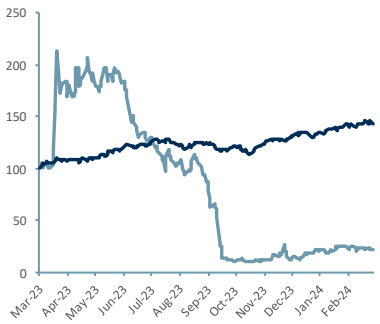
CIC

52 Wk. Lo/Hi

0.13 – 3.46



BCLI (lighter line) vs. Nasdaq price relative

Wednesday, 13 March 2024

Close Price	0.308
52 wk Range Low	0.13
52 wk Range High	3.46
MCAP (m)	$15.09
EV (m)	$16.56
Index: Public	XNAS
Financial YE	31-Dec
Reporting Currency	USD
Listing Currency	USD
Business Activity	
Healthcare	
Key Metrics	
Gross debt (m)	$2.89
Cash (m)	$1.42
Net Debt (Cash) (m)	$1.47
Net Operating Cash	-$21.82
Revenue (m)	N/A
Net Income (loss) (m)	-$16.63
Key Ratios	
(Net Cash) / Shareholder Equity %	9.74%

Healthcare Sector Research
NasdaqCM Market Index
ACF Healthcare Team
+44 20 7419 7928
healthcare@acfequityresearch.com

BrainStorm Cell Therapeutics

Core Investment Case – A Stem Cell Therapy ALS

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BrainStorm Cell Therapeutics Inc. (Nasdaq: BCLI) is a biotechnology company focused on developing autologous mesenchymal stem cell (MSC) therapies for the treatment of neurodegenerative diseases – BCLI's primary target is the fatal amyotrophic lateral sclerosis (ALS/MND/Lou Gehrig's). BCLI's's proprietary technology platform, NurOwn®, stimulates Mesenchymal Stem Cells to emit neurotrophic factors (MSC-NTF), which promote the survival of neurons across multiple disease states. BCLI is planning to launch a Phase 3b trial of NurOwn in ALS patients. Positive results from the trial are likely to act as a major catalyst for BCLI's valuation and the path for marketing approval.

- Stem cells - Biotech company focusing on stem cell therapies for neurogenerative diseases ;
- ALS - Significant unmet medical need for the treatment of fatal amyotrophic lateral sclerosis (ALS) – BCLI's lead indication;
- Orphan Drug (US/EU) - Fast Track designation for ALS by the U.S. FDA, and Orphan Drug Status in the U.S. and Europe;
- P3b - Late-stage pipeline – NurOwn for ALS in Phase 3b

USD (m)	MCAP	EV	RoA %	RoE %	NCO	Levered FCF
TTM	15.09	16.56	-142.26%	N/A	-21.82	-13.79

Multiples	EV/ Revs	P/ S	Trail PE	BV/ Share	P/ B	Current
TTM	N/A	N/A	N/A	-0.06	-5.14	0.24

Investment Case

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BrainStorm Cell Therapeutics Inc. (Nasdaq: BCLI) has developed a proprietary technology platform, NurOwn®, that induces autologous mesenchymal stem cells (MSCs) to secrete high levels of neurotrophic factors (NTFs), key to prolonging neuron survival and improving neurological function. NurOwn's lead indication treatment is for the fatal disease amyotrophic lateral sclerosis (ALS), which has significant unmet need. Additionally, BCLI is assessing NurOwn for other neurogenerative diseases including, progressive multiple sclerosis (PMS). BCLI plans a Phase 3b study of NurOwn for ALS and has also submitted a Special Protocol Assessment (SPA) request to the U.S. FDA.

NurOwn: A Unique Cell Therapy for Neurogenerative Disorders –BCLI's differentiated and specialised MSC-NTF cells release various neurotrophic factors and immunomodulatory cytokines, which appear to enhance the survival of neurons and contribute to improved neurological function. The lead indication for NurOwn is ALS, the platform has broad potential for addressing a spectrum of neurodegenerative diseases, encompassing progressive multiple sclerosis (PMS), Parkinson's disease (PD), autism spectrum disorder (ASD), and Huntington's disease (HD).

