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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: Preclinical Data Shows NurOwn®-Derived Exosomes Effective in ARDS Model…

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 $10.00/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (01/25/21)	$5.30
Valuation	**$10.00**

OUTLOOK

On January 20, 2021, BrainStorm Cell Therapeutics, Inc. (BCLI) announced the publication of results from a preclinical study evaluating NurOwn®-derived exosomes in a mouse model of acute respiratory distress syndrome (ARDS), a common complication of severe COVID-19. ARDS results from small blood vessels in the lungs leaking fluid into the alveoli and preventing proper oxygen exchange. There are currently no approved therapies for treating ARDS aside from supportive care. The results published by BrainStorm showed that NurOwn-derived exosomes significantly decreased the lung disease severity score and improved other markers including lung function, fibrin accumulation, and blood oxygenation levels. While BrainStorm remains fully committed to advancing NurOwn toward regulatory approval in ALS, these results show an additional potential indication for the exosome-based platform.

SUMMARY DATA

52-Week High	**$17.73**
52-Week Low	**$3.99**
One-Year Return (%)	**28.02**
Beta	**0.37**
Average Daily Volume (sh)	**668,452**
Shares Outstanding (mil)	**32**
Market Capitalization ($mil)	**$167**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**22**
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	**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)
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

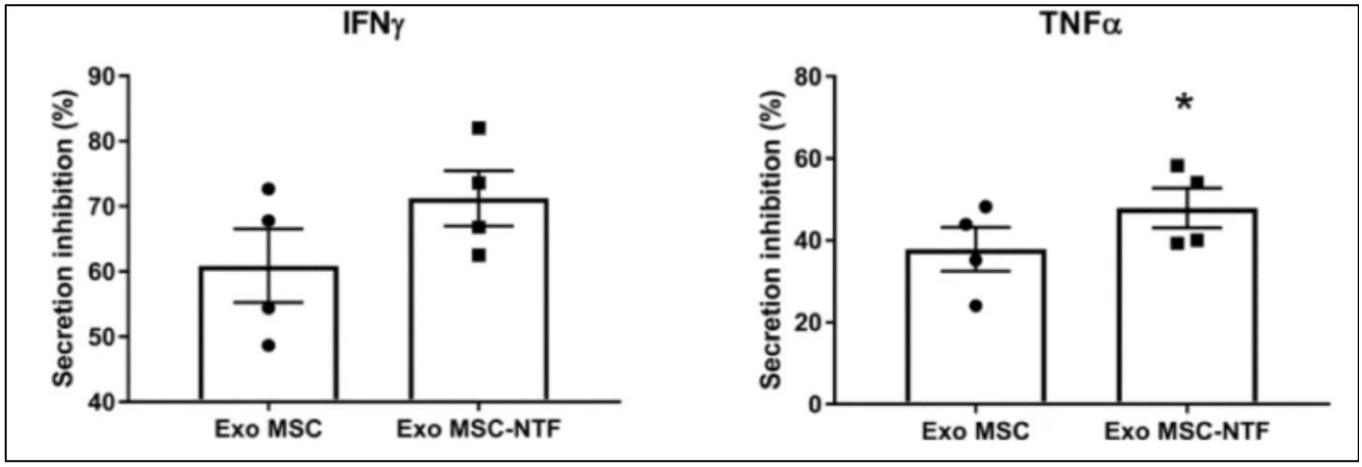
Business Update

NurOwn®-Derived Exosomes Show Promise in COVID-19 ARDS

On January 20, 2021, BrainStorm Cell Therapeutics, Inc. (BCLI) announced the publication of results from a preclinical study that evaluated NurOwn-derived exosomes in a mouse model of acute respiratory distress syndrome (ARDS) (Kaspi *et al*., 2021). The publication, entitled "MSC-NTF (NurOwn®) exosomes: a novel therapeutic modality in the mouse LPS-induced ARDS model", described results showing that treatment with intratracheal administration of NurOwn-derived exosomes results in a statistically significant reduction in the lung disease severity score and improvements in a number of other ARDS markers, including lung function, fibrin, neutrophils, and blood oxygenation.

