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Brainstorm (NASDAQ/BCLI)

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BUY ALS Remains an Unmet Medical Need

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Brainstorm uses autologous cell therapy to treat amyotrophic lateral sclerosis (ALS) or Lou Gehrig's disease. The company is now in a Phase 3 pivotal trial, which if successful has the potential to be transformational for the company and for ALS patients.

Investment Highlights

Meeting an unmet medical need. ALS is a progressively fatal neurodegenerative disease for which there are few approved treatments that work, and most of them have side-effects which make an already difficult situation, worse. Brainstorm is developing a cell-based treatment which has a benign side-effects profile, and which may slow down the progression of this fatal disease. The hope is that NurOwn, the company's lead cell therapy, may provide an improved and extended quality of life for patients.

What is NurOwn? It is an autologous (your own cells) cell therapy which has been modified so that the cells act like potent miniature drug factories, secreting trophic factors that can treat neural disorders. The company uses a proprietary growth media to induce these adult autologous mesenchymal stem cells (MSCs) to differentiate into specialized neuron-supporting cells that secrete neurotrophic, nerve-growth supporting factors, MSC-NTFS. The cells are then administered via intramuscular and, or intrathecal injection, which is painless and considered safe. The cells are believed to promote motor neuron growth, protect existing motor neurons and help re-establish nerve-muscle interaction. The ALS opportunity represents an unmet medical need, and while it is designated as an orphan disease, it does have significant market potential. ALS affects 30,000 people in the U.S. and 450,000 worldwide. 5,000 new cases are diagnosed annually in the U.S. The average life expectancy is 2-5 years, and care is almost exclusively palliative. Advanced-stage patient care can reach \$200,000 per year representing a \$6 billion cost to the healthcare system. Changes in regulations for the approval of cell therapy in the U.S., such as the 21st Century Act, and similar legislative changes in Europe and Japan should support the application for NurOwn, provided the pivotal trial demonstrates positive data. Brainstorm's initial focus will be on the U.S. and E.U. markets but has had early discussions with potential partners in Japan.

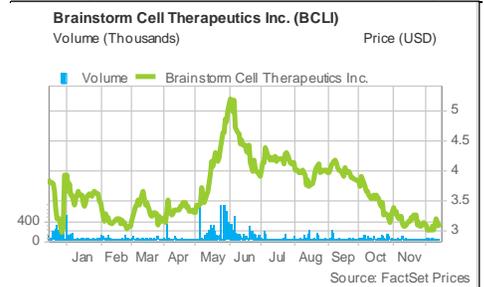
Proof of Concept (POC). The Phase 2 study was a double-blind, placebo-controlled trial in n=48 ALS patients across three U.S. clinical sites. The endpoints in the trial were the change in the slope of Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) score and the change in Slow Vital Capacity (SVC) and muscle strength. The trial demonstrated the greatest effect in the more rapidly progressing (subgroup) of ALS patients. This group comprised approximately half of the subjects in the study. Almost all of these patients (94%) treated with NurOwn (n=18), achieved 50% improvement in slope at 2 weeks, compared to only 20% in the placebo (n=5) group (p = 0.0027). At 4, 8, 12, 16 and 24 weeks, the proportion of responders in the active treatment group compared to placebo were 78% vs. 40%, 78% vs. 40%, 61% vs. 33%, 50% vs. 17% and 39% vs. 17%.

Current Price \$3.03
Price Target \$12.00

| Estimates | F2017A | F2018E | F2019E |
|-------------------|--------|---------|---------|
| Revenues (\$000s) | \$0 | \$1,500 | \$6,000 |
| 1Q March | \$0 | \$0 | \$1,500 |
| 2Q June | \$0 | \$0 | \$1,500 |
| 3Q September | \$0 | \$0 | \$1,500 |
| 4Q December | \$0 | \$1,500 | \$1,500 |

| | F2017A | F2018E | F2019E |
|---------------|--------|--------|--------|
| EPS (diluted) | (0.26) | (0.51) | (0.12) |
| 1Q March | (0.10) | (0.12) | (0.04) |
| 2Q June | (0.06) | (0.16) | (0.03) |
| 3Q September | (0.13) | (0.15) | (0.03) |
| 4Q December | 0.01 | (0.08) | (0.03) |

| | |
|---|-----------------|
| EBITDA/Share | |
| EV/EBITDA (x) | |
| Stock Data | |
| 52-Week Range | \$2.88 - \$5.35 |
| Shares Outstanding (mil.) | 21 |
| Market Capitalization (mil.) | \$63 |
| Enterprise Value (mil.) | \$52 |
| Debt to Capital | 0.0% |
| Book Value/Share | \$0.31 |
| Price/Book | 12.7 |
| Average Three Months Trading Volume (M) | 0.0 |
| Insider Ownership | 12.7% |
| Institutional Ownership | 11.6% |
| Short interest (mil.) | 5.5% |
| Dividend / Yield | \$0.00/0.0% |



Price target and ratings changes over the past 3 years:
 Initiation - December 18, 2018 - Buy - Price Target \$12

Please find Important Disclosures beginning on Page 16.

Will the Phase 3 trial be successful? The enrollment criteria for the pivotal trial is designed to include only the fast progressing patients who demonstrated superior outcomes in the prior Phase 2 trial. In this way, we view the trial as “enriched”. The trial itself is a 200 patient, randomized, placebo-controlled, double-blind, multi-dose trial conducted at six sites in the U.S. The primary outcome measure for the study will also use the ALSFR-S score responder analysis. We also note that these ALS patients in the current pivotal trial can now be treated with multiple doses. Once the patient’s cells are initially harvested, they will be sent to the lab where they can be processed and then cryopreserved. Brainstorm has already successfully demonstrated the equivalence of cryopreserved cells to fresh cells. We view cryopreservation as an important part of the Brainstorm fundamental story as it allows a high cost of goods to be spread out across multiple doses, improving manufacturing margins. The idea of multiple doses is consistent with our knowledge of how cell therapy works, as cells have a half-life, and doses will need to be refreshed over the course of treatment.