On 8th March 2024, competitor Amylyx, using a very different therapeutic approach from BCLI's stem cell therapy approach, announced results of its P3 AMX0035 therapy for ALS, the results were disappointing and though the Amylyx results are a significant set-back for those with the extremely upsetting ALS condition, BCLI's own therapy offers continued near term hope and may become the only efficacious therapy for mild and moderate ALS sufferers.

Amylyx P3 AMX0035 (sodium phenylbutyrate and taurursodiol) Phoenix study 'did not meet its primary endpoint of reaching statistical significance (p=0.667) as measured by change from baseline in the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) total score at Week 48, nor was there statistical significance seen in secondary endpoints' according to the Amylyx release. BCLI is using a stem cell approach, which is a radically different therapy. BCLI's therapy is also within the P3 stage process.

In BCLI management's view NurOwn's clinical evidence and the unique mechanism of action provide alternative and continued hope for patients.

ALS: High Unmet Medical Need: Amyotrophic lateral sclerosis (ALS) is a fatal neurodegenerative disorder that affects motor nerve cells in the brain and the spinal cord. This degeneration leads to muscle weakness, disability, and ultimately, fatality. Nearly 450,000 patients worldwide are estimated to have the ALS condition, with 30,000 in America and 51,000 in Europe. The median survival rate for patients is currently between 2 to 5 years. Current treatment options (Riluzole and Radicava) deliver limited efficacy. There remains a high unmet need for an effective treatment alternative that can slow, halt or reverse ALS disease progression.

SPA Submission to De-risk Phase 3b Trial: BCLI is planning a Phase 3b trial and has submitted a trial design to the US FDA. Around 200 individuals experiencing early in their ALS disease course will participate in a two-part study. BCLI has also submitted a Special Protocol Assessment (SPA) request to the FDA on its design of the P3b trial. An SPA signifies consensus with the FDA on the overall adequacy and acceptability of the protocol design. We are encouraged by participation in the SPA as it helps de-risk the regulatory process.

Catalysts

Rerating - Approval by the U.S. FDA on the design of the Phase 3b Trial; **Increased NPV** - Progress on the other pipeline candidate targeting progressive multiple sclerosis (PMS).

Operational Strategy

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BCLI's strategy is to advance its proprietary technology platform, NurOwn, for the treatment of neurogenerative diseases, particularly ALS, its lead indication. BCLI is also targeting other neurological diseases, such as Progressive Multiple Sclerosis (PMS), where the Company has already completed a Phase 2 study. BCLI has been granted Fast Track designation for ALS and has also received Orphan Drug Status in the U.S. and Europe. This status offers the potential for an extended period of exclusivity. BCLI is attempting to resubmit NurOwn through the regulatory approval process after an earlier failed attempt wherein its Phase 3 trial data failed to provide sufficient evidence for the therapy's efficacy, in the view of U.S. FDA.

There has since been a regulatory **reorganisation** spearheaded by the Center for Biologics Evaluation and Research (CBER) via which, **a new super office, the Office of Therapeutic Products (OTP) has been formed** that deals with Brainstorm's therapy approvals. The OTP has undergone a change of leadership that comes with what appears to be a more **balanced/constructive approach.** BCLI is currently targeting the cohort of patients who are early in their ALS disease course.

Phase 3b Trial Design Announced; SPA Submitted to the U.S. FDA

The company is optimistic that the forthcoming Phase 3b trial will generate sufficient data on the therapeutic benefits of its ALS stem cell therapy for early stage and perhaps mild to moderate ALS sufferers, facilitating the submission of a new marketing application for regulatory approval.

BCLI has argued over time that its NurOwn therapy for ALS is best applied to early stage and perhaps mild to moderate ALS patients.

Around 200 individuals experiencing **mild-to-moderate ALS** will participate in a two-phase study. The initial phase, Part A, spans 24 weeks and involves a randomized, double-blind design. The subsequent phase, Part B, extends for an additional 24 weeks and adopts an open-label approach. The study's main goal will be to assess whether NurOwn has the potential to slow the decline in patients' functional abilities. This assessment will be based on the changes observed in the Revised ALS Functional Rating Scale (ALSFRS-R) scores.

