INITIATION

VALUE RANGE

$5.95 – 6.57

Price relative BCLI (lighter line) vs. Nasdaq Biotech (NBI)

Monday, 10 June 2024

Intrinsic Price (USD)	6.26
Value Range Low (USD)	5.95
Value Range High (USD)	6.57
Implied MCAP (USD) (m)	463.44
Implied EV (m)	463.10
XNAS	BCLI
Year End	31-Dec
Currency	USD

Business Activity
Biotechnology & Medical Research

Key Metrics

Close Price (USD)	0.411
MCAP (USD) (m)	28.81
Net Debt (Cash) (m)	0.34
EV (m)	29.15
52 Wk Hi	2.91
52 Wk Lo	0.13

Key Ratios

Net Cash / Shareholder Equity %	-1.19%

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BrainStorm Cell Therapeutics

PIIIb Transformative Catalyst

BrainStorm Cell Therapeutics Inc. (Nasdaq: BCLI, Biotech) is focused on developing autologous mesenchymal stem cell (MSC) therapies for the treatment of neurodegenerative diseases (NDDs) – BCLI's primary target is the fatal amyotrophic lateral sclerosis (ALS/MND/Lou Gehrig's). Post hoc analysis of BCLI's PIII trial data shows BCLI's NurOwn® (debamestrocel, MSC-NTF), has statistically significant clinical effects on early-stage ALS sufferers and that placebo trialists deteriorate faster. Peer reviewed research (Mar 2024) indicated that BCLI's NurOwn® has a positive impact on NfL biomarkers for ALS. These and other factors have persuaded the FDA to sign up to the SPA binding commitment for a NurOwn® PIIIb ALS trial. BCLI has regained regulatory minimum value NASDAQ compliance. Our valuation captures only the smaller by patients US market and excludes the larger EU/UK market.

- PIII post hoc analysis reveals NurOwn® clinical effectiveness;
- Fatal ALS/MND - Significant unmet medical need - lead indication;
- Orphan Drug status obtained (US/EU) - Fast track designation;
- Positive Special Protocol Assessment (FDA);
- Cash & CE 1Q24A USD 0.779m vs. 1.485m YE23A.

ACF est. USD (m)	Revenue	EBITDA	FCFF	EPS	EPS (diluted)	CPS
2029E	371.2	184	176	0.62	0.60	0.0008
2030E	610.2	307	127	1.03	1.00	0.0013

Multiples	EV/ Sales	EV/ EBITDA	EV/ FCF	P/ EPS	P/ EPS (diluted)	P/ CPS
2029E	0.1x	0.2x	0.2x	0.7x	0.7x	528.4x
2030E	0.0x	0.1x	0.2x	0.4x	0.4x	324.3x

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Share Price History	No. of Shares in issue	Fully diluted
NoSh (m)	70.1	74.0
Implied Intrinsic Price	6.61	6.26
Value Range Low	6.28	5.95
Value Range High	6.94	6.57
XNAS	BCLI	
Financial YE	31-Dec	
Reporting Currency	USD	

NoSh (m)	70.08
NoSh (m) expected dilution (Exp D)	74.05
NoSh (m) full dilution (FD)	74.05

Key Metrics	$	adj.
MCAP (m)	28.8	28.8
Net Debt (Cash) (m)	0.3	0.3
EV (m)	29.2	29.2
52 Wk Hi	2.91	2.91
52 Wk Lo	0.13	0.13
Free Float	86.5%	86.5%
Effective Free Float	66.7%	66.7%

*Key Metrics FCF adj.	2029E	2030E
CPS ($)	0.0008	0.0013
CPS (Exp D) ($)	0.0008	0.0013
CPS (FD) ($)	0.0008	0.0013
P/CPS	528.4x	324.3x
P/CPS (Exp D)	528.4x	324.3x
P/CPS (FD)	541.7x	324.3x

Current treatment options primarily focus on managing symptoms rather than disease modification include riluzole (generic), edavarone (US, Canada) and deliver very limited efficacy. Tofersen addresses just 2% of ALS sufferers. High unmet need to slow/reverse ALS progression.

Our valuation excludes the larger European/UK markets, which provide considerable additional upside.

Investment Case

BrainStorm Cell Therapeutics Inc. (Nasdaq: BCLI) has developed a proprietary technology platform, NurOwn® (debamestrocel, MSC-NTF), that induces bone marrow derived autologous mesenchymal stem cells (MSCs) to secrete high levels of neurotrophic factors (NTFs); key to prolonging neuron survival and improving neurological function. NurOwn® has shown positive statistically significant clinical effects for the treatment of ALS in early-stage sufferers (peer reviewed post hoc analysis of PIII trial data). BCLI is also assessing NurOwn® for other neurogenerative disease indications including progressive multiple sclerosis (PMS). In a highly conservative valuation approach we have excluded the larger by patients EU/UK market, capturing only the US market.

Post hoc analysis of BCLI's PIII early stage (mild-moderate) ALS sufferers (baseline ALSFRS-R scores >=35) treated with BCLI's NurOwn® (debamestrocel, MSC-NTF) revealed positive clinical responses with respect to slowing of ALS disease progression (primary endpoint). However the PIII trial cohort consisted (unexpectedly) of 23% advanced ALS sufferers, clouding the primary and secondary end point statistical analysis (possible floor effects). The new PIIIb trial is designed to recruit a cohort of participants with ALSFRS-R scores >=35. Additionally, more recent peer reviewed research found that certain biomarkers involved in ALS pathology, specifically NfL, LAP and Galectin-1 were found to be predictive of positive clinical outcomes in NurOwn® (debamestrocel, MSC-NTF),-treated participants. If the new trial design is successfully executed, as we forecast, we expect a strongly positive valuation inflection point for BCLI.

ALS: High Unmet Medical Need Amyotrophic lateral sclerosis (ALS) is a fatal neurodegenerative disorder (NDD) that affects motor nerve cells in the brain and the spinal cord. There are an estimated ~450k ALS patients worldwide (30k US and 51k European). Median survival post diagnosis is 2 to 5 years. Current treatment options have very limited efficacy. Tofersen addresses just 2% of ALS sufferers. There is a high unmet need to slow/reverse ALS progression.

SPA approved - De-risks Phase IIIb Trial (n~200): The PIIIb design focusing on recruitment of ALSFRS-R>=35 patients has been committed to by the US FDA, which helps de-risk the regulatory process .

Catalysts

Rerating – Approved U.S. FDA design Phase IIIb trial commencement; PIIIb results; **Increased NPV** – Inclusion of European ALS market in our DCF; Progress on pipeline candidate targeting progressive multiple sclerosis (PMS).

Phase III Post Hoc Analysis – Clinical Effectiveness

Throughout this note to help reader recall we use three interchangeable terms for BCLI's ALS therapy/platform – these are NurOwn®, debamestrocel and MSC-NTF. Increasingly in publicly available sources the noun of choice is NurOwn, reflecting BCLI's closeness to commercialization of its ALS therapy.

NurOwn (debamestrocel, MSC-NTF), therapy PIII trial results post hoc analysis of the data suggests that there is a clinically significant effect on earlier stage ALS patients, as defined by using the ALSFRS-R scale.

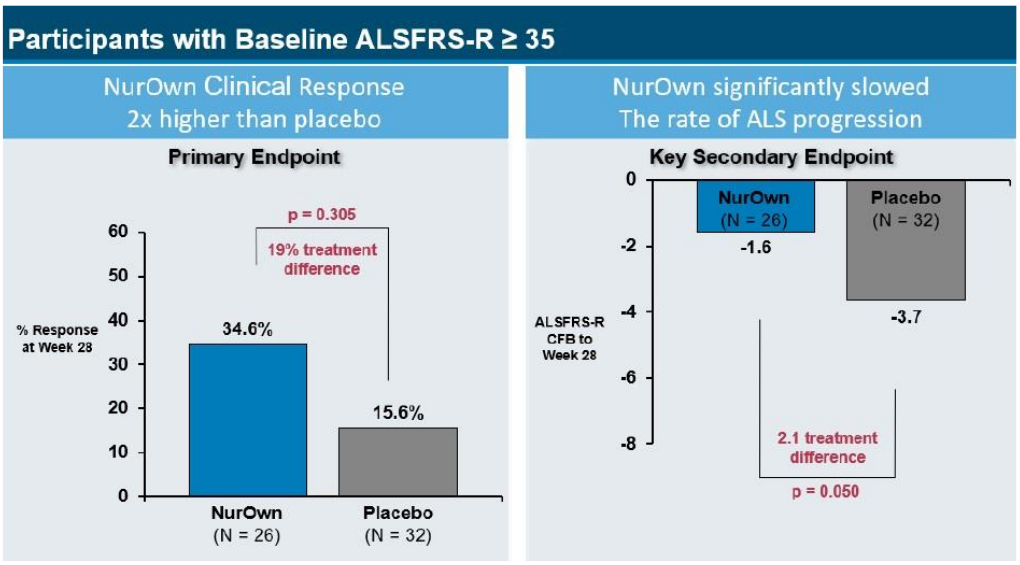
Though the peer reviewed PIII clinical paper (Muscle & Nerve, accepted 7th Dec 2021) states both in the results and discussions sections that across the entire trial cohort primary efficacy and secondary endpoints were not met, this is a long way from the full and positive clinical story.

A floor effect renders statistical analysis less revealing.

The PIII clinical paper referred to above concluded that a) for the primary endpoint there was no difference in the response rate (participants with at least 1.25 points/month change in rate of disease progression as measured by the ALSFRS-R slope) and that b) the secondary endpoints were also not met, as summarized by a >=100% improvement measured by the ALSFRS-R slope , CAFS and SVC. However, **post-hoc analysis of cohort pre-specified study sub-groups revealed a different outcome**.

PIII post hoc analysis revealed several key points –

Exhibit 1: **BCLI's NurOwn – Effective in Mild-Moderate ALS**



Sources: BCLI's 2024 MDA Poster Design of NurOwn P3b Clinical Trial.