Valuation. With a market capitalization of just \$63M, we see the company as trading at a distressed valuation. Brainstorm today is now a pivotal company with a product that has orphan designation, in a market where the need is both desperate and unmet. The Phase 2 trial demonstrated a high safety margin, so if efficacy is demonstrated in the pivotal trial it creates a favorable risk-reward scenario. This combined with changes in legislation around the approval of cell therapy in the U.S., Europe, and Japan should create in our opinion a significant opportunity. In our model, we apply a 50% probability of success in our therapeutic models and a 30% discount rate in our valuation metrics. Using these metrics, we model the market potential and discount back in our FCFF, discounted EPS, and sum-of-the-parts models, rounded to the nearest whole number to arrive at a \$12.00 price target.

Risk to our thesis, include the following: (1) clinical; (2) regulatory; (3) commercial; (4) manufacturing; (5) financial; (6) liability; and (7) intellectual property. We review these and other risks in the risk section of this report.

Company Overview

Brainstorm is an emerging regenerative medicine company focused on developing cell-based therapies for incurable and often fatal neurodegenerative diseases, leveraging the promise of stem cells. Stem Cell therapies are one of the most promising areas of medicine. Brainstorm has developed proprietary techniques and methods aimed at unlocking the healing power of adult autologous stem cells. Brainstorm, by using autologous stem cells avoid the risk of rejection and the need for immunosuppressive agents which are expensive, wrought with side effects, and which can introduce new set of complications for patients and doctors. By using autologous cells, the company avoids the controversy associated with the use of embryonic or fetal-derived stem cells. NurOwn cells are derived from the patient's own bone marrow. The cells are then processed in a lab where they are treated to secrete large amounts of neurotrophic factors. A portion of the cells at this stage are cryopreserved, while another portion can be transplanted back into the patient via intrathecal and intramuscular injections. The total cost of the process can be spread across multiple doses.

NurOwn uses proprietary growth media to induce bone marrow-derived mesenchymal stem cells (MSC) to secrete neurotrophic factors. Neurotrophic factors are critical to maintain motor neuron health and promote neuron growth. Currently indicated for ALS, NurOwn also has potential for treating several other neurodegenerative diseases and has orphan drug status in both the U.S. and EU. NurOwn has been successfully evaluated in a Phase 2 proof of concept study and is now in a Phase 3 pivotal trial. While ALS is an orphan disease, it is one with a substantial patient population of an estimated 30,000 U.S. patients and 55,000 in Europe who suffer from the condition. Currently, the only approved treatments for ALS are mostly palliative and have complex dosing regimens and side effects associated with the therapy. Brainstorm's cell-based therapy is delivered to the patient in a painless intrathecal injection and safety is excellent with no serious side-effects, and transient, mild AEs reported, which may be more disease-related than therapy driven.

Brainstorm's main focus today is on amyotrophic lateral sclerosis (ALS), a debilitating and fatal disease characterized by upper and lower motor neuron degeneration, muscle atrophy and muscle wasting. Patients typically succumb to the disease and expire from respiratory failure. Beyond ALS, there is potential for the company to expand to other CNS disorders such as Parkinson's disease (PD), multiple sclerosis (MS) and spinal cord injury (SCI).

It's generally accepted that neurotrophic factors are vital to neuronal health. These factors act to protect and help establish nerve-muscle communication. Patients diagnosed with ALS have a progressive degeneration of motor neurons and nerve-muscle communication ultimately leading to muscle atrophy and eventually death. NurOwn is believed to act by re-establishing nerve-muscle communications through induction of new neuronal growth and repair of existing and or damaged neurons. We believe the concept of a modified, super secretor mesenchymal cell for CNS growth factors, such as GDNF and BDNF, make sense in this disease. So where is the controversy? Brainstorm's approach is autologous, or your own cells. We know that other recent cell therapies such as Chimeric Antigen Receptor-T cells or CAR-T, which are autologous too, represent the leading edge of personalized medicine today. The key issue in the future will be if the same results can be accomplished with an allogeneic version of the therapy. This model is more like pills in a bottle and could represent an off the shelf ready therapy, with pharmaceutical like margins. Another area of controversy among experts is what is the right starting cell type? A mesenchymal cell or a CNS cell such as an Astrocyte? What is the goal of the therapy, extension of life, slowing the rate of disease progression? We recognize these are all valid questions, but we see the signs of incremental progress in the clinical progress that NurOwn has accomplished, now in a pivotal study. We see the desperate unmet medical need and the positive changes in global regulations in the cell therapy space that should support the approval of new therapies like NurOwn provided they show safety and efficacy.

Exhibit 1. Pipeline

| Product | Indication | Development | Pre-clinical | Phase I | Phase II | Phase III | Marketed | Peak Sales (MM) |
|---------|---------------------|-------------|--------------|---------|----------|-----------|----------|-----------------|
| Nurown™ | ALS | | | | | | | 30k US Patients |
| Nurown™ | Progressive MS | | | | | | | |
| Nurown™ | Autism | | | | | | | |
| Nurown™ | Parkinson's Disease | | | | | | | |
| Nurown™ | Spinal Cord Injury | | | | | | | |

Source: *Brainstorm*.