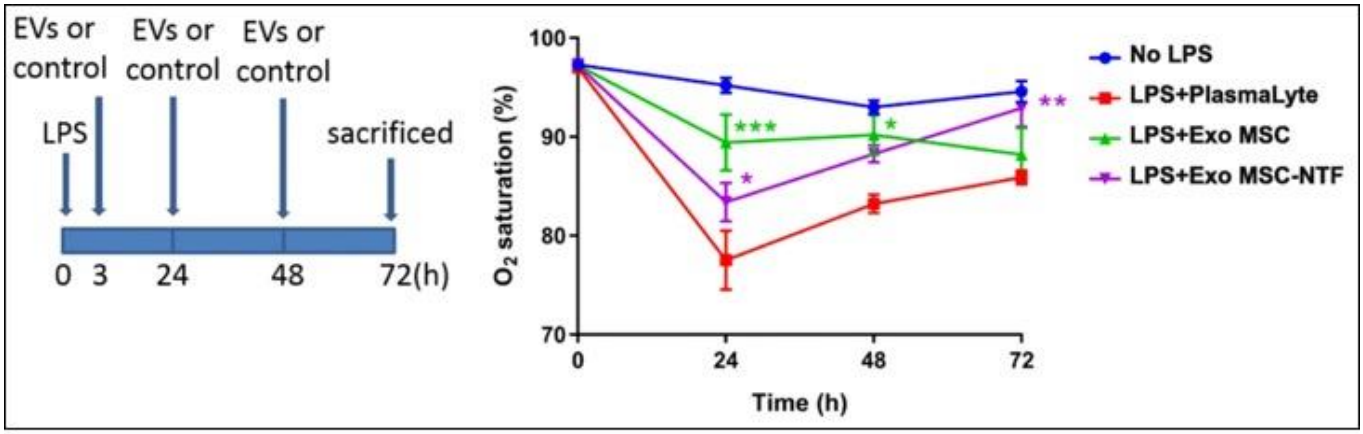
ARDS results in the small blood vessels of the lung leaking fluid that fills up the alveoli, thus preventing proper oxygen exchange (Stevens *et al*., 2018). There are many causes of ARDS, including infections (e.g., pneumonia), severe burns, pancreatitis, inhalation of smoke or chemicals, or other serious illnesses, including COVID-19. An excessive inflammatory response appears to be involved in the pathogenesis of ARDS (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).

In this preclinical study, exosomes derived from both bone marrow mesenchymal stem cells (MSCs) and neurotrophic factor secreting MSCs (MSC-NTF; NurOwn) were studied for their effectiveness in a lipopolysaccharide (LPS)-induced ARDS model (Chen *et al*., 2010). Exosomes are nano-sized extracellular vesicles that are secreted by various cells, including MSCs, and are responsible for cell-cell communication through delivery of miRNA, mRNA, lipids, and proteins (Yanez-Mo *et al*., 2015). Exosomes can be administered in a number of different ways, including intratracheally, and have numerous advantages over traditional cell therapy including low immunogenicity, high stability, no potential for differentiation, and enhanced tissue penetration. Evaluation of the exosomes produced for this study showed similarity between MSC and MSC-NTF-derived exosomes in regards to median size (146 nm vs. 114 nm) and expression of CD44 and CD29 (MSC markers). Exosomes are thought to exhibit their therapeutic effect through immunomodulation, and while there was a similar level of interferon gamma (IFN-γ) inhibition (lower left figure), MSC-NTF-derived exosomes were statistically significantly more effective at inhibiting tumor necrosis alpha (TNF-α) secretion compared to MSC-derived exosomes (lower right figure, $P<0.05$) from activated peripheral blood mononuclear cells (PBMCs).