1) Unexpected floor effect - As BCLI's PIII NurOwn treated ALS trial cohort reflected the distribution of participants relative to the general population and this included a high concentration (23%) of late-stage sufferers (this was unexpected at the trial design stage). This distribution of progression of ALS within the PIII trial participants (23% late-stage ALS sufferers) created a challenge in measuring ALS disease progression during the trial with the ALSFRS-R scale, which is relatively insensitive in later stage ALS disease progression. This problem is referred to as the floor effect. The floor effect in this trial may well be due to a lack of sensitivity in the ALSFRS-R test in assessing the late stages of ALS disease progression.

The ALSFRS-R scale is necessarily a subjective test based on a physician's judgement. A floor effect renders statistical analysis less revealing because it is less likely to pick up positive, clinically significant, changes in many late-stage patients.

2) Earlier stage patients clinically responsive – Earlier stage patients (participants) showed positive clinical effect as a result of treatment with BCLI's NurOwn (debamesctrocel, MSC-NTFs), which was statistically significant in these same patients. Placebo patients deteriorated faster than NurOwn (debamesctrocel, MSC-NTF) treated patients.

Earlier diagnosis of ALS and the identification of one or more reliable biomarkers would improve identification of the population of patients for future studies. However, key to the next trial design (PIIIb) will be optimization of the inclusion criteria to ensure that patients in earlier stages (ALSFRS-R >=35), where the ALSFRS-R scale is most sensitive, are more likely to be selected. This in turn, all things being equal, ought to render statistical testing of ALS therapy trial results more reliable and useful.

Given the extremely high unmet need for a therapy for such a catastrophic neurodegenerative disease, it is clear to us that a PIIIb trial is:

a) justified (PIII demonstrated that BLCI's NurOwn, (debamesterocel, MSC-NTF) therapy is safe according to the peer review) and;

b) in our view, given the post-hoc PIII analysis in the Cudkowicz 7 December 2021 peer reviewed paper (plus erratum and post hoc analysis) and the indicative biomarker data from the 2024 peer reviewed study, there is good reason to infer that BCLI's NurOwn (debamestrocel, MSC-NTF), therapy, has a reasonable probability of delivering a statistically significant clinical effect, at least in ALS early-stage sufferers, in the new PIIIb trial cohort.

Given the post-hoc analysis, BCLI's PIII experience and the inclusion criteria for the PIIIb trial (ALSFRS-R>=35), we're confident the trial will recruit and focus on earlier stage sufferers in the PIIIb cohort compared with the PIII trial, and in our assessment, significantly improving the chances of delivering data that demonstrates further clinical efficacy.

Phase IIIb Summary

Throughout this note to help reader recall we use three interchangeable terms for BCLI's ALS therapy/platform – these are NurOwn®, debamestrocel and MSC-NTF. Increasingly in publicly available sources the noun of choice is NurOwn, reflecting BCLI's closeness to commercialization of its ALS therapy.

Treatment – NurOwn (debamestrocel, MSC-NTF), is a therapy based upon autologous bone marrow derived MSCs enriched, propagated ex-vivo and induced to secrete NTFs including glial derived growth factor (GDNF), brain derived neurotrophic factor (BDNF), vascular endothelial growth factor (VEGF), galectin-1 and hepatocyte growth factor (HGF).

Clinical Trial Objectives:

Regulatory approval - Obtain pivotal support for regulatory approval of NurOwn as a treatment for mid-to-moderate ALS.

Efficacy - Primary objective is to evaluate the efficacy (effectiveness) of NurOwn compared to the placebo for the treatment of ALS based on the ALSFRS-R scale.
PIIIb Trial Design Summary

Design:

The PIIIb BCLI NurOwn (debamestrocel, MSC-NTF), trial design is divided into Part A and Part B.

Part A - a double-blind placebo controlled 24-week trial with ~200 participants (n~200), randomized 1:1 NurOwn and placebo groups. There will be a single bone marrow aspiration to obtain autologous MSCs from each participant. The MSCs will be propagated for ~2 weeks and cryopreserved. The MSCs will be thawed ~10 days prior to dosing and propagated and induced into MSC-NTF (debamestrocel, NurOwn) cells, which will then be administered by intrathecal injection 3 times, once every 8 weeks.

Part B - an open-label extension period of 24 weeks. Eligible participants will have completed Part A and have the option of entering Part B, in which NurOwn or the placebo will be administered a further 3 times over 24 weeks, once per 8 weeks.

Operational Strategy

PIII biomarker analysis lends support to PIII subgroup clinical effectiveness of NurOwn. Recently released peer reviewed PIII study results - Treatment with NurOwn (debamestrocel, MSC-NTF) led to significant, directionally positive, CSF biomarker concentration changes spanning pathways involved in ALS pathology. Certain biomarkers, specifically NfL, LAP and Galectin-1 were found to be predictive of positive clinical outcomes in NurOwn (debamestrocel, MSC-NTF), treated participants.

BCLI's differentiated and specialized MSC-NTF cells release neurotrophic factors and immunomodulatory cytokines, which appear to enhance the survival of neurons, improving neurological function.

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

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 generate new evidence to advance 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 **re-organization** 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 IIIb Trial Design Announced; SPA committed to by U.S. FDA. The company is optimistic that the forthcoming Phase IIIb 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.

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 IIIb trial, which has been accepted. The SPA program enables BrainStorm to agree with the FDA regarding the design of the Phase IIIb trial, ensuring that the study is deemed sufficient by the FDA to support a subsequent marketing evaluation.

Operational Strategy - ESG / Sustainability

BrainStorm does not yet have an Environmental, Social, and Governance (ESG) policy statement. However, given its operations – treatment of neurodegenerative diseases – it will focus on integrating sustainability principles into its operations. We would expect BCLI to adopt and document some or all of the steps below. ESG policies with metrics bring cultural change that leads to risk reduction and is reflected in lower discount factors and so a higher valuation. It is also an essential approach to attract a significant proportion of total available institutional investment. Without an ESG policy with metrics a significant proportion of all AUM globally are unable to invest.

Environmental data:

R&D - use renewable energy and minimize waste during cell production.
Supply Chain - collaborate and ensure suppliers adhere to sustainable best practices and ensure responsible sourcing of materials.
Facilities - design or remodel facilities to operate with energy efficiency.
Clinical Trials - minimize the environmental/carbon footprint of clinical trials by, for example, reducing travel-related emissions and optimizing trial locations.
Reporting - begin to capture reporting data on environmental initiatives and progress.

BCLI's human capital resource objectives include identifying, recruiting, retaining, incentivizing, and integrating existing. and new employees, advisors and consultants to develop and launch a novel cell therapy for neurodegenerative diseases.

Social data:

Patient Access - ensure equitable access therapies for patients across all backgrounds.
Workforce - foster a diverse and inclusive workforce (according to DEI – Diversity, Equity, Inclusion) – policies and prioritize employee well-being and professional development.
Community Engagement - engage with local communities where clinical trials or facilities are located.
Ethical Research – publish data and metrics that reinforce BCLI funded research based on integrity, transparency and respect for patient rights.

Governance data:

Leadership - demonstrate board members and executives' commitment to ESG/Sustainability principles.
Risk Management – data showing risk management related to cell therapy development and deployment.
Compliance – evidence of compliance with general and specific regulatory requirements and ethical guidelines.
Transparency - disclose information related to ESG practices within specific ESG reports.

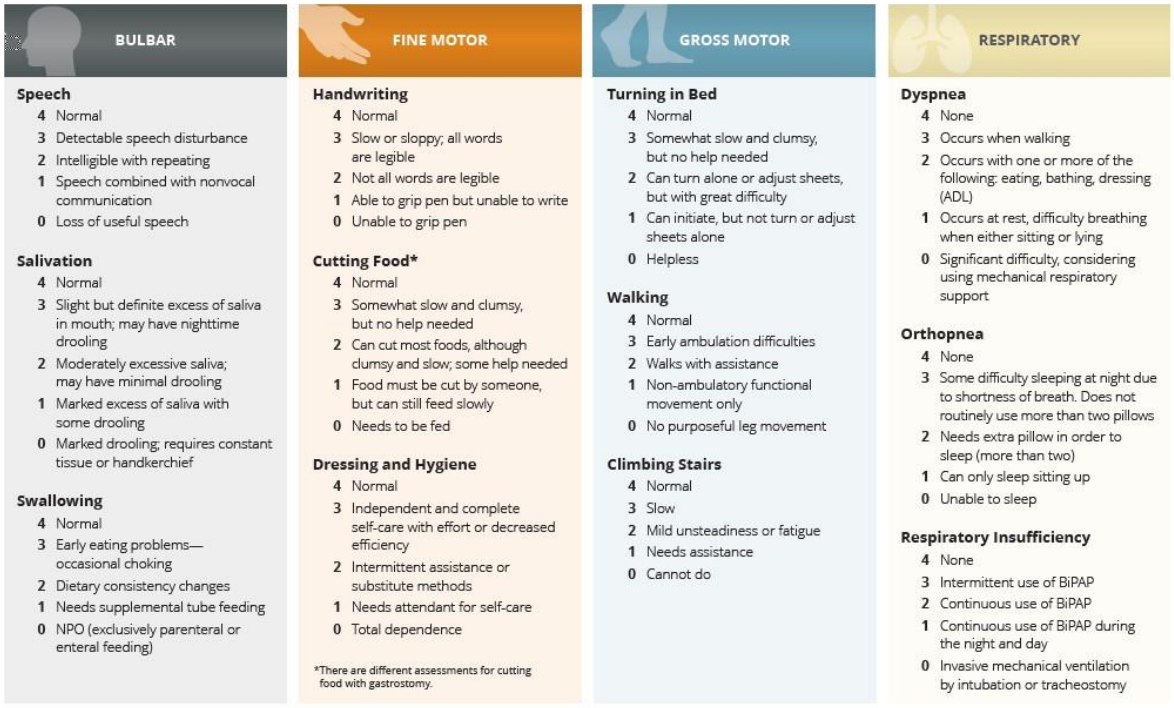
ALS – Amyotrophic lateral sclerosis

What is ALS? Amyotrophic lateral sclerosis (ALS), also known as motor neuron disease (MND) in the UK or Lou Gehrig's disease in the United States, is, arguably, the most common form of a complex condition - motor neuron disease, a neurodegenerative disease (NDD). Death typically occurs within 2-5 years. **There is currently no cure**.