Exhibit 2. Catalysts Table

| Product | Geography | Indication | Event | Timeline | Impact |
|------------------|-----------|------------|--|----------|-----------|
| Manufacturing | | | BioReactor (3D) Process development moves to Pilot Scale | Mid.2015 | completed |
| CryoPreservation | | | Validation for Clinical Use | 2H17 | completed |
| Nurown™ | US | ALS | Phase III patient enrollment, (begin trial) | 1H18 | completed |
| Nurown™ | US | ALS | Phase III patient enrollment, (complete) | 1H19 | + |
| Nurown™ | US | ALS | Phase III complete data report | 2H19 | ++ |
| Nurown™ | US | ALS | FDA approval, commercialization | 2H20 | +++ |
| Nurown™ | Israel | ALS | EMA approval, commercialization | 2H20 | +++ |
| Nurown™ | | | IND Second Indication (CNS Related) - MS | 1H19 | completed |
| Nurown™ | | | PI/II Trial in Second Indication | 2H19 | + |

Stock Significance Scale: + of moderate importance; ++ higher level; +++ highly

Source: *Dawson James estimates*.

The bull case. BCLI is an emerging biotechnology company in the regenerative medicine space with proprietary technology and proven methods for the induction of autologous adult mesenchymal stem cells to become neurotrophic factor secreting cells (MSC-NTFs). The company's first product, NurOwn, (indicated for ALS), is now in a Phase 3, pivotal trial. The trial is based on the Phase 2 study which demonstrated proof of concept data, which we believe creates a favorable (enriched) probability of success for the current pivotal trial. Critical to understand is the fact that NurOwn is considered to be a safe therapy with very mild, transient, adverse events and convenient dosing, both of which differentiate the product from its competitors in the ALS landscape. With a cryopreserved product now available the initially high cost of goods can now be spread across multiple treatments (doses). Multiple doses make sense as cells themselves have a half-life. ALS remains an unmet medical need and an orphan disease, but it is so with a significant number of patients. We estimate there are up to 30,000 ALS patients in the U.S. and 55,000 in the EU. The global regulatory environment for cell therapy has been changing, based on recognition of the differentiated mechanism of action. These changes in the U.S., Europe, and Japan create a potentially more rapid pathway for NurOwn to the marketplace, provided the pivotal trial meets its primary endpoint with a statistically significant result ($P \leq 0.05$). Brainstorm's pivotal trial is being supported by a \$16 million grant from CIRM and a \$2.1 million grant from the Israeli Innovative Authority. The company over the past year has strengthened the management team with a diverse group of experienced executives at the operating level as well as an active board. Lastly, we see a favorable risk-reward ratio as the company trades at a distressed valuation.

The bear case. The autologous adult stem cell space is still developing, and major questions—related to cell source and cost of goods—abound. There may be certain benefits to the autologous model versus the allogeneic model when evaluating cell half-life and cell integration, but bears will see expensive, personalized cost of manufacturing (but bulls will point out that cryopreservation may lead to an allogeneic-like cost of goods). Bears will point to the complexity of developing an ALS therapy (which has been a developer's graveyard). Data from the recent Phase 2 study may not be reproduced in the current pivotal trial. Though NurOwn is still in clinical development and a larger Phase 3 trial is underway, showing efficacy beyond the six-month follow-up period and overall long-term survival benefits have yet to be demonstrated. Additional long-term trials may be required for approval which requires additional capital, which could trigger dilution. Further, the adult stem cell space is becoming intensely competitive, and there are other groups with MSC-based therapies that could pursue an ALS indication in addition to the embryonic players previously discussed.

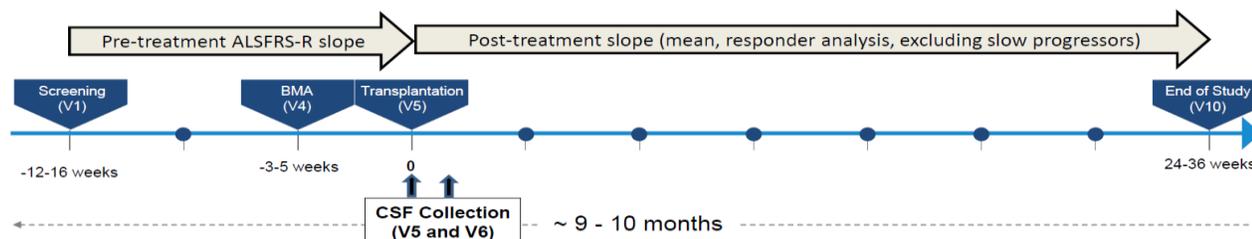
Our take. We believe the concept of modified autologous MSCs (super secretors for CNS growth factors such as GDNF and BDNF) to treat ALS via IT/IM administration makes sense. MSCs are natural "repair" cells that home in the body. This is a major point of competitive differentiation versus others in the landscape. Safety hurdles are important, as we see ALS as a disease driven at least in part by inflammation. Ease of administration is another mission-critical element. Cryopreservation is a key positive in our thinking, as it allows an expensive manufacturing process to be spread out across multiple treatments. Clinically, we have met with one of the prior principal investigators (in Israel), and we agree that early signs of efficacy seen in ALS patients from two independent trials are encouraging. Today, we are excited to see the progression of the pivotal program in the U.S. BCLI's autologous approach versus allogeneic and modified MSCs versus embryonic or fetal-derived cells could translate into the right therapy designed for these patients. Extension of life, no need for immune suppressive drugs/rejection of grafts, ease of administration of the cells, and overall safety justify the cost of using autologous MSCs versus other indications in which that argument might not be true, in our view.

