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BrainStorm Cell Therapeutics, Inc. (BCLI-NASDAQ)

BCLI: KOL Event Gives Overview of the use of NurOwn® in Alzheimer's Disease; Raising Valuation to $25/Share…

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 $25.00/share. This model is highly dependent upon continued clinical success of NurOwn® and will be adjusted accordingly based upon future clinical results.

Current Price (07/09/20)	$12.83
Valuation	**$25.00**

OUTLOOK

On July 8, 2020, BrainStorm Cell Therapeutics, Inc. (BCLI) held a Key Opinion Leader (KOL) webinar on the company's Alzheimer's Disease (AD) program. The event included presentations from Dr. Philip Scheltens and Dr. Bruno Dubois, two lead investigators from the company's planned Phase 2 trial. It is expected to enroll 40 patients with prodromal to mild AD at medical centers in France and the Netherlands. The primary objective of the 52-week trial is the evaluate the safety and efficacy of NurOwn® with secondary objectives examining biomarkers in the blood and cerebrospinal fluid (CSF).

SUMMARY DATA

52-Week High	**$12.83**
52-Week Low	**$3.54**
One-Year Return (%)	**201.88**
Beta	**1.12**
Average Daily Volume (sh)	**972,038**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$378**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**13**
Insider Ownership (%)	**21**
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 E	0 E	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	-$0.21 E	-$0.22 E	-$0.25 E	-$0.96 E
2020					-$0.80 E
2021					$0.10 E

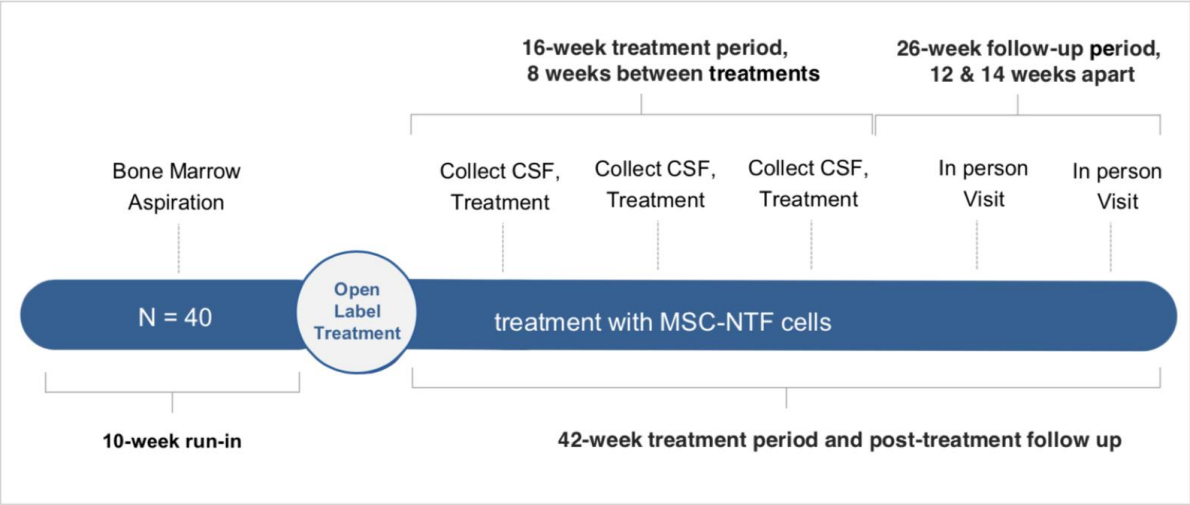
Business Update

KOL Event for Alzheimer's Program

On July 8, 2020, BrainStorm Cell Therapeutics, Inc. (BCLI) conducted a Key Opinion Leader (KOL) webinar to discuss the company's upcoming Phase 2a clinical trial of NurOwn® in patients with Alzheimer's Disease (AD). The event included presentations by two of the lead investigators for the upcoming trial, Dr. Philip Scheltens, Professor of Cognitive Neurology and Director of the Alzheimer Centre at VU University Medical Center in Amsterdam, Netherlands, and Dr. Bruno Dubois, Professor of Neurology at the Neurological Institute of the Salpétrière University Hospital in Paris, France. The presentation can be found here.