ALS describes the progressive loss of biochemical functionality in both upper motor neurons (UMNs) and lower motor neurons (LMNs) that normally control voluntary muscle contractions. Other cell types in the central nervous system that support motor neurons, called glia, including astrocytes and oligodendrocytes, are also affected in ALS. Genetic variations, in e.g., alleles of gene UNC13A C, may also influence ALS progression and survival and serve as pharmacogenomic biomarkers.

ALS disease progression is evaluated using the ALS Functional Rating Scale-Revised (ALSFRS-R). ALSFRS-R is a clinician assessed (subjective) set of 12 characteristics scored from 4 to 0 (see exhibit below), totaling 48 points, where the higher the score the less affected the patient is by ALS. A baseline degradation progression of the loss of 1 point per month is cited in some sources as a reasonable median rate of progression when guiding patients on their likely rate of physical decline.

Exhibit 2: **Evaluating the progression of ALS using ALSFRS-R**



Sources: ACF Equity Research Regenerative Medicine Thematic Jun 2024; alspathways.com; Mitsubishi Tanabe Pharma America.

ALS is a terminal complex multifactorial neurodegenerative disease. ALS's occurrence in the general population is rare and there is neither a current cure nor effective therapy to extend life substantively.

Throughout this note to help reader recall we use three interchangeable terms for BCLI's ALS therapy/platform – these are NurOwn®, debamestrocel and MSC-NTF. Increasingly in publicly available sources the noun of choice is NurOwn, reflecting BCLI's closeness to commercialization of its ALS therapy.

Is ALS just one condition with many sub-types that are patient specific, or is it a family of diseases that present with conditions and outcomes currently referred to as ALS? This conundrum suggests to us that drug specific approaches to treatment come with particularly high medical and investment risk.

In contrast, the nature of stem cells, as for example in BCLI's NurOwn (debamestrocel, MSC-NTF), therapeutic approach, may have the best and safest chance of capturing a family of different diseases with ALS symptoms, given that the damage caused by all sub-types of ALS appears to be both to the U and L Motor Neuron cells. Treatment with NurOwn (debamestrocel, MSC-NTF), suggested its potential ability to reduce inflammation, neuronal protection, nerve cell damage and disease progression. NurOwn (debamestrocel, MSC-NTF), multimodal effects on biomarker pathways in amyotrophic lateral sclerosis are linked to clinical outcomes, Muscle & Nerve, 09 Apr 24).

Exhibit 3: **Selection of ALS variants and sub-types**

Selected ALS variants and sub-types	Apperance in ALS population	Genetic / Environmental
Sporadic ALS	90-95%	No clear genetic pattern
Familiar ALS (FALS)	5-10%	Genetic mutations associated
ALS-FTD	rare	Uncertain
Progressive Muscular Atrophy (PMA)	rare	Unknown
Primary Lateral Scleroris (PLS)	rare	Unknown
Respiratory-Onset ALS	rare	Unknown
Guamanian ALS	region of Guam	Uncertain genetic/ environmental
Juvenile ALS	rare	Unknown
ALS-PDC (Parkinsonism Dementia Complex)	rare	Unknown
ALS Cognitive (C) Impairment	rare	Unknown
ALS Behavioural (B) Impairment	rare	Unknown
ALS Combined C & B impairment	rare	Unknown
Comorbid ALS & AD (Alzheimer's Disease)	rare	Possible combination genetic/environmental

Sources: ACF Equity Research Regenerative Medicine Thematic Jun 2024; ACFEquity Research Estimates.

PIII Biomarker Data – Supports Clinical Effect

Throughout this note to help reader recall we use three interchangeable terms for BCLI's ALS therapy/platform – these are NurOwn®, debamestrocel and MSC-NTF. Increasingly in publicly available sources the noun of choice is NurOwn, reflecting BCLI's closeness to commercialization of its ALS therapy.

Experimental PIII design summary and biomarker aims – The primary goal was to identify and select ALS biomarkers that are most important in terms of their relationship with NurOwn (debamestrocel, MSC-NTF), and with its impact on clinical outcomes via the ALS Function Rating Scale-Revised (ALSFRS-R).

The PIII design leveraged current biomarker scientific literature linked to ALS disease progression, with the aim of moving closer to identification of reliable ALS cerebral spinal fluid (CSF) biomarkers. In addition, the PIII was designed to evaluate the effect of NurOwn (debamestrocel, MSC-NTF), on CSF biomarker concentrations and the concentration relationship with ALS disease progression via ALSFRS-R.

The PIII trial used a double blind (neither patient nor physician is given confirmation as to whether placebo or therapy is used), 1:1 NurOwn : placebo split over 28 weeks. NurOwn was injected three [3] times over 28 weeks and seven [7] CSF samples were collected from the trial patients.

- 196 original participants, 189 received at least one treatment with NurOwn (debamestrocel, MSC-NTF) or the placebo. 144 patients completed the study;
- 45 associated biomarker concentrations were analyzed - **33** were CSF ALS pathway specific;
- 7 CSF samples were collected;
- Clinical responses were assessed using ALSFRS-R.

Stepwise regression models and causal inference were used to identify the presence of clinical outcomes in NurOwn (debamestrocel, MSC-NTF) treated patients.

Some samples could not be collected because of Covid-19 restrictions.

Biomarker classifications - BCLI grouped its chosen CSF biomarkers linked to key cellular changes within ALS disease patients into four [4] categories. These categories are: **Neuroinflammatory** (pro inflammatory expected to decrease in response to treatment, anti-inflammatory expected to increase), **Neurodegenerative** (expected to decrease in response to treatment), **Neuroprotective** (expected to increase in response to treatment), Other (belong to other pathways, may increase/decrease in response to treatment).

Results summary PIII trial – treatment with BCLI's NurOwn (debamestrocel, MSC-NTF) reduced NfL concentrations, which is predictive of positive clinical outcomes.

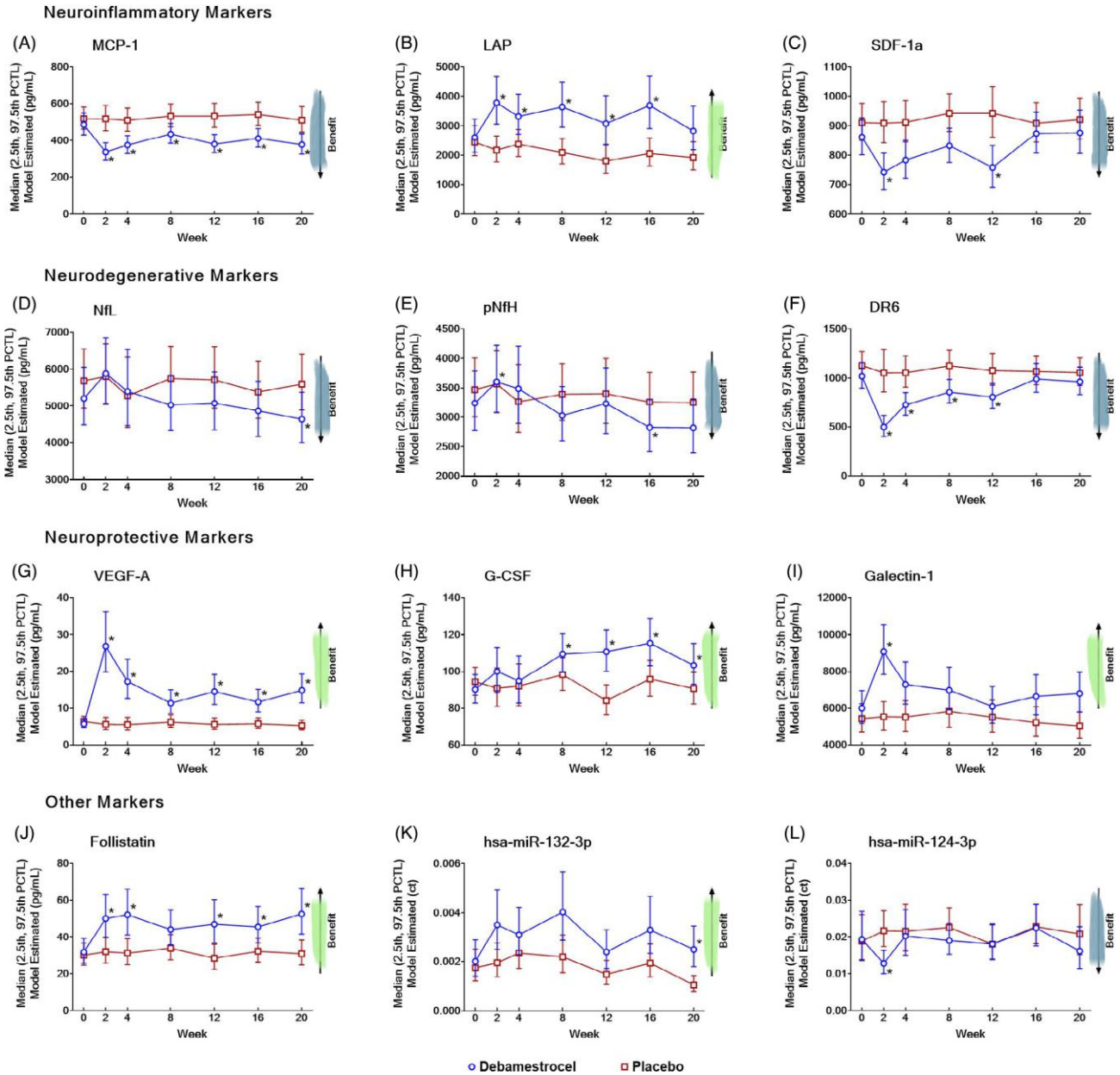
Biomarker results summary for PIII trial lends support to NurOwn PIII positive clinical outcomes – Treatment with NurOwn (debamestrocel, MSC-NTF), led to significant CSF biomarker concentration changes spanning pathways involved in ALS pathology. Certain biomarkers, specifically NfL, LAP and Galectin-1 were found to be predictive of positive clinical outcomes in NurOwn-treated participants.