The Phase 3 trial. The trial is designed as a randomized, double-blind, placebo-controlled, multi-dose trial. The clinical plan is to enroll 200 patients with a 1:1 randomization. Six leading U.S. ALS clinical sites are supporting the trial, and two of the sites participated in the prior Phase 2 study. The trial is actively recruiting and enrolling patients today. The trial protocol calls for patients to be treated for approximately a year. Critical aspects of this trial include design elements that were learned from the Phase 2 trial. Specifically, all patients are to be evaluated for approximately three months to establish a disease baseline. This will be used to determine the ALSFRS-R slope, a measure of disease progression. Patients who demonstrated less than a three-point decline on the ALSFRS-R; which likely represents about half of all patients, will be excluded. This ensures that the therapy will be treating patients with active disease, in theory, making it easier to see the effect of slowing disease progression. The trial design is to treat these patients with three doses over a four-month period. Patient enrollment began in October 2017. Patients will be evaluated 28 weeks after the first dose. The primary endpoint of the trial will be an ALSFRS responder analysis, with a responder defined as greater than a 1.25-point improvement per month. We expect to see top-line data in the latter half of next year. The Phase 3 trial will also expand upon Phase 2 biomarker evaluations to further understand their potential to predict ALS disease progression, and treatment response as well as confirm the biology of NurOwn in a larger study population. We also note that FVC (forced vital capacity) has been shifted to a secondary endpoint as it has proven to be a very variable history in ALS patients.

The Phase 2 trial. The Phase 2 study was a multi-center, double-blind, placebo-controlled trial in n=48 ALS patients across three U.S. clinical sites. Patients were randomized to receive NurOwn cells administered via combined intramuscular and intrathecal injection (n= 36), or placebo (n=12). They were followed monthly for approximately three months before treatment and six months following treatment, assessed at 2, 4, 8, 12, 16 and 24 weeks. The pre-specified efficacy analyses measured the change in the slope of Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) score, the change in Slow Vital Capacity (SVC), muscle strength, a responder analysis (the percentage of subjects who improved post-treatment compared with pre-treatment), and a subgroup analysis excluding slowly progressing patients who are less likely to have a detectable benefit from NurOwn. The more rapidly progressing subgroup, comprising approximately half of the subjects in the study, showed a marked benefit from NurOwn treatment. In that group 94% of those treated with NurOwn (n=18) achieved 50% improvement in slope at 2 weeks, compared to only 20% in the placebo (n=5) group (p = 0.0027). At 4, 8, 12, 16 and 24 weeks, the proportion of responders in the active treatment group compared to placebo were 78% vs. 40%, 78% vs. 40%, 61% vs. 33%, 50% vs. 17% and 39% vs. 17%.

Exhibit 3. Phase 2 Study Design

**NurOwn® BCT-001-US
Phase 2 Study Design**



- 48 participants (16 per site)
- Randomized 3:1

- **IM:** 24 injections (12 into R biceps, 12 into R triceps); 2 million cells each
- **IT:** 125 million cells in 4mL

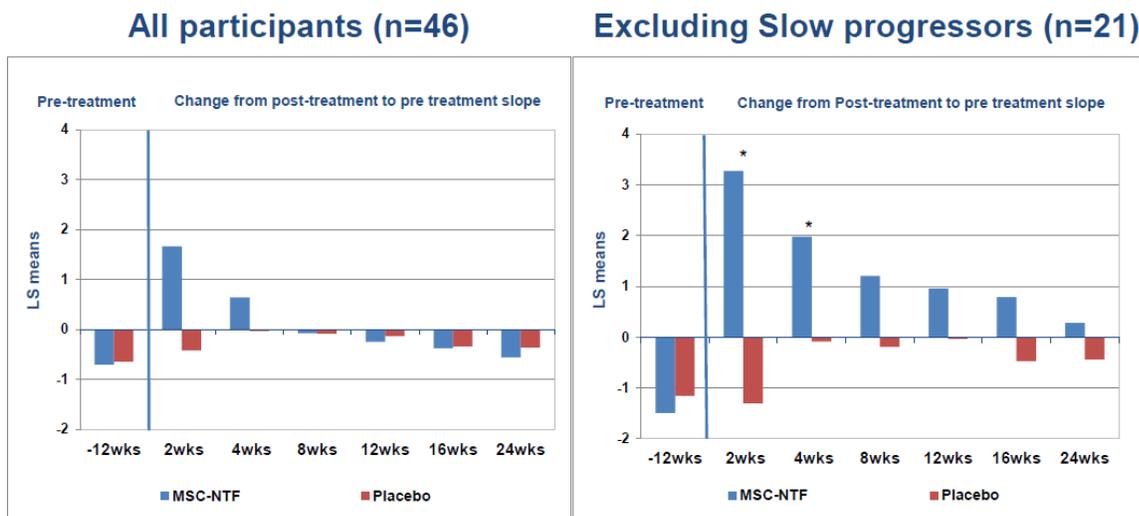
BMA: Bone Marrow Aspirations

● Monthly visits

8

Source: Brainstorm.

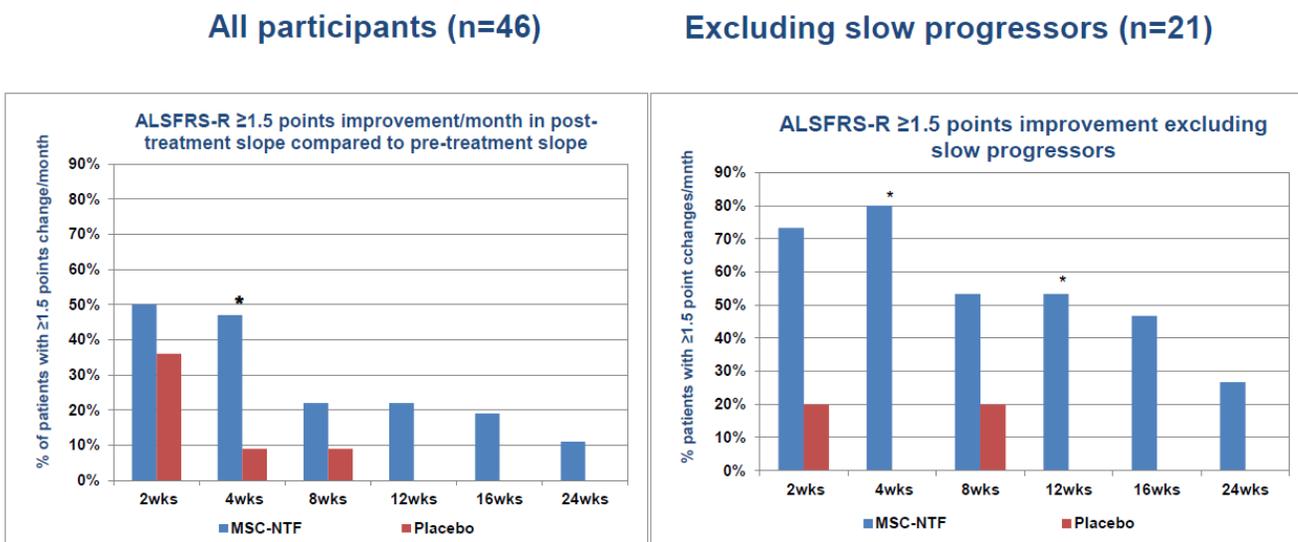
Exhibit 4. Phase 2 Outcomes, MEAN ALSFRS-R Slope Improvement



