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

BCLI: Manufacturing Agreement with Catalent; Recent Sell-off Unwarranted…

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 $33.00/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (10/23/20)	$10.19
Valuation	**$33.00**

OUTLOOK

On October 22, 2020, BrainStorm Cell Therapeutics, Inc. (BCLI) announced a manufacturing agreement with Catalent (CTLT) for the production of NurOwn®, which is currently being evaluated in a Phase 3 clinical trial for the treatment of Amyotrophic Lateral Sclerosis (ALS). The agreement calls for Catalent to undertake the manufacturing process and provide cGMP clinical supply of NurOwn from a new 32,000 square-foot cell manufacturing facility in Houston, Texas. In addition, the agreement will likely extend to include commercial supply upon FDA approval of NurOwn. We expect very high demand for NurOwn if approved by the FDA, and having a partner in place to manufacture it shows the importance the company places on expeditious patient access.

SUMMARY DATA

52-Week High	**$17.73**
52-Week Low	**$3.62**
One-Year Return (%)	**165.23**
Beta	**0.83**
Average Daily Volume (sh)	**880,492**
Shares Outstanding (mil)	**32**
Market Capitalization ($mil)	**$322**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**20**
Insider Ownership (%)	**22**
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	**Above Avg.**
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)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 A	0 A	0 A	0 E	0 E
2021					0 E
2022					50 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.24 A	-$0.23 A	-$0.25 A	-$0.34 A	-$1.06 A
2019	-$0.29 A	-$0.25 A	-$0.14 A	-$0.24 E	-$0.91 E
2020					-$0.80 E
2021					$0.10 E

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WHAT'S NEW

Business Update

Manufacturing Agreement with Catalent

On October 22, 2020, BrainStorm Cell Therapeutics, Inc. (BCLI) announced an agreement with Catalent, Inc. (CTLT) for the manufacture of NurOwn®, which is currently being evaluated in a Phase 3 clinical trial in patients with amyotrophic lateral sclerosis (ALS). The agreement calls for Catalent to produce cGMP clinical supply of NurOwn at its new 32,000 square foot cell therapy manufacturing facility in Houston, TX. Upon FDA approval of NurOwn, we anticipate the companies extending the agreement to include production of commercial supplies of NurOwn from the same facility.

This is an exciting development for the company as we anticipate patient demand to be very high should the Phase 3 clinical trial be successful and NurOwn is approved by the FDA. Thus, having a high-quality manufacturing partnership in place shows that BrainStorm is serious about meeting that demand and not letting access to therapy be an issue for patients.

Exosome Therapy Featured at Recent Conference

On October 19, 2020, BrainStorm announced a poster presentation at the New York Stem Cell Foundation Conference titled: "MSC-NTF (NurOwn®) Exosomes: A Novel Therapeutic Modality in the Mouse LPS-induced ARDS model Analysis". Acute respiratory distress syndrome (ARDS) is a severe complication seen in some patients suffering from COVID-19 that involves an excessive inflammatory response leading to lung damage (Li *et al*., 2019). Current treatment options involve supportive care while the lungs heal, which involves oxygen therapy supplied through a ventilator. There are no pharmacological treatments specifically for ARDS and approximately 40% of hospitalized patients die from it (Siegel *et al*., 2020).

The study conducted by BrainStorm utilized a lipopolysaccharide (LPS)-induced mouse model and showed that intratracheal administration of NurOwn-derived exosomes resulted in a statistically significant improvement in functional lung recovery, reduction in pro-inflammatory cytokines, and attenuation of lung damage. These results suggest that NurOwn-derived exosomes are more efficacious than exosomes derived from non-induced MSCs and may be effective in treating ARDS in COVID-19 patients.

Stock Sell Off Unwarranted

Following release of the 3Q20 financial results, BrainStorm's stock has decreased by approximately 40% for no discernible reason. During the 3Q20 conference call the company reaffirmed that results for the Phase 3 ALS trial will be available by the end of November 2020 and we know of no change to that schedule over the past week. While it's not unusual for stocks to be highly volatile ahead of binary data readouts, which is how we view the Phase 3 ALS results, we have heard concern from some investors that the recent price drop represented a possible unblinding of the data. However, this is not correct, the study remains blinded, and the schedule for releasing the results remains the same. We believe investors who understand the risk of the upcoming data readout could use the recent sell-off as a buying opportunity.