- 64% of ALS pathway biomarkers changed CSF concentration as a result of treatment with NurOwn (debamestrocel, MSC-NTF) (compared with a placebo) indicating a possible reduction in disease activity and nerve cell damage.

Though not a pre-requisite, all trial participants were permitted to enter the BCLI PIII trial on a stable dose of riluzole (considered the standard of care at that time). As a result riluzole use was relatively balanced across the two treatment groups. Riluzole was not observed to influence treatment outcomes.

Data in the exhibit below indicates that the effect of BCLI's NurOwn (debamestrocel, MSC-NTF), therapy was fast in terms of reducing concentrations of proinflammatory and increasing concentrations of anti-inflammatory biomarkers. The greatest magnitude of change relative to the control group who were administered the placebo occurred at the first post treatment measurement -2 weeks after first treatment.

Exhibit 4: **CSF biomarker concentrations & treatment effect (time)**



Sources: ACF Equity Research Regenerative Medicine Thematic Jun 2024; ACF Equity Research Graphics; Muscle&Nerve (Wiley) accepted 19 March 2024 – NurOwn (debamestrocel, MSC-NTF) multimodal effects on biomarker pathways in amyotrophic lateral sclerosis are linked to clinical outcomes.

Whilst there is a statistical risk of false positives due to multiple testing runs, NurOwn (debamestrocel, MSC-NTF) trial data showed positive impacts on the levels of both inflammatory and degenerative process biomarkers and this was sustained over the trial period – longer courses of treatment might deliver greater positive effects, which, if demonstrated, would be a positive for BCLI and for ALS patients.

Exhibit 5: El Escorial Criteria (revised)

Diagnostic category	Inclusion criteria
Definite ALS	Presence of upper motor neuron and lower motor neuron signs in three anatomical regions
Probable ALS	Presence of upper motor neuron and lower motor neuron signs in at least two regions with upper motor neuron sign rostral to lower motor neuron signs
Probable ALS, laboratory results supported	Presence of upper motor neuron and lower motor neuron signs in one region with evidence by EMG of lower motor neuron involvement in another region
Possible ALS	Presence of upper motor neuron and lower motor neuron signs in one region or upper motor neuron signs in two or three regions, such as monomelic ALS, progressive bulbar palsy, and primary lateral sclerosis

Sources: ACF Equity Research Regenerative Medicine Thematic Jun 2024; ACF Equity Research Graphics; Revised El Escorial classification of ALS (). Four anatomical regions, bulbar, cervical, thoracic, and lumbar are included for disease stratification - Amyotrophic Lateral Sclerosis - NCBI Bookshelf (nih.gov).

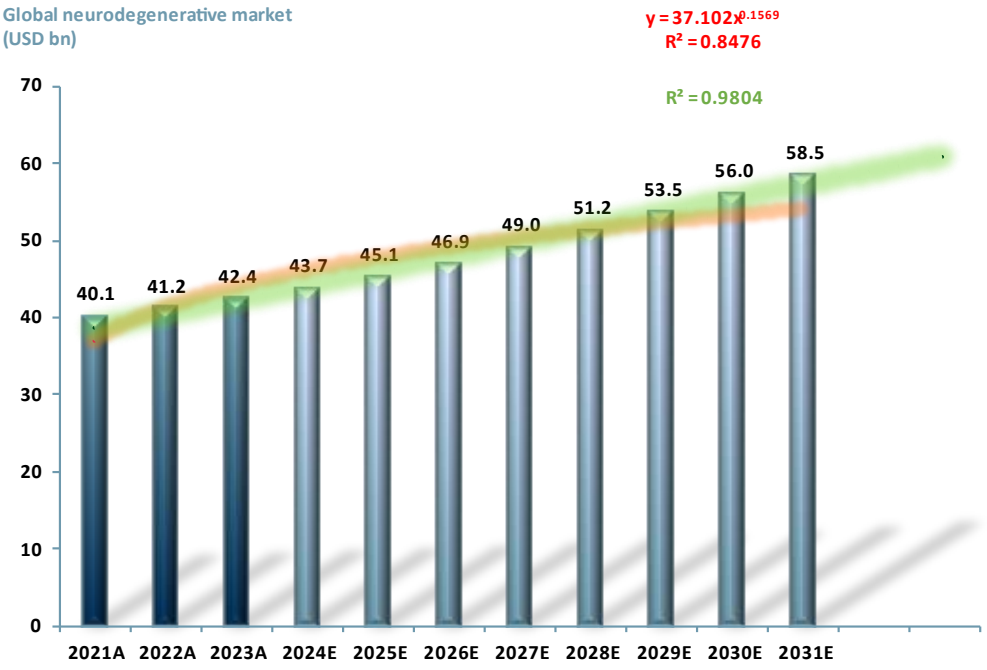
Neurodegenerative Disease Market

Neurodegenerative diseases (NDDs) are characterized by the progressive loss of the structure or function of neurons (nerve cells that enable functions such as breathing, talking, eating, walking and thinking). Neuronal damage can ultimately lead to cell death.

The types of neurodegenerative diseases include amyotrophic lateral sclerosis (ALS), Alzheimer's Disease, Parkinson's, Huntington's, multiple sclerosis, multiple system atrophy, tauopathies, and prion disease. Symptoms can include impaired mental function, loss of muscle control, memory loss, disorientation, emotional blunting, social withdrawal, hallucinations, delusions, and depression.

Based on our market consensus research, we assess that the neurodegenerative disease market may reach USD 50bn by 2031E, up from USD 40bn in 2021A, with an average CAGR of 4.5% (sources Mordor Intelligence, Straits Research, GlobeNewswire, Research and Markets, ACF Estimates). Growth is driven primarily by the rising occurrence of neurological diseases, increased awareness of these diseases and a strong and viable product pipeline for disease treatment.

Exhibit 6: Global neurodegenerative market 2021A-2031E



The green line is the CAGR linear (best fit) forecast line indicating a direction and 'rate of travel' beyond the end of the forecast period 2031E, with an R^2 value of 0.9892. The red line is the power trend line, R^2 0.9892 and indicates in this case that our expectation for the rate of acceleration is that it will decline. We describe our forecast as an interplay between better diagnosis and deteriorating environmental factors accelerating the rate of growth vs. knowledge, driving behavior changes that moderate this acceleration rate over time. It is not that we expect our forecast numbers to be explicitly met it is more that we want to help investors think about our forecasting approach over prolonged periods.

Sources: ACF Equity Research Regenerative Medicine Thematic Jun 2024; ACF Equity Research Estimates & Graphics; Mordor Intelligence; Straits Research; GlobeNewswire; Research and Markets.

Market growth and demand

Market growth has been temporarily held back by a Covid enforced delay in product approvals.

The Covid-19 pandemic, much like the biotechnology market, has significantly impacted the neurodegenerative disease market. The pandemic disrupted workflows of clinical trials, R&D, and the development of therapies for these diseases. We assess there is likely to be a spate of new therapy approval applications as the industry catches up on delivery timelines.

Global population demographics are leading to an increase in the absolute number of neurodegenerative disease patients. The National Institute of Environmental Health Sciences (NIEHS – US based) reported that in the US in 2022, ~62m people had Alzheimer's and ~1m had Parkinson's (out of a population of ~332m). In Europe, the total number of disability-adjusted like-years (DALYs) attributed to neurological disorders in 2020 was 21m and in the WHO-EU region it was 41.1m (Lancet Journal).

~6.5m Americans aged 65+ were living with Alzheimer dementia in 2022A. This number is expected to increase ~2x to 12.7m by 2050E (Alzheimer's Association).

The US FDA launched an action plan in 2022 for the manufacturing of safe and effective drugs to treat rare neurodegenerative diseases, including ALS.

Regional insights - The neurodegenerative disease (NDD) market is distributed across North America, Europe, Asia-Pacific, South America, the Middle East, and Africa. North American expected market revenues 2023E of USD ~18bn (Straits Research) by 2023E up from USD ~17bn in 2021A, a CAGR of 2.5% (Straits Research). The US population is growing at 0.6% or ~1.8m p.a.. NDDs occur relatively rarely in the general population. Market value forecasts may be reliant on both a growth in incidence and a growth in diagnosis effectiveness.

By 2021, the National Institute of Health (NIH) had allocated USD 4.1m to neurodegenerative diseases hoping to attract larger market players. The US also dominates NDD R&D spend/investment. NDD R&D is sponsored/funded by academic and R&D institutions as well as public (and private) pharma and biotech companies.

Key market players:

AbbVie (ABBV, MCAP ~$300bn)
Amneal Pharmaceuticals (AMRX, MCAP ~$2bn)
Boehringer Ingelheim International (private)
F. Hoffman-La Roche (ROG.SW, MCAP ~$215bn)
Merck (MRK, MCAP ~$330bn)
Pfizer (PFE, MCAP ~$160bn)
Teva Pharmaceuticals (TEVA, MCAP ~$19bn)
Novartis (NVS, MCAP ~$220bn)

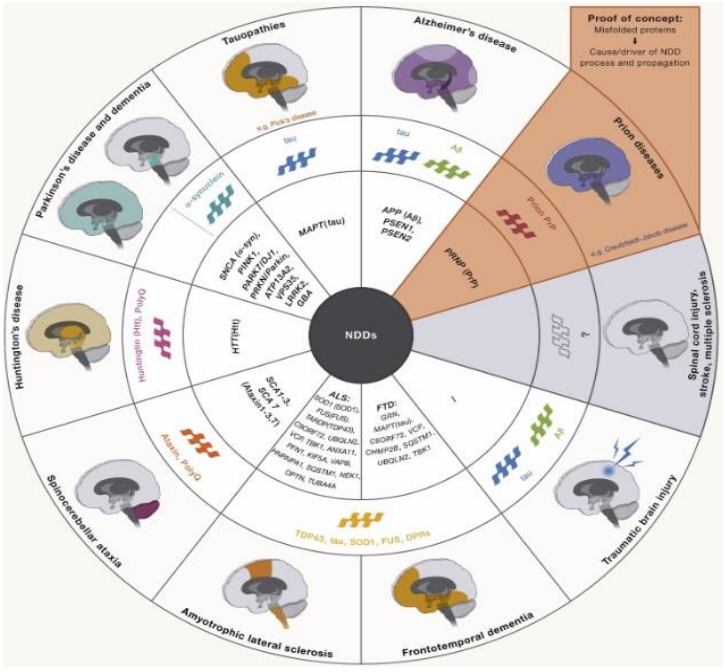
Europe is the second largest NDD market with revenues 2023E are expected to have reached USD 12.3bn up from USD 11.5bn 2021A, a CAGR of 3.5% (Straits Research). Germany dominates the European region, providing a base for global companies to develop neurodegenerative drugs. Our consensus market forecasts suggest that major pharma companies In Germany will deliver an increase in drug launches driven by the increasing prevalence (and or detection) of NDDs. Some sources suggest that the number of people with dementia in Germany is expected to increase to 2.8m by 2050E up from 1.6m in 2018A.

