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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Meeting with FDA to Discuss Development Plan 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 $0.50/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (10/23/23)	$0.18
Valuation	**$0.50**

OUTLOOK

On October 18, 2023, BrainStorm Cell Therapeutics, Inc. (BCLI) announced that the U.S. FDA has invited the company to request an expedited meeting to discuss the regulatory path forward for NurOwn® as a treatment for amyotrophic lateral sclerosis (ALS). The company also announced that it is withdrawing the Biologics License Application (BLA) for NurOwn. This decision was coordinated with the FDA as a withdrawal without prejudice. BrainStorm will be conducting a Phase 3b trial for NurOwn in ALS and we anticipate details of the trial after the company meets with the FDA.

SUMMARY DATA

52-Week High	**$3.56**
52-Week Low	**$0.16**
One-Year Return (%)	**-94.40**
Beta	**-0.21**
Average Daily Volume (sh)	**4,846,158**
Shares Outstanding (mil)	**45**
Market Capitalization ($mil)	**$8**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**21**
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 A	0 E	0 E	0 E
2024					0 E
2025					0 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	-$0.28 A	-$0.14 E	-$0.15 E	-$0.70 E
2023					-$0.47 E
2024					-$0.47 E

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WHAT'S NEW

Business Update

Meeting with the FDA to Discuss Development Plan for NurOwn® in ALS

On October 18, 2023, BrainStorm Cell Therapeutics, Inc. (BCLI) announced that the U.S. Food and Drug Administration (FDA) has invited the company to request an expedited meeting to discuss the path forward for NurOwn® as a treatment for amyotrophic lateral sclerosis (ALS). The company also announced that it is withdrawing the Biologics License Application (BLA) for NurOwn. This was not a surprising decision following the negative outcome to the Advisory Committee meeting last month and the FDA is viewing it as a withdrawal without prejudice. BrainStorm remains committed to advancing NurOwn as a therapy for ALS, with a registrational Phase 3b trial necessary in order to seek regulatory approval.

Conclusion

We are not surprised by the decision to withdraw the BLA for NurOwn and are encouraged that the FDA has invited BrainStorm to conduct an expedited meeting regarding NurOwn's development plan. We anticipate details regarding a Phase 3b registrational trial for NurOwn in ALS after the company meets with the FDA, which will also hopefully include details about how the company is planning to finance the trial. We have made no changes to our model and our valuation remains at $0.50.

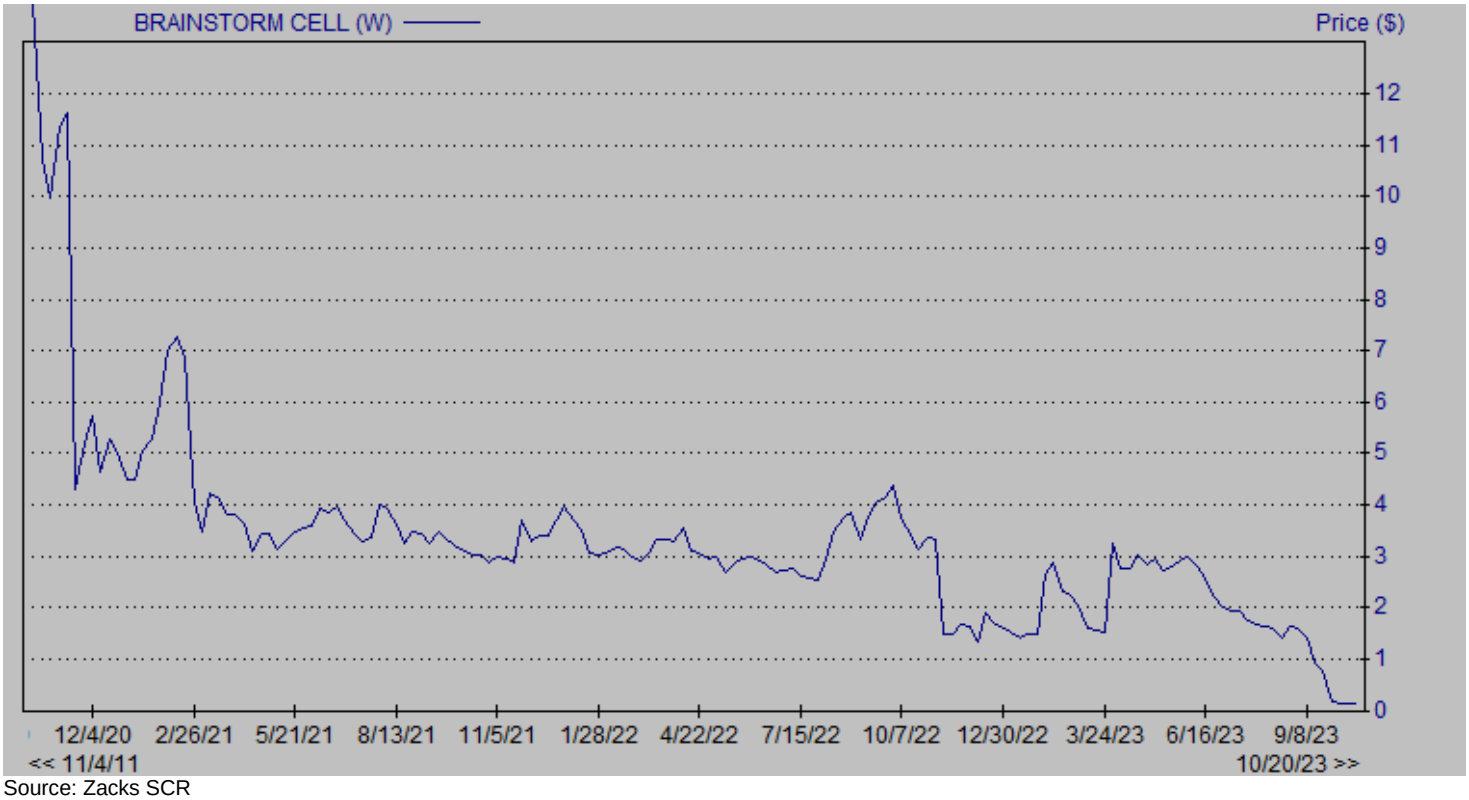
PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 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	$14.0	$2.9	$5.7	$3.6	$3.9	$16.1	$15.0	$20.0
% R&D	-	-	-	-		-	-	-
SG&A	$10.9	$2.2	$4.9	$2.9	$3.2	$13.2	$13.0	$13.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($24.8)	($5.2)	($10.6)	($6.5)	($7.1)	($29.4)	($28.0)	($33.0)
Net Other Income	$0.5	$0.1	($0.2)	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($24.3)	($5.1)	($10.8)	($6.5)	($7.1)	($29.4)	($28.0)	($33.0)
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)	($10.8)	($6.5)	($7.1)	($29.4)	($28.0)	($33.0)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.67)**	**($0.14)**	**($0.28)**	**($0.14)**	**($0.15)**	**($0.70)**	**($0.47)**	**($0.47)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	36.5	36.7	38.2	45.0	47.0	41.7	60.0	70.0

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

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