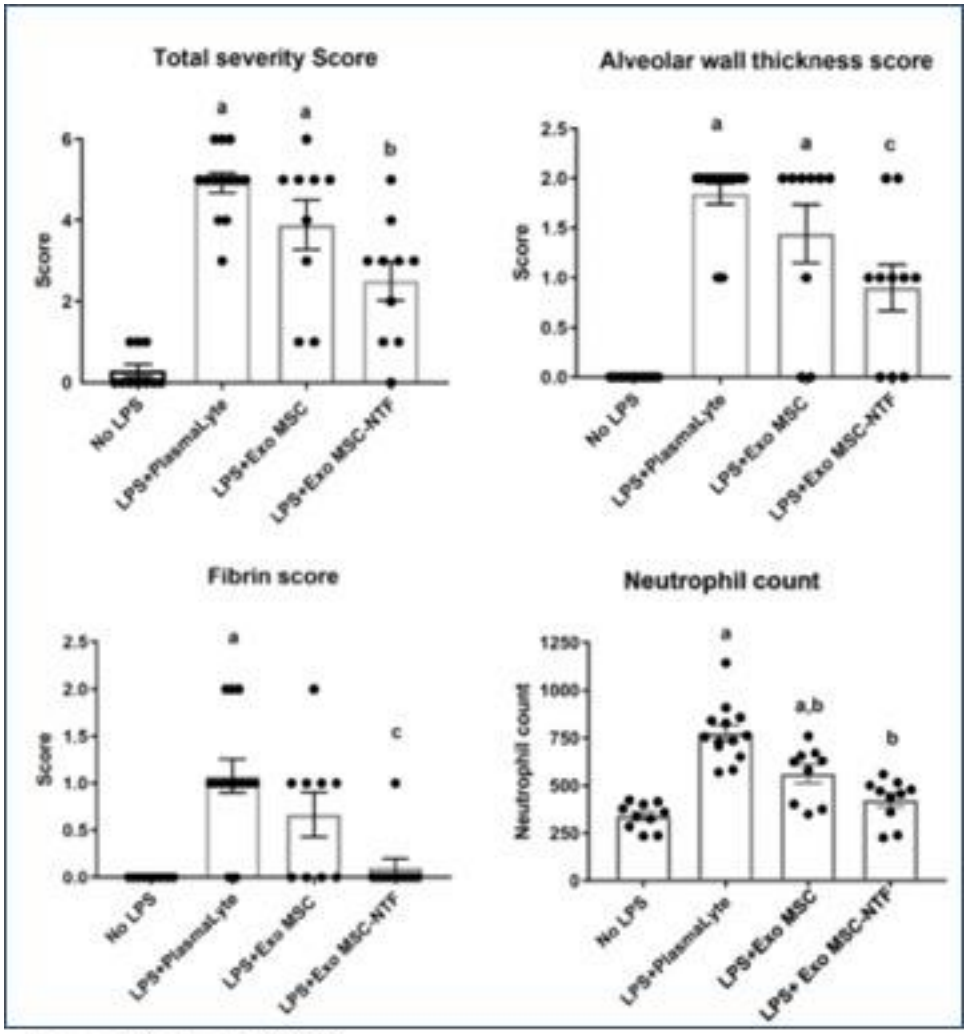
Source: Kaspi *et al*., 2021

The following figure on the left shows a timeline for the LPS-induced ARDS model, in which LPS is administered followed by treatment at 3, 24, and 48 hours with all animals sacrificed at 72 hours. The following figure on the right shows that both MSC-derived and MSC-NTF-derived exosomes increased blood oxygen saturation compared to administration of LPS and placebo.