Market segmentation - Amyotrophic Lateral Sclerosis (ALS) forms part of the neurodegenerative disease (NDD) market. See top level segmentation below.

Exhibit 7: **Market segments – neurodegenerative diseases (NDDs)**

NDD Market Top Level Segments by Indidcation	Description
MND/ALS/Lou Gehrig's	Progressive loss of biochemical functionality in both upper motor neurons (UMNs) and lower motor neurons (LMNs) that normally control voluntary muscle contractions.
Parkinson's	Progressive brain damage from nerve cell loss, primarily the dopamine producing neurons.
Alzheimer's	Progressive starting with mild memory loss and moving to dementia.
Multiple Sclerosis (MS)	Brain and spinal cord; the immune system attacks [mistakenly] the CNS.
Huntington's	Brain, inherited/genetic, damages nerve cells degrading their function.

NDD Market by Therapy	Description
Receptor Antagonists	E.g. N-methyl-D-aspartate (NMDA) – are commonly used to treat Alzheimer's (as well as having anesthetic indications).
Cholinesterase Inhibitors	Break down acetylcholine a (neurotransmitter that serves memory, learning, attention, arousal, and muscle movement), treats Alzheimer's.
Dopamine Agonists	Activate brain/dopamine receptors, key for treating coordination disorders, e.g., Parkinson's.
Immunology Therapies	Includes stem cells, gene editing and drugs – modify the immune response, enhances/suppresses the immune system, used to treat MS.



Sources: ACF Equity Research Regenerative Medicine Thematic Jun 2024; Hallmarks of neurodegenerative diseases, 16 Feb 2023, sciencedirect.com.

ALS Therapy Landscape

We estimate that there are currently 4 unique ALS therapies with FDA approval for marketing. One of these, riluzole, is now a generic with various reformulations. With the possible exception of tofersen all current FDA licensed ALS therapies could be characterized better as alleviating symptoms and improving quality of life, rather than making a meaningful extension to life expectancy. None of the current therapies represent a cure for ALS.

Exhibit 8: **Current ALS FDA approved treatments**

FDA Approved ALS/MND Therapies	Description	Marketed by	Brand name	FDA licence year	US$ launch price per annum	Qualifying ALS patients estimated
tofersen	Developed to treat ALS associated with the superoxide dismutase 1 (SOD1) gene mutuation	Biogen	Qalsody	2023	172,120	2%
edavarone	The first new treatment specifically for ALS in 22 years. Oral formulation approved 2022	Mitsubishi Pharma	Radicava™	2017	145,000	5%
riluzole (generic)	Inhibits glutamate release - prolongs life by appox three months. Riluzole is the generic name of Rilutek.	Sanofi et al	Rilutek	1995	8,000	NA
riluzole oral film	Riluzole re-formulation for ALS sufferers with severe swallowing difficulties. The oral film is placed on top of the person's tongue and dissolves, where swallow pills or liquids would be difficult	Sanofi	Exservan	2019		NA
riluzole thickened	Riluzole re-formulation designed to avoid potential cahllenges involved in the crushing of tablets	Sanofi	Tiglutik	2018		NA

Sources: ACF Equity Research Regenerative Medicine Thematic Jun 2024; ACF Equity Research Estimates.

We estimate that globally there are currently at least 27 ALS potential therapies under development, of which 16 are funded by listed companies ranging from large cap to nano cap. We estimate that 2 of these are stem cell therapies (one of which is BCLI's). As far as we are aware US listed BCLI's NurOwn (debamestrocel, MSC-NTF), is the only US, Canadian, UK, European, South African or Australian ALS stem cell therapy (private or public) under development. We also estimate that since 2020, one therapy with FDA approval has been voluntarily withdrawn (Amylx's Relyvrio) and 8 investigations have been stopped because of lack of clinical effect, a stop rate of 25% (9/36).

Exhibit 9: **Current ALS treatments and therapies under investigation**

Sponsor / Funding	Tkr	Therapeutic investigations ALS	Pathway/Approach	Phase
Brainstorm Therapeutics	BCLI	NurOwn (NCT04681118)	Stem cells	Phase IIIb
Corestemchemom	166480.KQ	Lenzumestrocel (NCT04745299)	Stem cells	Phase III
Gold Coast Hospital & Health Service	Private	CBD oil (NCT03690791)	Excitotoxicity	Phase III
Peking University Third Hospital	Private	Huolingshengji granules (NCT04950933)	Oxidative stress	Phase III
Macquarie University, Australia	Private	Triumeq (NCT05193994)	Neuroinflammation	Phase III
AB Science SA	AB.PA	Masitinib (NCT03127267)	Neuroinflammation	Phase III
Eisai Co., Ltd	4523.T	Methylcobalamin (NCT03548311)	Reduces denervation and muscle weakness	Phase III
Eisai Co., Ltd	4523.T	Insulin-like growth factor (NCT00035815)	Blockage of cell death pathways	Phase III
Ionis Pharmaceuticals, Inc.	IONS	Jacifusen/ION363 (NCT04768972)	Gene specific–ASO, FUS-mutations	Phase III
Prilenia Therapeutics	Private	Pridopidine (NCT04615923)	Oxidative stress	Phase II/III
LifeArc	Private	Deferiprone (NCT03293069)	Oxidative stress	Phase II/III
MedicNova, Inc	MNOV	MN-166/Ibudilast (NCT04057898)	Neuroinflammation	Phase II/III
Biohaven Pharmaceutical	BHVN	Verdiperstat (NCT04436510)	Neuroinflammation	Phase II/III
Seelos Therapeutics	SEEL	Trehalose (NCT05136885)	Enhances autophagy, decreases SOD1 aggregates	Phase II/III
Clene Inc.	CLNN	CNM-Au8 (NCT04615923)	Energy Metabolism	Phase II/III
University Medical Centre Goetingen	Private	Fasudil (NCT03792490)	rho Kinase inhibitor - Post-translational modifications	Phase IIa
Alector, Inc.	ALEC	AL001 (NCT05053035)	Monoclonal AB, C9orf72	Phase II
AL-S Pharma	Private	AP-101 (NCT05039099)	Monoclonal AB, SOD1	Phase II
Annexon, Inc.	ANNX	ANX-005 (NCT04569435)	Monoclonal AB	Phase II
Anelixis Therapeutics	Private	AT-1501 (NCT04322149)	Monoclonal AB	Phase II
Genentech	Private	Tocilizumab (NCT02469896)	Monoclonal AB	Phase II
Wave Life Sciences	WVE	WVE-004 (NCT04931862)	Gene specific–ASO, mutant C9orf72	Phase I/II
Uniqure N.V.	QURE	APB-102	SOD1 microRNA	Phase I/II
Biogen Inc.	BIIB	BIIB105 (NCT04494256)	Gene specific–ASO, ATXN2	Phase I
Uniqure N.V.	QURE	AMT-161	C9orf72 microRNA	Substance in developmen
Uniqure N.V.	QURE	AAV-miQURE	Mutant C9orf72 microRNA	Substance in developmen
InSightec	Private	Blood-Brain Barrier Opening Using MR-Guided Focused Ultrasound (NCT03321487)	Blood-Brain Barrier Opening	NA

Sources: ACF Equity Research Regenerative Medicine Thematic Jun 2024; ACF Equity Research Graphics; https://www.ncbi.nlm.nih.gov.

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 IIIb 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.

➢ Board Director (Ex Co-CEO), Stacy Lindborg.

In preparation for the PIIIb trial and future potential marketing, since the publication of our Core Investment Case (CIC), Stacy Lindborg has relinquished her role as Co-CEO to join BCLI's Board of Directors.

Ms. Lindborg joined BrainStorm Cell Therapeutics in June 2020 and was appointed as the co-CEO in January 2023. In April 2024 Stacy announced she was stepping down from the Co-CEO role and joining BCLI's Board of Directors. 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 (Texas, USA).

➢ Executive Vice President (EVP) and CMO, Bob Dagher.

In preparation for the PIIIb trial and future potential marketing, since the publication of our Core Investment Case (CIC), Bob Dagher has recently been promoted from Chief Development Officer (CDO) to Chief Medical Officer (CMO).

Mr. Dagher joined Brainstorm Cell Therapeutics in July 2023. Bob serves as EVP and Chief Medical Officer (CMO). 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 (PA, USA) and Bordeaux (France) universities joint program and his residency was completed at Boston University School of Medicine (USA).