The company's Phase 2a trial (BCT-201-EU) is expected to enroll approximately 40 patients with prodromal to mild AD. It will be taking place at medical centers in France and the Netherlands. To be eligible for the trial, patients must have been diagnosed with prodromal to mild dementia at least six months prior to enrollment. In addition, patients must score between 20-30 on the Mini-Mental State Exam (MMSE) and have a Clinical Dementia Rating (CDR) global score of 0.5-1.0. The MMSE is a series of questions that are designed to assess a patient's mental skills, with the maximum score being 30 points and a score of 20-24 suggesting mild dementia. The CDR is a scale used to characterize six domains of cognitive and functional performance with a score of 0.5 suggesting very mild dementia and a score of 1.0 suggesting mild dementia.

The primary objective of the trial is to assess the safety and tolerability of three intrathecal injections of NurOwn® in AD patients. Following bone marrow aspiration during a 10-week run-in period, patients will be treated three times with NurOwn®, with eight weeks between treatments. Follow-up visits will occur 12 and 26 weeks following the final injection of NurOwn® for a total trial length of 52 weeks. The following figure gives an overview of the trial design.



Source: BrainStorm Cell Therapeutics, Inc.

Cerebrospinal fluid (CSF) and serum will be collected prior to treatment and again at Weeks 0, 8, and 16 to assess changes in various neurotropic, neurodegenerative, and inflammatory factors (e.g., VEGF, HGF, NfL, NfH, MCP-1, IL-6), markers associated with amyloid deposition (e.g., aβ40, aβ42), and markers of tau protein levels (e.g., p-tau, t-tau). Additional clinical outcome measures will be analyzed through administration of the following tests:

- Clinical Dementia Rating Scaled–Sum of Boxes (CDR-SB)
- Free and Cued Selective Reminding Test (FCSRT)
- Neuropsychological Test Battery (NTB)
- Delis-Kaplan Executive Function System (D-KEFS) subtests
- Mini Mental State Examination(MMSE)
- AmsterdamInstrumentalActivitiesofDailyLivingQuestionnaire-ShortVersion(A-IADL-Q-SV)

Alzheimer's Disease

Alzheimer's disease (AD) is the most common form of dementia in older adults. The disease is named after Dr. Alois Alzheimer, who identified the first case in a 50-year-old woman named Auguste Deter in 1902. Dr. Alzheimer followed her case until her death in 1906, at which point he first publicly reported on it (Alzheimer, 1907).

After Ms. Deter's death, Dr. Alzheimer examined her brain and found many abnormal clumps (now known as amyloid plaques) and tangled bundles of fibers (now known as neurofibrillary tangles). Over the next five years, 11 similar cases were reported in the medical literature, with some of them already using the term Alzheimer's disease (Berchtold *et al*., 1998).

The most common early symptom of AD is a gradually worsening ability to remember new information. This is due to neurons associated with forming new memories dying off first. As neurons in other parts of the brain die, individuals experience different symptoms, which include:

- Memory loss that disrupts daily life
- Inability to plan or solve problems
- Difficulty completing familiar tasks
- Confusion with location and time
- Difficulty with visual images and spatial relationships
- Problems with words in speaking or writing
- Withdrawal from social activities
- Changes in mood, including apathy and depression

Each person progresses through AD at a different rate, and little is known about how or why there is such a marked variation, thus predicting how it will affect someone is quite difficult. One thing that is common to everyone diagnosed with AD is that his or her cognitive and functional abilities will gradually decline. As the disease progresses symptoms can include confusion, irritability, aggression, mood swings, and long-term memory loss. In the final advanced stage of the disease, people need help with the basic activities of living (e.g., bathing, dressing, eating, and using the restroom), they lose the ability to communicate, fail to recognize loved ones, and eventually become bed bound and reliant on round-the-clock care (Förstl *et al*., 1999). The inability to move makes them more prone to infections, including pneumonia, which are often a contributing factor to the death of those with AD.

Competing Theories for the Cause of Alzheimer's

The root cause of Alzheimer's is still unknown; however, it is likely to involve a number of different factors as opposed to being due to one single cause. These factors are likely a combination of genetic, environmental, and lifestyle. There are a number of hypotheses that exist to explain the cause of the disease, with the two dominant hypotheses focused on amyloid and tau.