* p<0.05 (two-sided T test)

Source: *Brainstorm*.

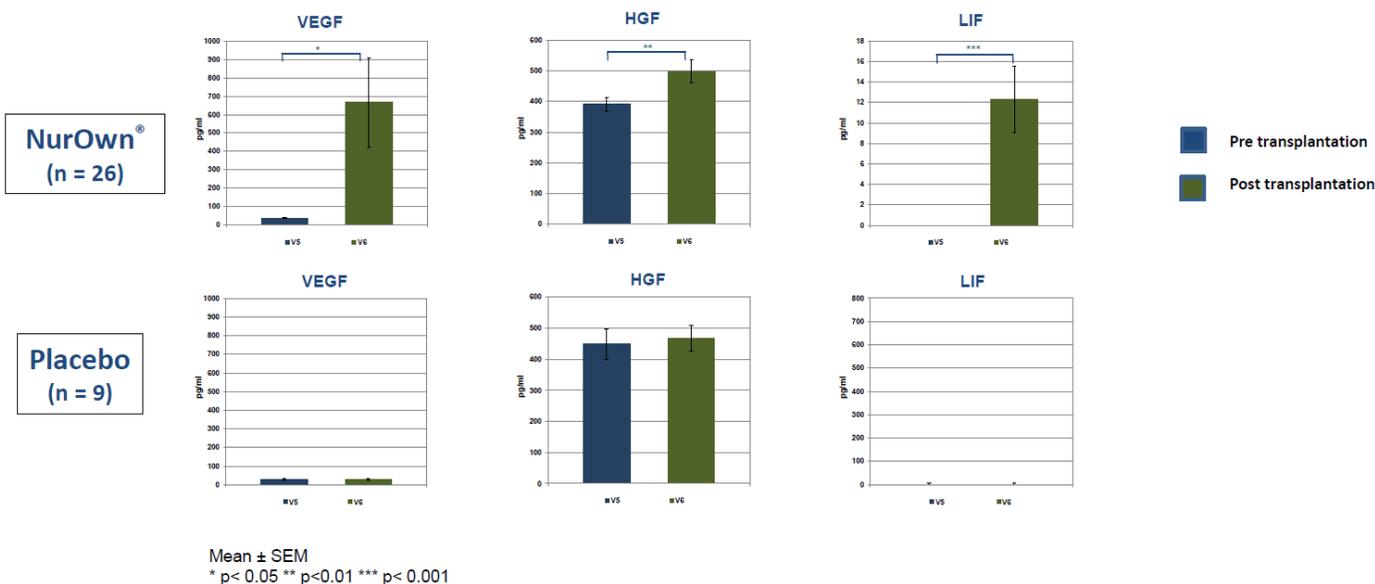
Exhibit 5. NurOwn Phase 2 Responder Analysis: ≥ 1.5 Points per Month



* p<0.05 (two-sided Fisher's exact test)

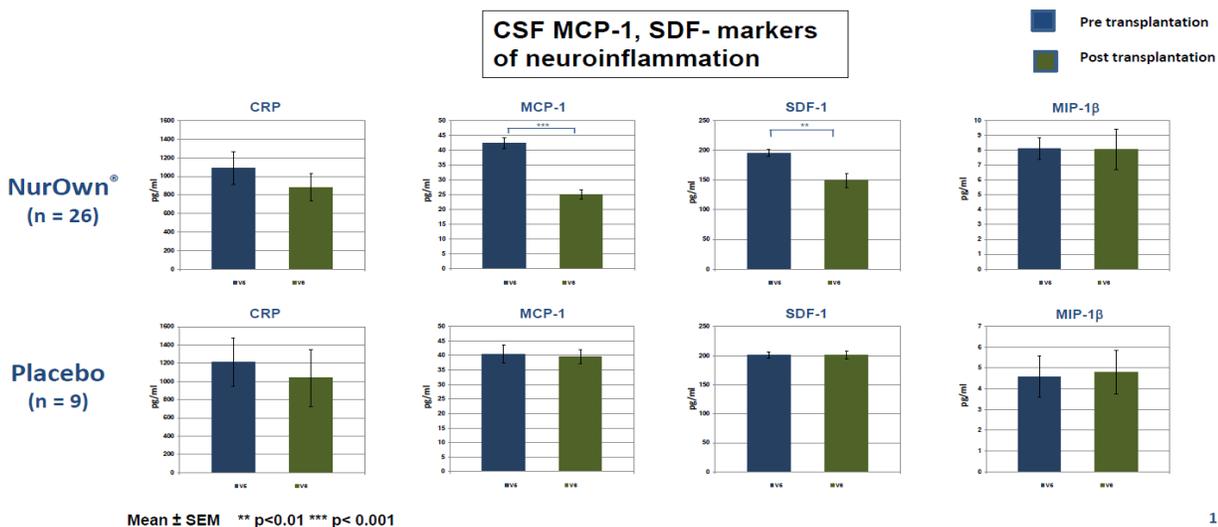
Source: *Brainstorm*.