Forecasts

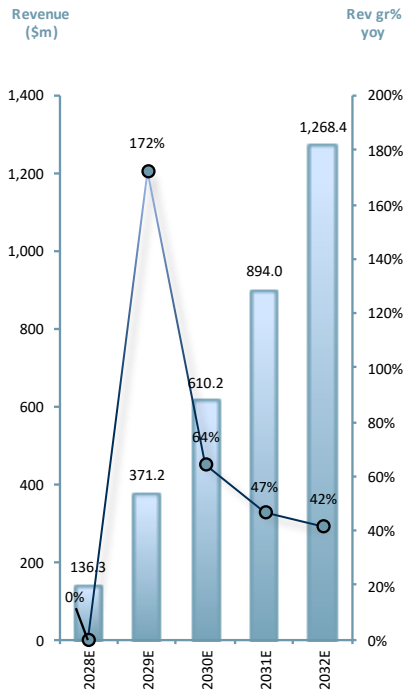
*

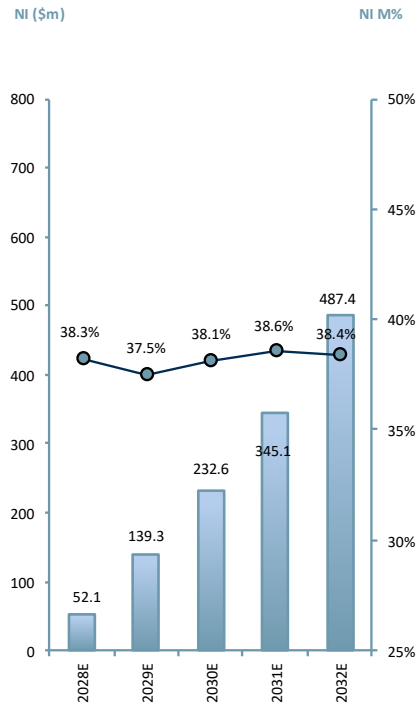
Exhibit 10: BCLI financial metrics

The charts show our 5-year forecasts for key metrics for BCLI beginning at first commercialization in 2028E for the ALS NurOwn® therapy and 2029E for the MS NurOwn® therapy.

Note that columns and lines show our forecast values.

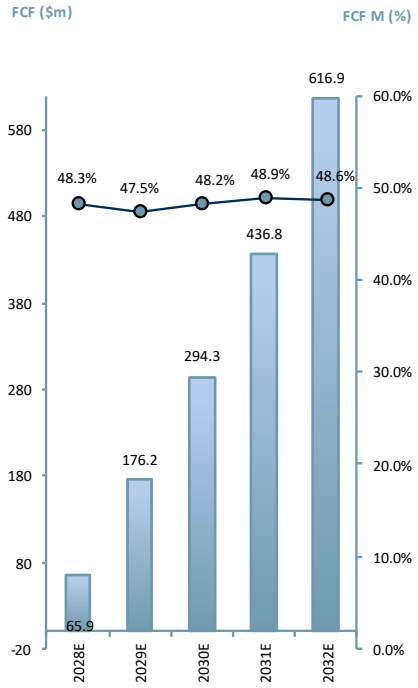
The revenues chart shows dramatic acceleration in growth in 2028E for the ALS NurOwn® therapy and 2029E for the MS NurOwn® therapy.

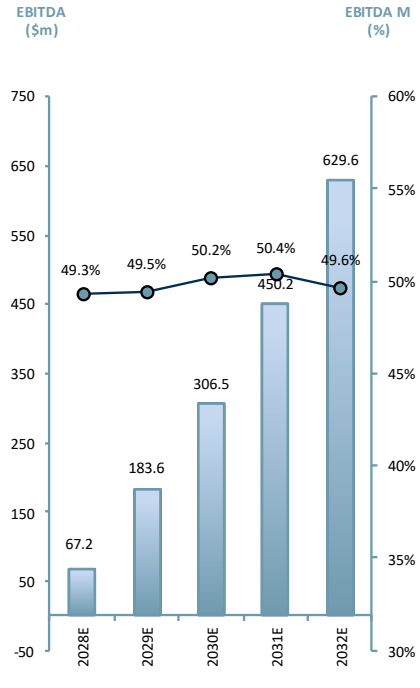




Revenues will increase after first commercialization with the increase in patients (#s) taking the drugs as the US population increases over time.

Currently BCLI is non-revenue generating.





Our forecasts are based upon management guidance and our own sensitivity analysis. We focus on cash proxies (EBITDA) and free cash flow (FCF). However, Net Income remains important for assessing elements of balance sheet strength, nevertheless we are strongly of the view that only cash matters.

Valuation

Exhibit 11: **BCLI WACC, DCF and Value Range**

ACF est. USD (m)	2026E	2027E	2028E	2029E	2030E
Revenue	0	0	136	371	610
EBITDA	-23	-17	67	184	307
Net Income	-24	-18	52	139	233
FCFF	-24	-18	66	176	294
CPS (diluted)	-0.0001	-0.0001	0.0003	0.0008	0.0013

We see current fair value for BCLI at $6.26 per share (fully diluted) for phase 3 ALS and MS clinical trials.

BrainStorm Therapeutics WACC Calc	
Pre-tax cost of debt	0.0%
ETR	21.0%
After-tax cost of debt	0.0%
Current leverage	3.9%
Debt/(Cash)	1.1
Equity	28.8
Target Leverage	50.0%
D / (D+E)	3.7%
ACF β adj levered	2.00
rf	4.0%
ERP	4.2%
Cost of equity	12.5%
Risk adj.	2.0%
WACC	14.01%

Note: Successful issue of draft EIS and permitting will significantly reduce our WACC.

Valuation Range - Base Case BCLI	NPV (USD m)	% of valuation
NurOwn - ALS US Market Only	340	73%
NurOwn - MS US Market Only	124	27%
Total NPV	**463.78**	
(Cash)	0.78	
Debt	1.12	
Implied equity	**463.44**	
Shares Fully Diluted (m)	74.05	
Fair value per share $	**6.26**	
Close Price $	0.41	
VR (low - high)	**5.95**	**6.57**
VR Spread	5.0%	
Implied VR Return (low - high)	1346.3%	1498.5%

Note: implied value range in this ACF research note is based upon diluted shares in issue at the date of this note.

Project NPV

We have excluded the larger European ALS market in our valuation. Europe/UK represents significant additional NPV value for BCLI.

Our maintenance capex is aggressively high post commercialization and may be revised in future notes.

ACF has taken a highly conservative valuation approach. We value BCLI on a sum of the parts (SOTP) DCF valuation at PIII trials for its ALS and MS therapies. Revenue assumption – growth based on US patients with ALS / MS vs. the US pop (9.1/100,000 vs 288/100,000). WACC – Conservative at ~15% given that BCLI is pre-revenue and first commercialization is expected in 2028E. Equity risk premiums have risen. As milestones are reached, we would expect our valuation to rise. ALS and MS – Our base assumptions are informed by the number of eligible ALS patients in the US only for ALS and MS as a proportion of the US population. We assume that BCLI will reach 1st commercialization for ALS in 2028E and MS in 2029E.

Exhibit 12: **ALS & MS Cash Flow Models**

ALS DCF in $m	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E
Total drug revenue	0.0	0.0	0.0	0.0	136.3	328.5	467.1	606.7	691.8	833.0	835.6	838.1	840.5	842.8
COGS	0.0	0.0	0.0	0.0	40.9	95.3	130.8	163.8	186.8	224.9	225.6	226.3	226.9	227.5
R&D	7.0	7.0	8.0	2.0	2.7	6.6	9.3	12.1	13.8	16.7	16.7	16.8	16.8	16.9
G&A	1.0	1.0	2.0	2.0	6.8	16.4	23.4	30.3	34.6	41.6	41.8	41.9	42.0	42.1
Working capital	3.4	-1.9	0.3	-0.4	2.9	-20.8	-4.3	35.1	22.8	8.5	0.1	0.1	0.1	0.1
Capex	0.5	0.5	0.5	0.5	1.4	6.6	9.3	9.1	6.9	8.3	8.4	8.4	8.4	8.4
Cash flow pre-tax	**-8.1**	**-6.1**	**-8.0**	**-2.2**	**68.0**	**175.2**	**228.5**	**265.3**	**323.1**	**408.0**	**417.7**	**419.0**	**420.2**	**421.3**
Taxes	0.0	0.0	0.0	0.0	13.9	32.8	47.3	62.3	70.7	84.8	85.1	85.3	85.6	85.8
Effective FCFF Tax Rate (	0	0	0	0	0.20	0.19	0.21	0.23	0.22	0.21	0.20	0.20	0.20	0.20
Cash flow after-tax	**-8.1**	**-6.1**	**-8.0**	**-2.2**	**54.2**	**142.4**	**181.2**	**203.0**	**252.4**	**323.2**	**332.6**	**333.6**	**334.6**	**335.5**
Risk-adjusted NPV (rNP\	-4.3	-2.8	-3.3	-0.7	14.9	34.4	38.3	37.7	41.1	46.1	41.7	36.6	32.2	28.3
Total NPV ($m)	340													

MS DCF in $m	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E
Total CD-38 Diagnostic r	0	0	0	0	0	42.8	143.1	287.3	576.5	867.7	870.4	873.1	875.5	877.9
COGS	0	0	0	0	0	12.8	42.9	86.2	173.0	260.3	261.1	261.9	262.7	263.4
R&D	5	6	11	11	2	0.9	2.9	5.7	11.5	17.4	17.4	17.5	17.5	17.6
G&A	1	1	2	2	3	2.1	7.2	14.4	28.8	43.4	43.5	43.7	43.8	43.9
Working capital	0	0	0	0	0	-2.7	-1.3	16.6	19.0	8.8	0.1	0.1	0.1	0.1
Capex	0.0	0.0	0.0	0.0	0.0	0.9	2.9	4.3	5.8	8.7	8.7	8.7	8.8	8.8
Cash flow pre-tax	**-6.0**	**-7.0**	**-13.0**	**-13.0**	**-5.0**	**24.5**	**71.4**	**119.9**	**252.0**	**399.0**	**409.0**	**410.2**	**411.4**	**412.5**
Taxes	0	0	0	0	0	4.3	14.5	29.5	58.9	88.3	88.6	88.9	89.1	89.4
Effective FCFF Tax Rate (	0	0	0	0	0	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Cash flow after-tax	**-6.0**	**-7.0**	**-13.0**	**-13.0**	**-5.0**	**20.3**	**56.9**	**90.4**	**193.1**	**310.7**	**320.4**	**321.4**	**322.3**	**323.1**
Risk adjusted NPV	-2.7	-2.8	-2.7	-2.3	-0.7	2.4	6.0	8.4	15.7	22.2	20.1	17.6	15.5	13.7
Total NPV ($m)	124													

Sources: ACF Equity Research Estimates; Companies reports.