Brainstorm Cell Therapeutics (BCLI) has submitted a Special Protocol Assessment (SPA) request to the FDA for its design of the phase 3b trial. The SPA program will enable BrainStorm to establish agreement with the FDA regarding the design of the Phase 3b trial, ensuring that the study is deemed sufficient by the FDA to support a subsequent marketing evaluation. The FDA decision on the approval of the SPA request is awaited.

We look forward to the FDA's decision on the SPA as well as the design of the Phase 3b trial. We are encouraged by FDA participation in the SPA as it helps de-risk certain regulatory pathway aspects of the BCLI approval plan.

Management Team

- **CEO, Chaim Lebovits.**

Mr. Lebovits joined BrainStorm Cell Therapeutics (BCLI) in July 2007 and was appointed CEO in September 2015. Chaim has driven the transition of the Company from an early/preclinical stage company to its current phase 3b clinical program stage in the United States. More recently, Mr. Lebovits has been involved in recruiting several biotech executives with critical clinical development and path-to-market experience to support the development and regulatory filing of autologous MSC-NTF cells in ALS and MS.

- **Co-CEO, Stacy Lindborg.**

Ms. Lindborg joined BrainStorm Cell Therapeutics in June 2020 and was appointed as the co-Chief Executive Officer in January 2023. She has over 25 years of experience in the healthcare sector in R&D, regulatory, strategy development, analytics and big data. Previously, Stacy held senior level positions at Eli Lilly & Company and Biogen. She was actively involved in R&D strategy and helped work through regulatory manufacturing inspections citations. She holds a Ph.D. in statistics from Baylor University

- **Executive Vice President (EVP) and CDO, Bob Dagher.**

Mr. Dagher joined Brainstorm Cell Therapeutics in July 2023. Bob serves as EVP and Chief Development Officer (CDO). He brings particular expertise as a physician scientist and drug developer in the pharma sector. Bob has over 20 years of experience in Pharmaceuticals and was formerly a board-certified physician from the American Board of neurology and psychiatry and has a focus on neurodegenerative disorders. His professional roles include time at Sanofi Aventis, Genzyme and GSK. Prior to Brainstorm, Bob was CMO at Enveric Biosciences, WCG Medavante-Prophase and Cadent Therapeutics. He has **successfully delivered preclinical, P1, P2, P3 and P4 post marketing projects in drug development**. His medical degree (MD) was obtained via St. Joseph and Bordeaux universities joint program and his residency was completed at Boston University School of Medicine.

Risks

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Funding risk – The Company has incurred significant losses in prior periods and expects more losses over the coming years as it advances its development and commercial programs. The Company would need access to capital to fund these losses. To date, the Company has generated no revenue and is unlikely to do so in the near future. As such, we expect BCLI to raise additional funding. Failure to raise sufficient funds could raise doubts over its ability to remain a going concern.

Regulatory risk – The process of obtaining and maintaining regulatory approvals for new therapeutic products is time consuming, expensive, and uncertain. BCLI must provide the FDA and foreign regulatory authorities with preclinical and clinical data demonstrating that NurOwn is safe and effective before it can be approved for commercial sale. Any preclinical or clinical test may fail to produce results that are satisfactory to the FDA.

Competition risk - The biotechnology and pharmaceutical industry is highly competitive. There are many companies that are seeking to develop products and therapies for the treatment of the same range of diseases as BCLI. Many of the competitors have substantially greater financial resources and more experience in advancing the drugs through various stages of regulatory approvals and then to commercialization.

Intellectual Property risk – BCLI is near-term dependent on its proprietary technology platform, NurOwn, and therefore, its near-term success depends on its ability to protect its IP. BCLI holds 27 granted patents and 23 patent applications in the United States, Canada, Europe, and Israel, as well as in additional countries worldwide. This includes key patents related to the production method of the Company's proprietary stem cells. Failure to be able to protect its IP in practice could have an adverse impact on the business operations.

Personnel - Small and mid-sized companies are more dependent on their C-suite/executive management teams than large and mega-cap global companies. The loss of key personnel can have a disproportionate impact on valuation and investor perception compared to similar events at larger, more mature (often ex-growth) companies.

Notes [Intentionally Blank]

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Christopher Nicholson
Managing Director
Head of Research
ACF Equity Research Ltd

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ACF Equity Research Limited, 125 Old Broad Street, London, EC2N 1AR, U.K.
Tel: +44 (020) 7558 8974
Website: www.acfequityresearch.com