Exhibit 6. Bio-Marker Data: CSF NTFS Increased Two Weeks Post Treatment



Source: Brainstorm.

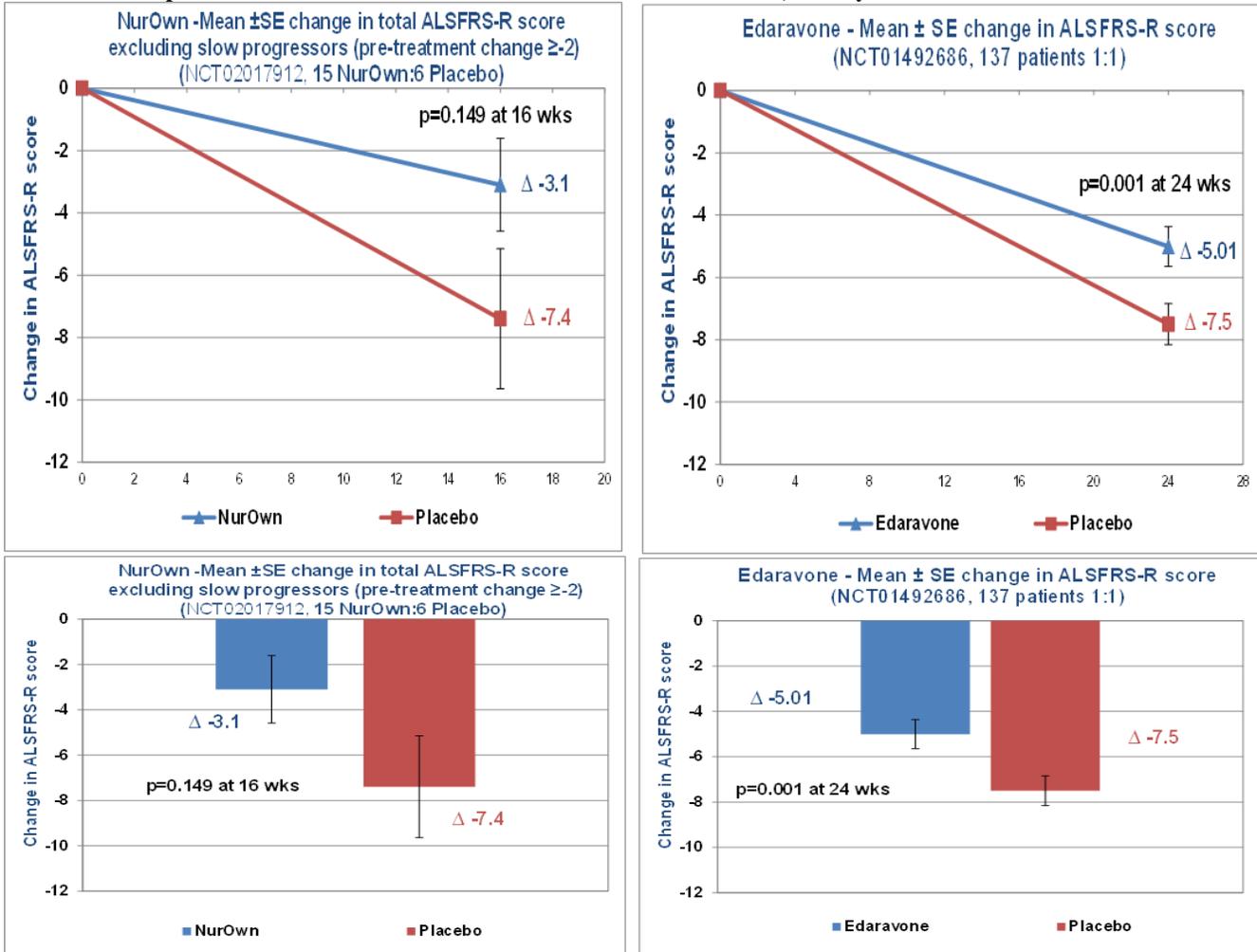
Exhibit 7. Bio-Marker Data: CSF Inflammatory Markers Decreased Post Treatment



Source: Brainstorm.

Is NurOwn safe? We think so, yes. The therapy showed very mild transient, over a 24-hour period, adverse events and convenient dosing, both of which differentiate the product in the ALS landscape. These are important factors as we have seen other approaches to cell-based therapies in ALS, one of which involves direct injection into the spine. Results of this approach were mixed, as a key risk may be the spinal injection itself. We view NurOwn as an essentially benign therapy with a convenient dosing schedule. If we compare NurOwn to the most recent approval in the ALS space, we see dramatic differences. Last May, the FDA approved Edaravone, a free radical binder which had been previously approved in Japan for stroke. Experts we spoke with were surprised as the data does not appear compelling. The administration of the drug is burdensome, with 64 infusions, 14 days daily on and 14 days off drug. The drug appeared to show no benefit in the initial Phase 3, 204-person trial but a sub-group analysis of patients diagnosed within two years showed an effect. A second Phase 3 trial in 137 patients was run in these patients splitting them between treatment and placebo arms. Over 24 weeks, those on Edaravone lost five points on the ALS-FRS, compared to 7.5 in the placebo group and the difference was statistically significant.

Exhibit 8. A comparison Between NurOwn Phase 2 Data and Edaravone Phase 3, efficacy outcomes



Source: Brainstorm.

