5.2)	($6.2)	($6.5)	($7.1)	($25.0)	($27.0)	$138.0
Net Other Income	$0.5	$0.1	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($24.3)	($5.1)	($6.1)	($6.5)	($7.1)	($25.0)	($27.0)	$138.0
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($24.3)	($5.1)	($6.1)	($6.5)	($7.1)	($25.0)	($27.0)	$138.0
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.67)**	**($0.14)**	**($0.15)**	**($0.15)**	**($0.17)**	**($0.61)**	**($0.59)**	**$2.94**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	36.5	36.7	40.0	43.0	43.0	40.7	46.0	47.0

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

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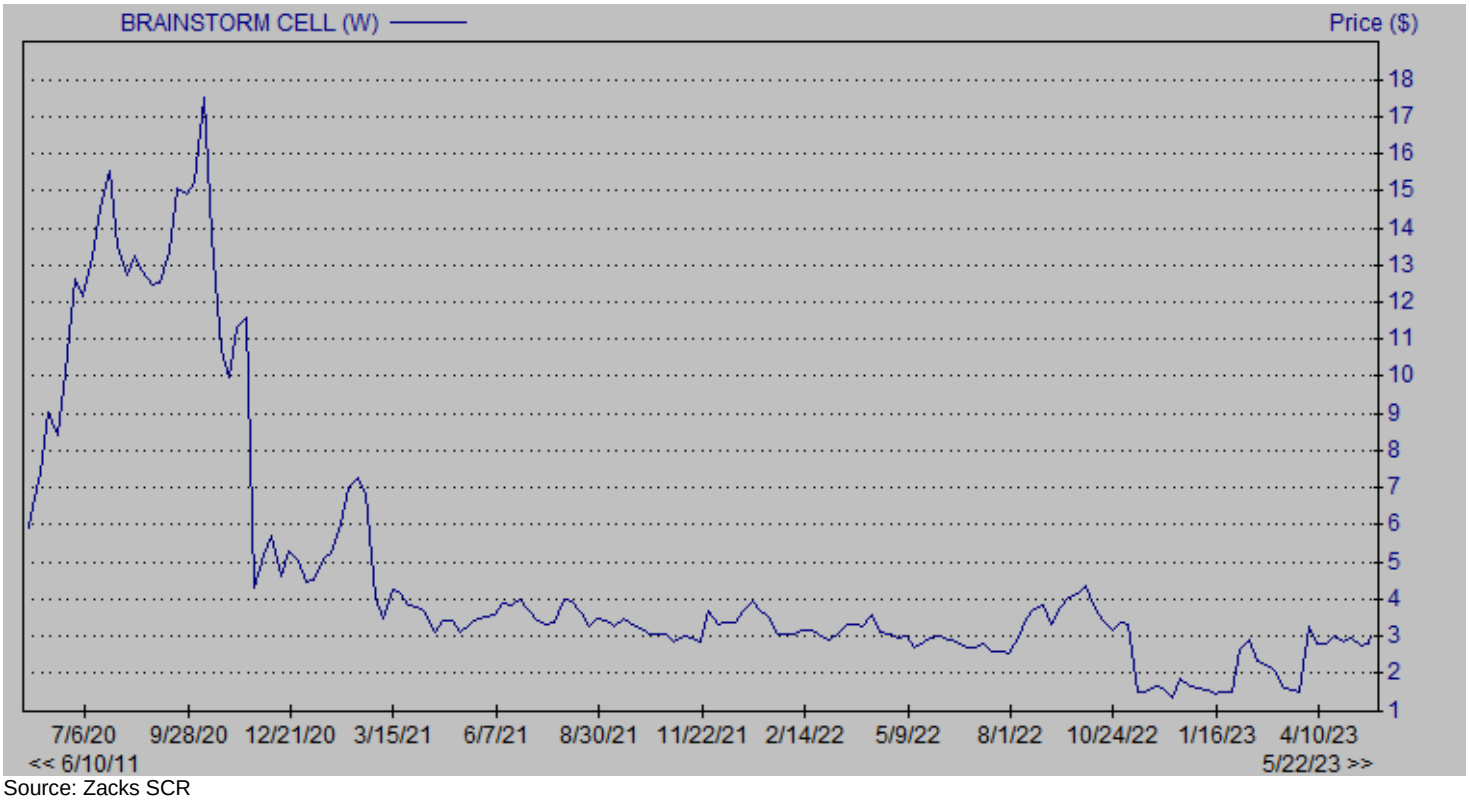

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