Peer Group

Exhibit 13: Trailing BCLI peer group metrics

TTM Metrics / Company Name	Market	Tkr	MCAP $(m)	EV $(m)	Revs $(m)	FCF $(m)	MCAP / REVS	EV / REVS	EV / FCF
Brainstorm Cell Therapeutics	**XNAS**	**BCLI**	**29**	**29**	**-0.07**	**-19.55**	**N/M**	**N/M**	**N/M**
Vertex Pharmaceuticals	XNAS	VRTX	124,650	116,213	10,181.60	3,479.30	12.24x	11.41x	33.40x
Vericel	XNAS	VCEL	2,157	2,179	207.78	2.04	10.38x	10.48x	1069.99x
Sangamo Therapeutics	XNAS	SGMO	119	95	18.76	-218.16	6.35x	5.05x	N/M
Cryo-Cell International	XNYS	CCEL	75	86	31.37	-0.80	2.38x	2.74x	N/M
Average							**7.84x**	**7.42x**	**551.70x**
Median							**8.37x**	**7.77x**	**551.70x**

Sources: ACF Equity Research; Refinitiv.

BCLI does not make up a constituent of our average or median values in the peer group metrics at the bottom of exhibit 13. We have excluded BCLI from these values to make comparison with the rest of the peer group as clean and undistorted as possible.

In our peer group we use companies focused on innovative therapies such as stem cells or that make up part of the stem cell value chain. Although the peers are all revenue generating, we suggest that these are useful peers. They suggest the trajectory/potential valuation multiples that can be achieved once BCLI reaches commercialization. In terms of exit multiples over the last 3 years, a significant number of M&A deals have exceeded 3x MCAP.

Peer Group Selection

Vertex Pharmaceuticals, Inc. (VRTX**, Nasdaq** listed) is a US global biotech company focused on developing and commercializing **innovative therapies**. It was the first to use rational drug design (the process of finding new medications based on knowledge of a biological target) and is renowned for its treatment of cystic fibrosis (CF). Vertex has 4 drugs that have reached market approval for CF – Ivacaftor, Lumacaftor, Tezacaftor and Elexacaftor. Vertex is expanding its pipeline to include other diseases such as sickle cell, beta thalassemia and Type 1 diabetes. Vertex sells its products to specialty pharmacies and distributors, retail pharmacies, hospitals and clinics.

Vericel Corp. (VCEL**, Nasdaq** listed) is a US biotech company that uses **cell and gene therapy** for sports medicine and severe burns cases. Vericel is in the commercial phase engaging in R&D, development, manufacturing, and distribution of cell therapies. Vericel has two primary products: MACI – used for cartilage defects in the knee and Epicel – used as a graft/permanent skin replacement for patients with severe burns. Vericel also holds an exclusive license (North America only) to the rights of NexoBrid® - a biological orphan product that has been approved for eschar (dead tissue that sheds or falls off the skin) removal of severe burns.

Sangamo Therapeutics, Inc. (SGMO, **Nasdaq** listed) is a US clinical-stage company focusing on the development of genomic medicine. The company's approach includes **gene therapy, cell therapy** and gene editing to address genetic diseases. Sangamo's proprietary zinc finger (ZF) platform, which is derived from naturally occurring human proteins - enables precise gene editing. Its CAR-Treg platform will aim to develop Treg (subset of immune cells that can control and reduce the body's **immune reactions**) therapies that have the potential to increase the prospects of long-term remission for autoimmune diseases.

Cryo-Cell International, Inc. (CCEL, **NYSE** listed) specializes in cellular processing and cryogenic cell storage, the collection and cryopreservation of umbilical cord blood and tissue **stem cells**. CCEL is a US listed world leader in private cord blood banks. Its stored stem cells are used in **regenerative medicine** to treat conditions such as ALS, MS, heart conditions, kidney disease, wound healing, auto-immune diseases, Alzheimer's, and Parkinson's. Cryo-cell plans to open an infusion clinic(s) to administer cell therapies that have been approved by the FDA under IND (New Drug Application) in patients with cerebral palsy, autism and traumatic brain injuries.

Financial Projections

P&L USD (m)	2024E	2025E	2026E	2027E	2028E
Revs	**0.00**	**0.00**	**0.00**	**0.00**	**136.31**
gr%		NM	NM	NM	NM
Total Expenses	-14.00	-15.00	-23.00	-17.00	-69.07
EBITDA	-14.00	-15.00	-23.00	-17.00	67.25
% Revs	NM	NM	NM	NM	0.49
EBIT	**-14.50**	**-15.60**	**-23.80**	**-17.90**	**65.88**
EBT	-14.38	-15.48	-23.68	-17.78	66.00
% Revs	NM	NM	NM	NM	48.42%
ETR	0.00%	0.00%	0.00%	0.00%	21.00%
NI	**-14.38**	**-15.48**	**-23.68**	**-17.78**	**52.14**
% Revs	NM	NM	NM	NM	0.38
Diluted EPS (c)	-0.13	-0.11	-0.13	-0.08	0.23
Balance Sheet USD (m)	2024E	2025E	2026E	2027E	2028E
PP&E	1.17	1.07	0.77	0.37	0.37
Total Fixed Assets	**7.17**	**7.57**	**7.77**	**7.87**	**7.87**
Current assets	0.60	0.90	1.10	1.50	5.65
Cash	2.63	1.65	0.77	0.69	52.96
Total Current Assets	**3.22**	**2.54**	**1.86**	**2.19**	**58.61**
Total Assets	**10.39**	**10.11**	**9.63**	**10.05**	**66.48**
Accounts payables	8.00	11.00	14.00	17.00	9.54
Accrued expenses	0.20	0.40	0.60	0.80	9.54
Operating lease liability	4.09	4.09	4.09	4.09	4.09
Other A/P	1.07	1.07	1.07	1.07	1.07
Total Liabilities	**13.36**	**16.56**	**19.76**	**22.96**	**24.24**
Net Assets	**-2.97**	**-6.45**	**-10.13**	**-12.90**	**42.24**
Share capital	0.01	0.01	0.01	0.01	0.01
Add'l paid-in capital	227.54	239.54	259.54	274.54	277.54
Accumulated deficit	-229.33	-244.81	-268.49	-286.26	-234.12
Treasury stock	-1.19	-1.19	-1.19	-1.19	-1.19
Total Equity	**-2.97**	**-6.45**	**-10.13**	**-12.90**	**42.24**
Total Equity & Liabilities	**10.39**	**10.11**	**9.63**	**10.05**	**66.48**
Diluted NAVPS	0.00	0.00	0.00	0.00	0.00
Diluted TBVPS	0.00	0.00	0.00	0.00	0.00
Cash Flow USD (m)	2024E	2025E	2026E	2027E	2028E
Profit/(loss)	-14.38	-15.48	-23.68	-17.78	52.14
Net CFO	-13.53	-12.48	-20.38	-14.58	50.64
Capex	-0.50	-0.50	-0.50	-0.50	-1.36
Cash Taxes	0.00	0.00	0.00	0.00	-13.86
WCap change	0.35	2.40	2.50	2.30	-2.87
FCFF	**-14.15**	**-13.10**	**-21.00**	**-15.20**	**49.15**
C&CE	**2.63**	**1.65**	**0.77**	**0.69**	**52.96**

Sources: ACF Equity Research Estimates; Companies reports.

Public Companies Mentioned in this Note

Exhibit 14: **Listed companies referred to in this note**

Company	Tkr	Listing Curr	MCAP (m)	EV	Revs	EV/ Sales	EV/ EBITDA	PEx	EV/ FCF
Mitsubishi Corporation	8058.T	JPY	13,359,027	18,771,983.8	21,571,973.0	0.9x	11.0x	14.7x	21.5x
Novo Nordisk A/S	NVO	USD	637,825	3,143,861.8	232,261.0	18.2x	36.0x	49.5x	88.3x
Eisai Co., Ltd.	4523.T	JPY	1,972,509	1,598,202.4	744,402.0	2.5x	20.1x	46.6x	43.8x
Johnson & Johnson	JNJ	USD	353,938	385,858.4	85,152.0	4.0x	11.9x	21.8x	19.4x
AbbVie Inc.	ABBV	USD	301,275	320,558.0	54,318.0	6.6x	19.4x	50.9x	16.3x
Merck & Co., Inc.	MRK	USD	333,052	305,942.7	59,871.0	5.9x	41.5x	146.1x	32.8x
Pfizer Inc.	PFE	USD	159,203	234,650.0	58,496.0	4.1x	27.4x	NM	44.7x
Novartis AG	NVS	USD	206,096	222,711.2	46,660.0	4.5x	11.9x	23.9x	22.1x
Roche Holding AG	ROG.SW	CHF	194,619	220,761.5	58,716.0	3.7x	11.1x	16.8x	20.3x
Bristol-Myers Squibb Company	BMY	USD	86,425	136,160.4	45,006.0	3.0x	7.7x	NM	10.8x
Gilead Sciences, Inc.	GILD	USD	81,298	120,002.5	27,116.0	3.7x	9.4x	181.3x	12.9x
Sanofi	SNY	USD	122,322	66,332.6	43,070.0	2.1x	6.9x	24.9x	17.5x
Biogen Inc.	BIIB	USD	32,909	43,732.3	9,835.6	4.1x	16.2x	28.3x	30.2x
Teva Pharmaceutical Industries Li	TEVA	USD	19,056	28,609.4	15,845.0	2.2x	8.2x	NM	30.7x
Cytokinetics, Incorporated	CYTK	USD	6,213	8,701.2	7.5	1825.1x	NM	NM	NM
Ionis Pharmaceuticals, Inc.	IONS	USD	5,804	8,298.3	787.6	9.6x	NM	NM	NM
Amneal Pharmaceuticals, Inc.	AMRX	USD	2,105	3,728.1	2,393.6	1.9x	15.6x	NM	38.7x
Biohaven Pharmaceutical Holding	BHVN	USD	3,070	2,828.5	0.0	NM	NM	NM	NM
Alector, Inc.	ALEC	USD	424	632.6	97.1	4.0x	NM	NM	NM
Wave Life Sciences Ltd.	WVE	USD	721	367.6	113.3	5.1x	NM	NM	NM
Zevra Therapeutics, Inc.	ZVRA	USD	195	232.9	27.5	7.0x	NM	NM	NM
uniQure N.V.	QURE	USD	262	219.8	15.8	29.5x	NM	NM	NM
AB Science S.A.	AB.PA	EUR	65	195.8	1.0	53.3x	NM	NM	NM
Annexon, Inc.	ANNX	USD	518	149.8	0.0	81.6x	NM	NM	NM
Seelos Therapeutics, Inc.	SEEL	USD	3	65.7	2.2	7.7x	NM	NM	NM
Clene Inc.	CLNN	USD	55	34.5	0.7	105.7x	NM	NM	NM
MediciNova, Inc.	MNOV	USD	65	22.8	1.0	83.0x	NM	NM	NM
Brainstorm Cell Therapeutics Inc.	BCLI	USD	31	11.7	0.0	NM	NM	NM	NM
Average						87.7x	16.9x	55.0x	30.0x
Median						**4.8x**	**11.9x**	**28.3x**	**22.1x**

Sources: ACF Equity Research Estimates; Refinitiv.