- Amyloid hypothesis: This hypothesis proposes that extracellular beta-amyloid deposits are the fundamental cause of the disease (Hardy *et al*., 1991). Beta-amyloid is a fragment of the larger protein amyloid precursor protein (APP), mutations of which are known to cause FAD. Several lines of evidence support the amyloid hypothesis: 1) the location of APP is on chromosome 21, while those with Down Syndrome (trisomy 21) almost all show signs of AD by 40 years of age (Lott *et al*., 2005); 2) APOEε4 is a major genetic risk factor for AD, and while apolipoproteins enhance the breakdown of beta-amyloid, some isoforms are less capable of performing this task than others, leading to more beta-amyloid buildup on the brain (Polvikoski *et al*., 1995); 3) mice that harbor a mutant form of APP develop amyloid plaques and Alzheimer's-like pathology (Games *et al*., 1995). Lastly, amyloid plaques are readily identifiable by microscopy in the brains of AD patients (Tiraboschi *et al*., 2004). While the brains of many older individuals develop some plaques, the brains of AD patients show severe pathological changes specifically within the temporal neocortex (Bouras *et al*., 1994).

- Tau hypothesis: Tau is a protein located mainly within the axonal compartment of neurons and is an important element in microtubule stabilization and neurite outgrowth. In AD, a proportion of tau protein becomes abnormally phosphorylated, dissociates from axonal microtubules, and accumulates in paired helical filaments inside the neuron (Goedert *et al*., 1991). When this occurs, the microtubules disintegrate causing the collapse of the neuron's transport system (Igbal *et al*., 2005). Just as with beta-amyloid plaques, tau tangles are readily observable in the brains of those affected by AD.

In addition to amyloid and tau, inflammation has been an underappreciated and often overlooked mediator in patients with AD (Akiyama *et al*., 2000). A multitude of inflammatory markers are found in AD patients' brains and a number of studies have shown a link between chronic inflammation and an increased risk of developing AD (Walker *et al*., 2017; Tao *et al*., 2018). Thus, a treatment such as NurOwn® that can decrease inflammatory mediators could prove beneficial in AD patients.

On Track to Repot Topline Data from Phase 3 ALS Trial in 4Q20

On July 2, 2020, BrainStorm announced that all doses have been administered in the pivotal Phase 3 trial ofrecen NurOwn® in patients with amyotrophic lateral sclerosis (ALS) and that it remains on track to report topline data in the fourth quarter of 2020.

The ongoing randomized, double blind, placebo controlled, multi-dose Phase 3 clinical trial is testing the ability of NurOwn® to alter disease progression as measured by the ALSFRS-R (NCT03280056). Cells were extracted once from each patient prior to treatment, with all administrations of NurOwn® derived from the same extraction of cells due to a cryopreservation process the company developed for long-term storage of mesenchymal stem cells (MSC). Just as with the company's prior studies, there was a 3-month run-in period prior to the first treatment with two additional NurOwn® treatments occurring two and four months following the first treatment. The company is focusing the trial on faster-progressing ALS patients since those patients demonstrated superior outcomes in the Phase 2 trial of NurOwn®.

BrainStorm Joins Russell 2000® and Russell 3000®; Granted SME Status by EMA

On June 23, 2020, BrainStorm announced that its shares would be included in the Russell 2000® Index and the Russell 3000® Index. The annual reconstitution of the Russell indexes is done to capture the 4,000 largest U.S. stocks by market capitalization.

On June 15, 2020, BrainStorm announced that the company has been granted Small and Medium-Sized Enterprise (SME) status by the European Medicines Agency (EMA). SME status allows the company to participate in a number of financial incentives including a 90-100% reduction in the EMA fee for scientific advice, clinical study protocol design, endpoints and statistical considerations, quality inspections of facilities, and fee waivers for selective EMA pre- and post-authorization regulatory filings, including Orphan Drug and PRIME designations.