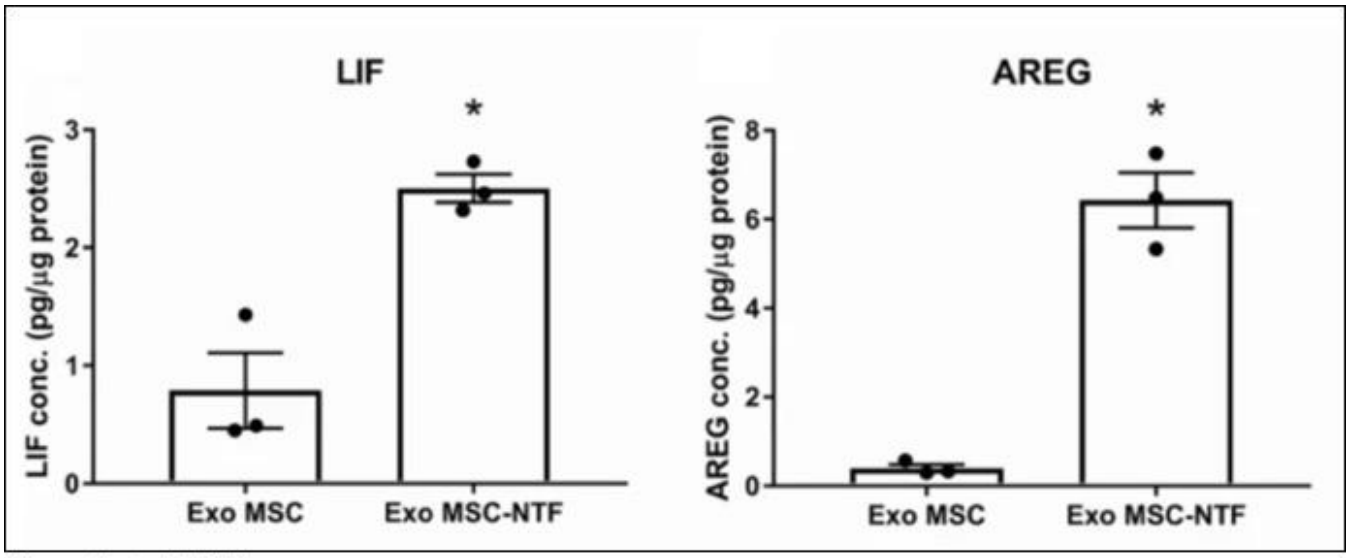
Source: Kaspi *et al.*, 2021

LPS treatment resulted in significant lung damage 72 hours after administration. Lung damage was quantified according to the criteria from the American Thoracic Society (Matute-Bello *et al*., 2011), which includes assessing alveolar wall thickness, presence of fibrin, and neutrophil count along with a total severity score. The following figure shows that treatment with MSC-NTF-derived exosomes significantly lowered the total severity score along with alveolar wall thickness, fibrin accumulation, and neutrophil accumulation. MSC-derived exosomes did not significantly affect any of those parameters but did somewhat reduce neutrophil count.



Source: Kaspi *et al.*, 2021

In order to understand the differences between MSC-NTF and MSC-derived exosomes the researchers examined the protein content of each type of exosome from three different donors. They focused on proteins that had previously been shown to be upregulated in MSC-NTF cells compared to naïve MSCs, proteins that were reported in the exosome database ExoCarta (Keerthikumar *et al*., 2016), and were reported to have a positive effect in models of ARDS. Four proteins met these criteria and were subsequently analyzed by ELISA. The following figure shows that AREG was 16-fold more prevalent in MSC-NTF exosomes compared to MSC-exosomes (*P*=0.013) and LIF was >3-fold more abundant in MSC-NTF exosomes compared to MSC exosomes (*P*=0.015).



Source: Kaspi *et al*., 2021

Conclusion

The data published by BrainStorm shows the potential application of their exosome technology as a treatment for ARDS, which in the near term could be utilized in the battle against coronavirus and in the long term could be used for ARDS caused by other ailments, for which there continues to be a pressing need for better therapies. While the company is excited about the exosome technology, the main focus continues to be on identifying a regulatory path forward for NurOwn in ALS. We anticipate an update on this process in the next few months. With no changes to our model the valuation remains at $10.

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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