Risks to our Assumptions

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 the Company 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. The Company must provide the FDA and foreign regulatory authorities with preclinical and clinical data demonstrating that its therapies are safe and effective before they 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 the Company. Many of the competitors have substantially greater financial resources and more experience in advancing drugs and therapeutics through various stages of regulatory approvals and then to commercialization.

Intellectual Property risk – The Company is near-term dependent on its proprietary technology platform and therefore, its near-term success depends on its ability to protect its IP. The Company holds granted patents and 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 risk - 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.

Glossary

(p< .005)	p-value - A probability value that measures how statistically significant outcome or observation is. P-values are a measure of how likely data would occur if no real (clinical) effect were present, i.e., if the null hypothesis were true. The lower the p-value the less likely the observed data is generated by chance alone. A p-value of p<.005 suggests that the probability of the data occurring by chance is less than 0.5% i.e., strong evidence against the H_0 hypothesis (the H_0 would typically be - our drug or therapy has no clinical effect).
ALS	Amyotrophic lateral sclerosis (ALS) is a neurodegenerative disease (NDD) also known as motor neuron disease (MND) and Lou Gehrig's disease.
ALSFRS-R	ALS Functional Rating Scale-Revised (ALSFRS-R) is a subjective (clinician's judgement) test used to define or describe the degree for functional decline in patients with ALS/MDN/Lou Gehrig's.
Biomarker	Biomarkers are measurable indicators of biological condition. They come in several broad types – molecular (e.g., DNA, RNA, proteins), physiologic (e.g., heart rate, glucose levels), histologic (e.g., cell and tissue characteristics observable under a microscope) and radiographic (e.g., anatomical changes detected by MRI or PET scans). Clinical biomarker applications can be divided into predictive (predict clinical outcomes), prognostic (disease progression), diagnostic (narrowing/filtering diagnoses), response (treatment response) and surrogate (indirect indicators e.g., cholesterol levels to assess cardiovascular risk).
CAGR	Compound Annual Growth Rate – Average annual growth rate over a period longer than one year.
Cargo	Cargo refers to molecules and substances transported within the cell often via small, membrane bound, structures called vesicles. They are often considered to be two categories of cargo – soluble proteins and transmembrane proteins. The process of moving cargo in cells is crucial to cell functioning.

Causal inference	Casual inference in biochemical research is the process of determining if a causal relationship exists between specific variables. There are two flavors – 1. The causal relationship investigating a direct relationship between one variable and another (genotype causes a phenotype). 2. The quantitative causal effect in which the aim is to establish not only if there is a direct relationship between the variables but also the quantity of that effect (1g of drug has Y effect, 2g has 2Y effect).
Cellular microenvironments	The cellular microenvironment is the local environment surrounding a cell. It contains physical and chemical signals that influence cell behavior and it includes the extracellular matrix. It is very dynamic in space and time and is bidirectional in terms of communications pathways and mechanisms.
CSF	Cerebrospinal fluid (CSF) is a clear fluid in all vertebrates found in the brain and spinal cord. CSF is produced by the ependymal cells in the choroid plexus in the brain's ventricles where it circulates. CSF acts as a shock absorber, immunological protection, cerebral autoregulator and a distribution mechanism for nutrients etc.. CSF is obtained or accessed by lumbar puncture.
CSF biomarkers	Biomarkers (see glossary) found in the CSF.
NurOwn (debamestrocel, MSC-NTF)	NurOwn (debamestrocel, MSC-NTF) also known as NurOwn® (Brainstorm Therapeutics, Nasdaq : BCLI) is made up of autologous mesenchymal stem cells (MSC) that secrete neurotrophic factors. NurOwn (debamestrocel, MSC-NTF)'s upcoming phase IIIb trial is designed to investigate the therapy as a treatment for ALS/MND.
EBIT	Earnings before interest and tax (also often referred to or equates to operating profit).
EBITDA	Earnings before interest, depreciation and amortization – the presentation of EBITDA by companies is not a requirement of UK GAAP or IFRS accounting standards. However, in certain cases it can act as a close proxy to free cash flow.
EBT	Earnings before tax. Also often expressed as profit before tax.

El Escorial criteria	The El Escorial criteria are a set of guidelines for diagnosing ALS, a neurodegenerative disease that affects the motor neurons. The criteria require the presence of signs of upper and lower motor neuron degeneration in different regions of the body, such as the bulbar region and spinal regions. The criteria also categorize ALS patients into four levels of diagnostic certainty, from clinically definite to possible ALS.
EPS	Earnings Per Share – value of earnings per outstanding share of common stock.
ESG	Environmental, Social and Governance – quantifiable metrics used to screen a company's sustainable business activities.
ETR	Effective Tax Rate – the % (percent) of income a corporation (or individual) pays in taxes.
EV	Enterprise Value
FCF	Free Cash Flow generated in ACF's models after all obligatory cash costs have been satisfied such as Interest payable (Ip), cash taxes and maintenance capex (as opposed to investment capex). FCF represents the cash remaining for theoretical distribution or investment after all obligatory cash-based costs including net interest payable have been deducted.
Glial cells	Glial cells or neuroglia are a class of non-neuronal cells that supply metabolites and physical support to neurons in the central and peripheral nervous systems. They facilitate inter-neuronal communication and regulate inflammation amongst other functions.

Intrathecal	Intrathecal means directly into the spinal canal. Intrathecally injected compounds reach the central nervous system (CNS) effectively.
JV	Joint Venture – generally a legal structure between two corporate entities involving participation in equity capital in the JV vehicle. JV can also refer to more informal arrangements.
MCap	Market Capitalization – total value of a publicly traded company's outstanding shares (formula = NoSh * s/p).
miR	MicroRNA (miR) biomarkers. MicroRNA are single stranded non-coding RNA of 21-23 nucleotides that are involved in gene regulation (RNA silencing), differentiation, cellular proliferation, apoptosis. Aberrant miR expression is linked to disease states. (15 biomarkers in BCLI's trial were excluded from multivariate analysis but included in univariate analysis. 13 of these multivariate analyses excluded biomarkers were miR biomarkers. These 13 miR biomarkers were excluded due to administrative censoring).
MSC	Mesenchymal stem cells (MSCs) are cells capable of differentiating into other cells. MSCs are present in bone marrow, umbilical cord, adipose tissue, adult muscle, corneal stroma or dental pulp of deciduous teeth (baby) teeth. In adults MSCs are most commonly obtained from bone marrow.
MSC-NTF	MSC-Neurotrophic Factor (MSC-NTF) are stem cells that are able to secrete neurotrophic factors that stimulate the body's own mechanism to engage in neuronal repair and maintenance.
Multimodal	Multimodal mechanism of action is when a drug or therapy affects biological systems via multiple distinct pathways.

Neurotrophic Factor (NTF)	Neurotrophic factors (NTFs) are biomolecules, the majority of which are peptides (2-50 aminos acids held together by peptide bonds) or small proteins (not all peptides are proteins due to their simpler structure and smaller size). NTFs support the growth, survival, and differentiation of developing and mature neurons. The mechanism of action is via signaling through tyrosine kinases. NTFs are capable of stimulating the regrowth of damaged neurons in-vitro and in animal models. NTFs come in three families – Neurotrophins, Glial cell-line derived neurotrophic factor family ligands (GFLs) and Neuropoietic cytokines.
NfL	Neurofilament light chain (NfL) is a protein that when elevated in cerebrospinal fluid (CSF) or blood is assessed to be indicative of neuronal damage or degeneration. NfL is used as a biomarker for NDDs such as ALS/MND, Alzheimer's, Parkinson's and MS.
NoSh	Number of Shares in issue (NoSh).
NPV	Net Present Value (NPV) refers to the current value of future cash flows generated by the project
Paracrine signaling	Paracrine signaling refers to a type of intercellular communication characterized by close physical proximity (very localized) and short duration.
Placebo	Placebo – is an inert dosage that closely resembles the active substance or treatment in order that the patient (and usually in research, the physician too) are unable to tell the difference between the placebo and the active substance. Therefore, attention must be paid to the appearance, color and flavor, etc., of the placebo. Patients receiving the placebo in clinical trials are referred to as the control group, whilst the experimental group receives the active substance or therapy. This is the central pillar of in-vivo clinical trials to determine if an active substance or therapy has a clinical effect when compared to non-treatment.

Shareholders' Equity	Shareholders' equity is a line on the balance sheet calculated from the deduction of total liabilities from total assets and represents the value (or lack of it) available for distribution to shareholders should the entity wind up operations. It differs from the equity value expressed in market capitalization (MCap), which is the number of shares in issue (NoSh) multiplied by share price. The ratio Debt/Equity commonly uses the Debt/MCap formula as opposed to the Debt/Shareholder equity formula.
Tofersen	Tofersen, marketed under the brand name Qalsody, developed by Ionis Pharmaceuticals and subsequently licensed to and co-developed by Biogen, is a medication specifically designed for the treatment of amyotrophic lateral sclerosis (ALS). **Mechanism of Action:** Tofersen is an antisense oligonucleotide (ASO). ASOs are small strings of DNA letters that bind to specific RNA molecules. Tofersen targets the RNA produced from mutated SOD1 genes. By doing so, it prevents the production of toxic SOD1 proteins associated with ALS.
WACC	Refers to the weighted average cost of capital for the firm.

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Christopher Nicholson
Managing Director
Head of Research
ACF Equity Research Ltd

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