

BrainStorm Cell Therapeutics, Inc.

(BCLI-NASDAQ)

BCLI: FDA Meeting Provides Clear Path for Planned Phase 3b Trial of 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 (12/08/23) \$0.22
Valuation \$0.50

OUTLOOK

On December 7, 2023, BrainStorm Cell Therapeutics, Inc. (BCLI) announced the outcome of a meeting with the U.S. Food and Drug Administration (FDA) to discuss the planned Phase 3b trial for NurOwn®. The company is going to be submitting documentation to support a Special Protocol Assessment (SPA), a process in which drug developers meet with the FDA to reach agreement on the design and size of a clinical trial. During the meeting, the FDA provided important feedback that the company will take into consideration in designing the Phase 3b trial for NurOwn. We believe a SPA will help to de-risk NurOwn's development from a regulatory perspective.

SUMMARY DATA

52-Week High \$3.30
52-Week Low \$0.15
One-Year Return (%) -84.69
Beta 0.14
Average Daily Volume (sh) 4,426,650

Shares Outstanding (mil) 49
Market Capitalization (\$mil) \$11
Short Interest Ratio (days) N/A
Institutional Ownership (%) 21
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 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 A	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	-\$0.03 A	-\$0.15 E	-\$0.70 E
2023					-\$0.47 E
2024					-\$0.47 E

WHAT'S NEW

Business Update

Clear Path Forward for Phase 3b Trial of NurOwn

On December 7, 2023, BrainStorm Cell Therapeutics, Inc. (BCLI) [announced](#) the company attended a meeting with the U.S. Food and Drug Administration (FDA) regarding the planned Phase 3b trial for NurOwn in amyotrophic lateral sclerosis (ALS). The company is going to be submitting a Special Protocol Assessment (SPA), which is a process by which a drug developer meets with the FDA to reach agreement on certain aspects of a clinical trial design that could support marketing approval. During the meeting with BrainStorm, the FDA provided constructive feedback regarding the design of the Phase 3b trial. After talking with management, we believe the company is on an expedited pathway to getting a SPA, which normally can take over a year. The FDA is working cooperatively with BrainStorm as the agency and company both recognize the urgent need to get additional effective therapies to ALS patients as quickly as possible. We view a SPA as an important means to de-risk certain parts of the regulatory pathway for NurOwn.