Exhibit 9. Reported Transient Adverse Events – 24 HRS From the Phase 2 Trial

| Adverse Event | NurOwn® (%) | Placebo (%) |
|----------------------------------|-------------|-------------|
| Headache and Procedural Headache | 80.6 | 66.7 |
| Back Pain | 72.2 | 8.3 |
| Pyrexia | 33.3 | 0 |
| Arthralgia | 33.3 | 0 |
| Injection Site Pain | 27.8 | 8.3 |
| Constipation | 25 | 8.3 |
| Pain in Extremity | 22.2 | 0 |
| Neck Pain | 19.4 | 0 |
| Myalgia | 16.7 | 0 |
| Cough | 16.7 | 0 |
| Nausea | 16.7 | 0 |

Source: Brainstorm.

Cryopreservation is key. Brainstorm has developed a cryopreservation process for the long-term storage of MSCs, that will allow multiple doses of NurOwn to be created from a single bone marrow aspirate in the multi-dose clinical trial and avoid the need for patients to undergo repeated bone marrow aspirations. A validation study was conducted last year. The study compared NurOwn, MSC-NTF cells derived from fresh mesenchymal stem cells to those derived from cryopreserved MSCs. Company scientists were successful in showing that the MSCs can be stored in the vapor phase of liquid nitrogen for prolonged periods of time while maintaining their characteristics. The cryopreserved MSCs can differentiate into NurOwn, similar to the NurOwn derived from fresh MSCs of the same patient/donor, before cryopreservation.

The market opportunity. According to the Centers for Disease Control (CDC) and National Institute of Neurological Disorders and Stroke, an estimated 30,000 Americans suffer from ALS, with 5,000 new cases annually. Most cases develop between 55 and 75 years of age, being more prevalent in men than women. The median survival is three to five years from diagnosis, leading to death from respiratory paralysis. To date, there is no cure for ALS, and the only FDA-approved drugs are Riluzole and Edaravone, (previously mentioned). We profiled some of our concerns on Edaravone as the dosing and efficacy leave a lot to be desired. Riluzole is believed to relieve symptoms only. The drug is marketed by Sanofi-Aventis (SNA; not rated). The oral pill (50 mg) is administered every 12 hours and priced at \$962 per monthly supply (50 mg, quantity of 60). Its mechanism of action is unknown, but it appears to address the glutamate excitotoxicity. It may protect nerve cells by reducing or inhibiting the release of the neurotransmitter glutamate, which is built up at very high levels in ALS patients. Riluzole extends survival time of ALS patients, by an average of two to three months, before reaching the end-stage of ventilator support. Clinical trials demonstrated no difference between placebo and Riluzole after 18 months of administration.

The estimated annual treatment costs for advanced stage patients can be as high as \$100,000-\$200,000 per annum with limited therapies that are available today. Given the unmet medical need and the established safety of NurOwn, we are hopeful that even if a modest benefit is shown the therapy can be successfully brought to the marketplace. In our model assumptions, we assume very modest pricing for treatment of \$151,000 per patient. Our analysis of other cell therapies suggests pricing could be substantially higher, even approaching \$1 million per patient. Our assumption may prove to be too conservative.

In February 2011, Brainstorm was granted an Orphan Drug Designation for NurOwn for the treatment of ALS in the United States. In July 2013, the company received Orphan Medicinal Product Designation for NurOwn for the treatment of ALS from the European Commission. Orphan designation grants a 10-year marketing exclusivity in the EU for the designated indication, as well as several other regulatory incentives.

Changes in the approval pathways for cell therapy. In December of 2016 new legislation was passed, called the 21st Century Cures Act. The 1000-page bill includes revisions to how the FDA regulates drugs, devices, and biologics while providing the agency with \$500 million over a 10-year period to implement the provisions. The provisions hope to support product approval, especially in areas that are both an unmet medical need and where the need and benefits to society are great. The goal is to accomplish this without sacrificing safety and efficacy approval standards. Advocates who supported the legislation point to both the modernization of the regulations, as well as increased funding for both the FDA and the National Institutes of Health, which combined could receive an increase of just under \$5 billion over the next decade. Part of the funding is to support the Precision Medicine Initiative which includes a section on regenerative medicine, including adult stem cells.

The 21st Century Act follows similar legislative changes in Europe and Japan. Japan's new Regenerative Medicine Law serves to shepherd new cell therapies and assumes a range of such technologies, including iPSC-based approaches and others. This new framework creates a more efficient path for medicines to reach patients and the market. In the broadest view, the Regenerative Medicine Law realigns the thinking and process of clinical trials for stem cell technologies. Currently, most developed countries are quite rigid in requiring three stages of clinical trials, including lengthy mid- and late-stage trials before new therapies are even considered for approval. With that structure, it's not uncommon for a drug to take a decade to reach commercialization. Japan's new policy requires an early stage clinical trial (call it a Phase I or small Phase II) at the minimum to confirm the safety of the therapy and provide some plausible evidence of efficacy. Rather than requiring that the therapy then is evaluated in subsequent trials before making it available to patients, Japan's new law will allow for "conditional approval," enabling the product to be brought to market and to obtain reimbursement in an accelerated manner.

Support from CIRM. Brainstorm's Phase 3, pivotal trial is supported by a \$16M grant from the California Institute of Regenerative Medicine (CIRM) and a \$2.1M grant from the Israeli Innovative Authority. The company also signed a Memorandum of Understanding, in Israel, that will allow them to treat and charge for therapy, ALS patients.

Valuation Analysis. Given the fact that the company's market capitalization is approximately ~\$63 million we see the valuation as distressed. We see a company with a pivotal trial, orphan designation, in a market where the need is both desperate and unmet. The Phase 2 trial demonstrated an excellent safety profile, and the results helped to enrich the probability of a successful pivotal trial by identifying the importance of excluding slow progressing patients. If the pivotal trial shows statistically significant p-values combined with changes in legislation around the approval of cell therapy in the U.S., Europe, and Japan, we could see a large global market opportunity. We also take note that the Phase 3 trial is being supported with non-dilutive capital from CIRM and the Israeli Innovative Authority.