Conclusion

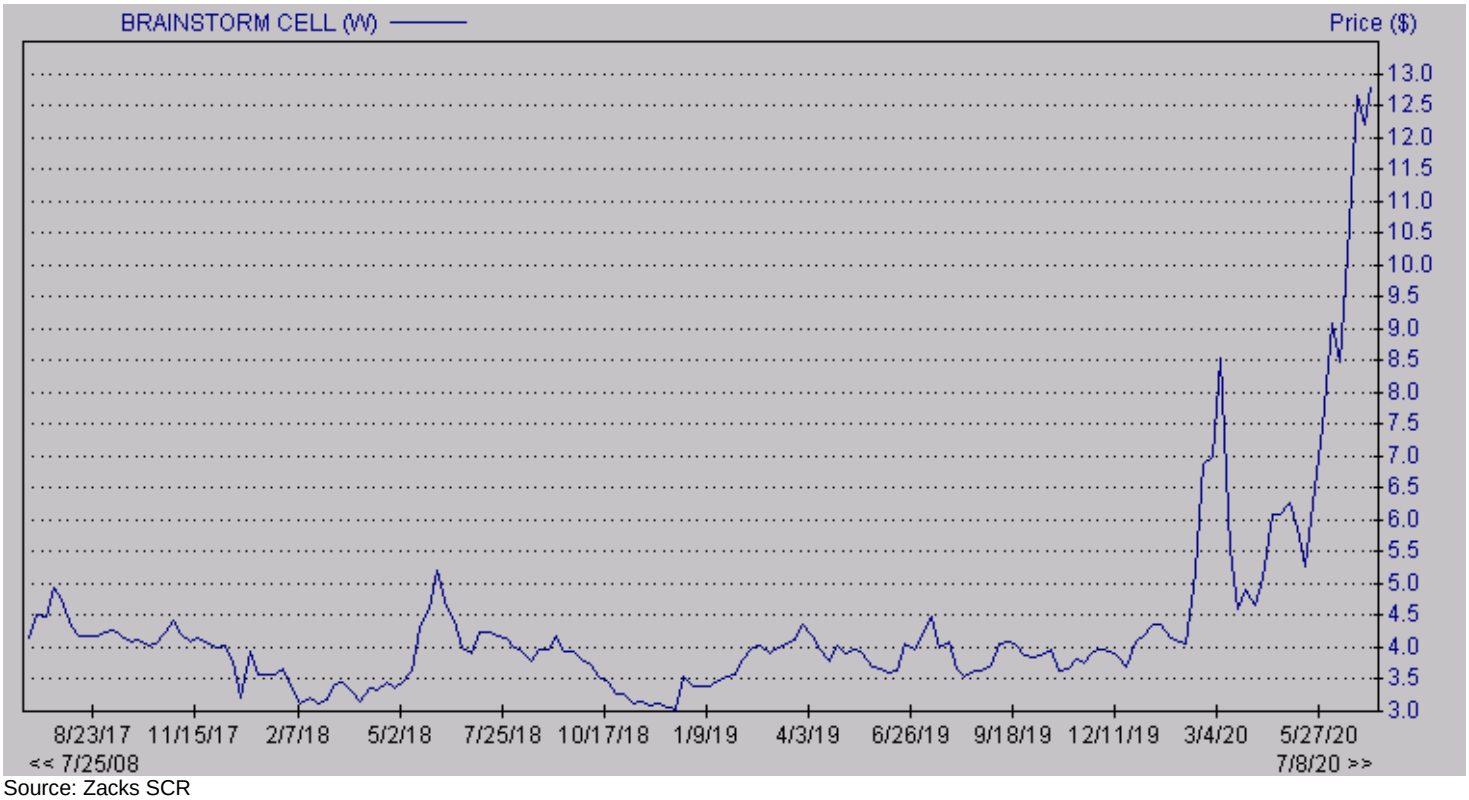
We're excited about the potential for NurOwn® in AD and we look forward to the initiation of the Phase 2a trial later in 2020. We have recently made a few changes to our model, including the inclusion of NurOwn® in AD and lowering of the discount rate from 20% to 15% for all indications. We model for the company to file for approval of NurOwn® in AD in 2026 and to be granted approval in 2027. We currently estimate peak sales of over $2 billion for NurOwn® in AD in both the U.S. and E.U. Using a 25% probability of approval leads to an NPV of $113 million. Combined with the NPV for NurOwn in ALS ($700 million) and MS ($41 million) along with the company's current cash position and potential cash from warrants leads to a valuation for the company of a bit less than $900 million. Dividing by the company's current fully diluted share count of 35.7 million leads to a valuation of $25 per share.

PROJECTED FINANCIALS

Brainstorm Cell Therapeutics	2019 A	Q1 A	Q2 E	Q3 E	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	$4.5	$5.0	$6.0	$21.4	$20.0	$20.0
% R&D	-	-	-	-		-	-	-
SG&A	$5.8	$2.4	$1.6	$1.6	$1.6	$7.2	$6.5	$19.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($23.0)	($8.3)	($6.1)	($6.6)	($7.6)	($28.6)	($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)	($6.1)	($6.6)	($7.6)	($28.4)	($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)	($6.1)	($6.6)	($7.6)	($28.4)	($26.5)	$3.5
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.06)**	**($0.29)**	**($0.21)**	**($0.22)**	**($0.25)**	**($0.96)**	**($0.80)**	**$0.10**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Avg Shares Outstanding	21.9	28.4	29.5	30.0	30.0	29.5	33.0	35.0

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

HISTORICAL STOCK PRICE



Source: Zacks SCR

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