Conclusion

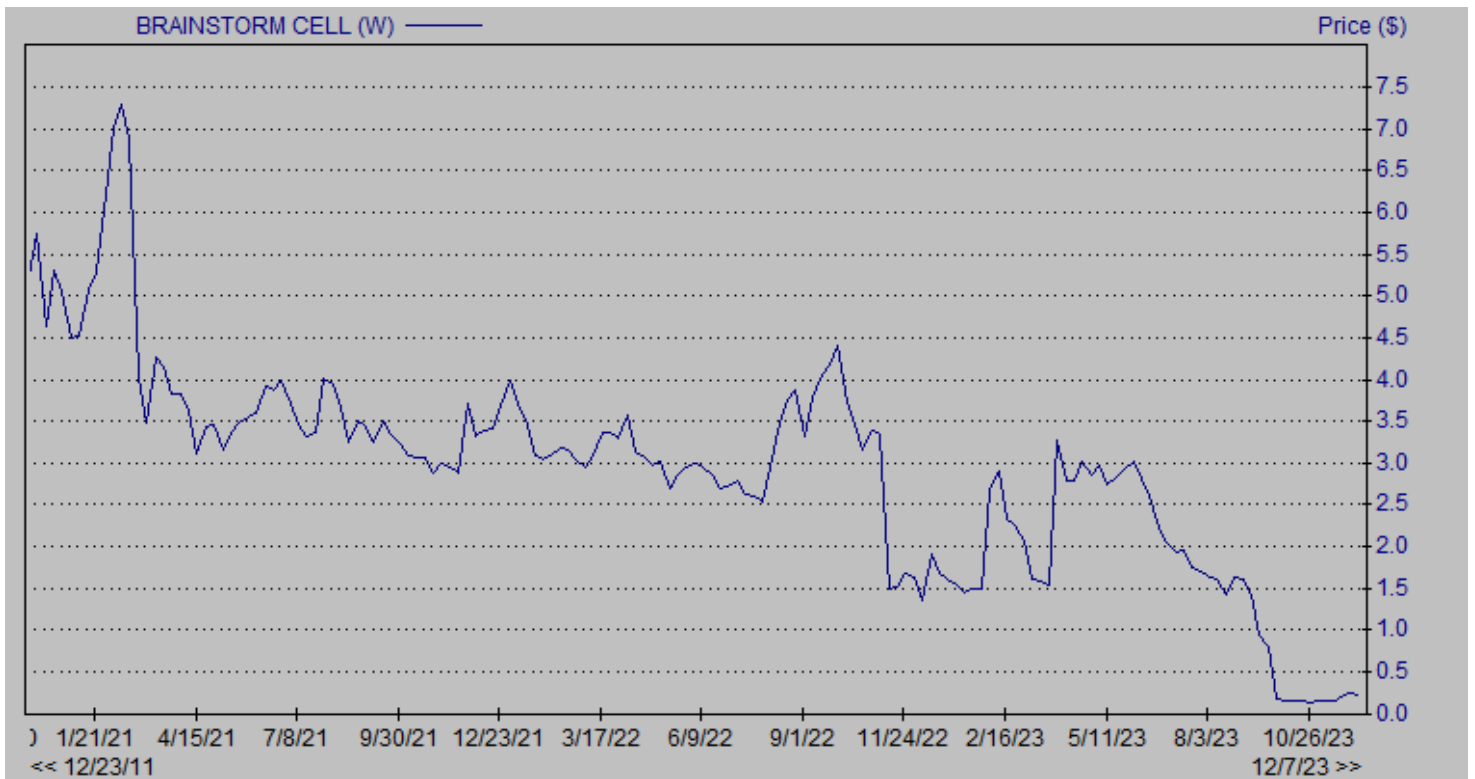
We're very encouraged to hear about the positive meeting with the FDA and the agency's willingness to work with BrainStorm to expeditiously get the Phase 3b trial underway. While we are unsure of an exact timeframe for the company to acquire the SPA, the fact that management believes it is on an expedited pathway leads us to believe that it will be quicker than the typical year-long process. We eagerly await additional updates from BrainStorm as it prepares the Phase 3b trial protocol and submits the necessary documentation to secure a SPA. With no changes to our model our valuation remains at \$0.50 per share.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2022 A	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 E
MSC-NTF Stem Cells	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Total Revenues	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Cost of Goods / Services	\$0.0	\$0	\$0	\$0	\$0	\$0.0	\$0.0	\$0.0
<i>Product Gross Margin</i>	-	-	-	-	-	-	-	-
R&D	\$14.0	\$2.9	\$5.7	\$3.3	\$3.9	\$15.9	\$15.0	\$20.0
<i>% R&D</i>	-	-	-	-	-	-	-	-
SG&A	\$10.9	\$2.2	\$4.9	\$2.7	\$3.2	\$13.0	\$13.0	\$13.0
<i>% SG&A</i>	-	-	-	-	-	-	-	-
Operating Income	(\$24.8)	(\$5.2)	(\$10.6)	(\$6.0)	(\$7.1)	(\$28.9)	(\$28.0)	(\$33.0)
Net Other Income	\$0.5	\$0.1	(\$0.2)	\$4.8	\$0.0	\$0.0	\$0.0	\$0.0
Pre-Tax Income	(\$24.3)	(\$5.1)	(\$10.8)	(\$1.2)	(\$7.1)	(\$28.9)	(\$28.0)	(\$33.0)
Taxes	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$24.3)	(\$5.1)	(\$10.8)	(\$1.2)	(\$7.1)	(\$28.9)	(\$28.0)	(\$33.0)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$0.67)	(\$0.14)	(\$0.28)	(\$0.03)	(\$0.15)	(\$0.70)	(\$0.47)	(\$0.47)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	36.5	36.7	38.2	44.3	47.0	41.6	60.0	70.0

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

HISTORICAL STOCK PRICE



Source: Zacks SCR

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