Conclusion

The manufacturing agreement with Catalent is great news for the company and patients, as it should alleviate what is likely to be significant demand for NurOwn upon approval. The next expected news from the company is the topline data release for the Phase 3 ALS trial, with those results expected before the end of November 2020. With no changes to our model our valuation remains at $33 per share as we anxiously await the results of the Phase 3 ALS trial.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2019 A	Q1 A	Q2 A	Q3 A	Q4 E	2020 E	2021 E	2022 E
MSC-NTF Stem Cells	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$50**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$50**
YOY Growth	-					-	-	-
Cost of Goods / Services	$0.0	$0	$0	$0	$0	$0.0	$0.0	$7.5
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$17.2	$5.9	$5.7	$1.9	$6.0	$19.5	$20.0	$20.0
% R&D	-	-	-	-		-	-	-
SG&A	$5.8	$2.4	$1.7	$2.6	$1.6	$8.3	$6.5	$19.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($23.0)	($8.3)	($7.4)	($4.5)	($7.6)	($27.8)	($26.5)	$3.5
Net Other Income	($0.3)	$0.2	$0.0	$0.0	$0.0	$0.2	$0.0	$0.0
Pre-Tax Income	($23.3)	($8.1)	($7.4)	($4.5)	($7.6)	($27.6)	($26.5)	$3.5
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($23.3)	($8.1)	($7.4)	($4.5)	($7.6)	($27.6)	($26.5)	$3.5
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.06)**	**($0.29)**	**($0.25)**	**($0.14)**	**($0.24)**	**($0.91)**	**($0.80)**	**$0.10**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	21.9	28.4	29.3	31.2	32.0	30.2	33.0	35.0

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

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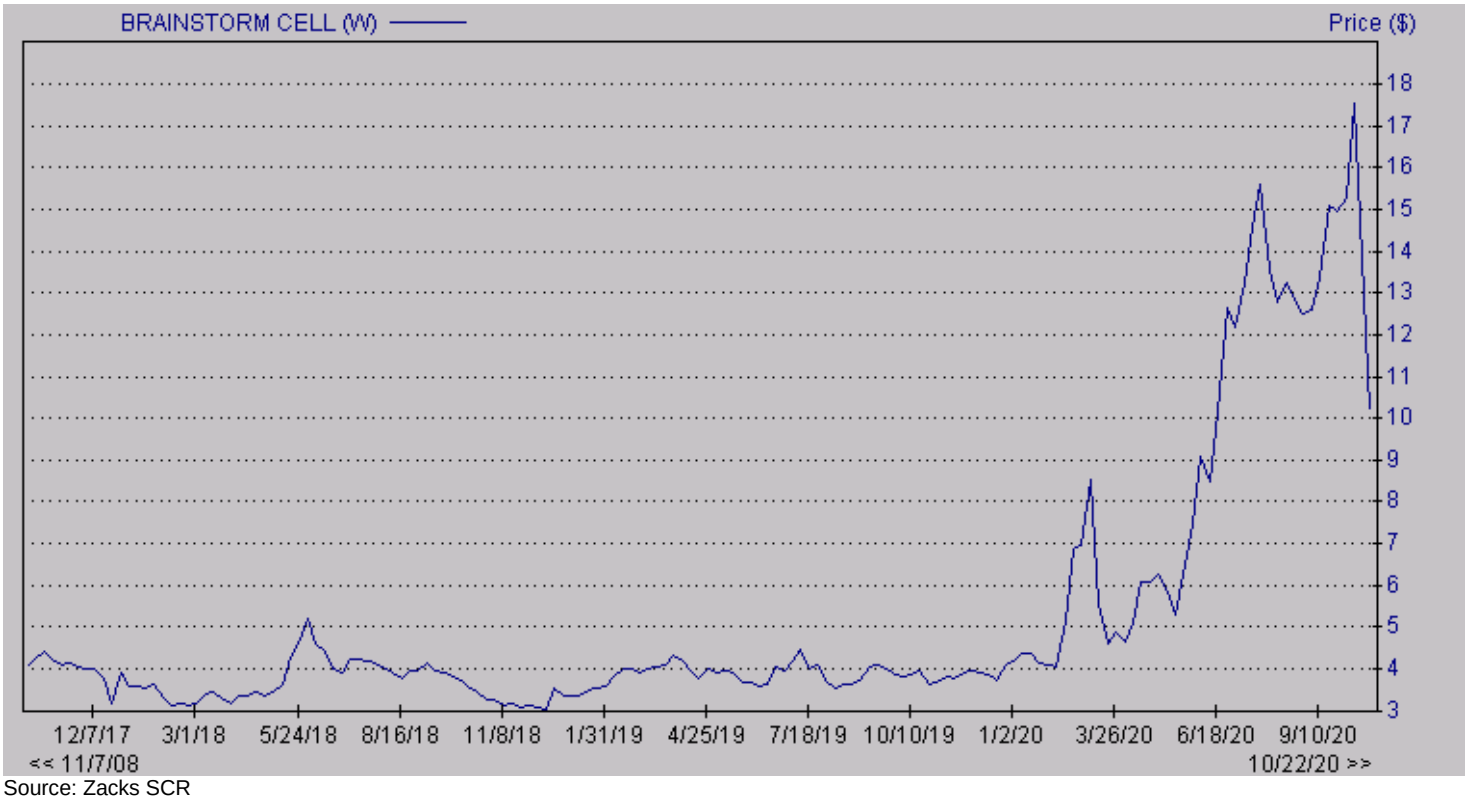
HISTORICAL STOCK PRICE



Source: Zacks SCR

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