Product Modeling Assumptions

1. We assume NurOwn's Phase 3 trial will demonstrate p-values on the primary and secondary endpoints and qualify for review and approval in the U.S. and Europe.
2. We assume pricing of \$151,000 per patient during the life of the patient, or duration of treatment in the U.S. and \$139,000 in Europe. Our price assumptions could prove to be too conservative as cell-based therapies typically charge multiples of our assumptions. We do this for conservatism.
3. We reduce the patient population pool by 25% to account for patients who may not have access to therapy or insurance.
4. We apply a 50% probability of success in our model, as NurOwn is not yet approved and we acknowledge the novel nature of both cell therapy, the variability of this disease and the complex nature of using Phase 2 data to predict a Phase 3 trial outcome.
5. We have not assumed revenues beyond the U.S. and Europe.

Exhibit 10. Market Model for the U.S. and Europe for Brainstorm's NurOwn in ALS Patients

| Amyotrophic Lateral Sclerosis (ALS) | | | | | | | | | | | | | | | | |
|--|--------|--------|--------|--------|--------|--------|--------|------------|------------|------------|--------------|--------------|--------------|--------------|--------------|--------------|
| ALS revenues model (US) | | | | | | | | | | | | | | | | |
| | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 |
| ALS Prevalence | 30,000 | 30,300 | 30,603 | 30,909 | 31,218 | 31,530 | 31,846 | 32,164 | 32,486 | 32,811 | 33,139 | 33,470 | 33,805 | 34,143 | 34,484 | 34,829 |
| Market Size Growth | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% |
| Eligible patients with insurance (75%) | 22,500 | 22,725 | 22,952 | 23,182 | 23,414 | 23,648 | 23,884 | 24,123 | 24,364 | 24,608 | 24,854 | 25,103 | 25,354 | 25,607 | 25,863 | 26,122 |
| Market Penetration | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 4% | 10% | 15% | 20% | 25% | 30% | 34% | 40% |
| Treatable Patients | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 975 | 2,461 | 3,728 | 5,021 | 6,338 | 7,682 | 8,993 | 10,249 |
| Average Price of Therapy | | | | | | | | \$151,000 | \$154,020 | \$157,100 | \$160,242 | \$163,447 | \$166,716 | \$170,051 | \$173,452 | \$176,921 |
| Price Growth | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 2% | 2% | 2% | 2% | 2% | 2% | 2% | 2% | 2% |
| Total Sales (\$M) | | | | | | | | | \$ 150,103 | \$ 386,591 | \$ 597,400 | \$ 820,588 | \$ 1,056,712 | \$ 1,306,350 | \$ 1,525,242 | \$ 1,848,594 |
| Probability of Approval | | | | | | | | | 50% | 50% | 50% | 50% | 50% | 50% | 50% | 50% |
| Total Sales (US) (\$M) | | | | | | | | | \$ 75,052 | \$ 193,296 | \$ 298,700 | \$ 410,294 | \$ 528,356 | \$ 653,175 | \$ 762,621 | \$ 924,297 |
| Amyotrophic Lateral Sclerosis (ALS) | | | | | | | | | | | | | | | | |
| ALS revenues model (Europe) | | | | | | | | | | | | | | | | |
| | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 |
| ALS Prevalence | 55,000 | 55,550 | 56,106 | 56,667 | 57,233 | 57,806 | 58,384 | 58,967 | 59,557 | 60,153 | 60,754 | 61,362 | 61,975 | 62,595 | 63,221 | 63,853 |
| Market Size Growth | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% | 1% |
| Eligible patients with insurance (75%) | 41,250 | 41,663 | 42,079 | 42,500 | 42,925 | 43,354 | 43,788 | 44,226 | 44,668 | 45,115 | 45,566 | 46,021 | 46,482 | 46,946 | 47,416 | 47,890 |
| Market Penetration | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 2% | 5% | 10% | 15% | 20% | 25% | 30% | 34% | 40% |
| Treatable Patients | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 885 | 2,233 | 4,511 | 6,835 | 9,204 | 11,620 | 14,084 | 16,121 | 19,156 |
| Average Cost of Therapy | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$139,000 | \$141,780 | \$144,616 | \$147,508 | \$150,458 | \$153,467 | \$156,537 | \$159,667 | \$162,861 |
| Price Growth | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 2% | 2% | 2% | 2% | 2% | 2% | 2% | 2% | 2% |
| Total Sales (\$M) | | | | | | | | \$ 122,947 | \$ 316,650 | \$ 652,426 | \$ 1,008,194 | \$ 1,384,856 | \$ 1,783,348 | \$ 2,204,646 | \$ 2,574,057 | \$ 3,119,757 |
| Probability of Approval | | | | | 0% | 0% | 0% | 50% | 50% | 50% | 50% | 50% | 50% | 50% | 50% | 50% |
| Total Sales (Europe) (\$M) | | | | | | | | \$ 61,474 | \$ 158,325 | \$ 326,213 | \$ 504,097 | \$ 692,428 | \$ 891,674 | \$ 1,102,323 | \$ 1,287,028 | \$ 1,559,878 |
| Total sales (US and Europe) (\$M) | | | | | | | | \$ 61,474 | \$ 233,377 | \$ 519,509 | \$ 802,797 | \$ 1,102,722 | \$ 1,420,030 | \$ 1,755,498 | \$ 2,049,649 | \$ 2,484,175 |

Source: Dawson James estimates.

Valuation. Our product models feed into our income statement and allow us to apply valuation metrics. For conservatism, we apply a 50% probability of approval in our product models as NurOwn is a new and novel therapy in a variable disease. Our product model reflects our assumptions for the product launch dates, product attributes, and pricing, to determine the future revenue streams. Our valuation conclusion is an equally weighted average of our FCFE, EPS, and sum-of-the-parts analysis discounted at a rate of 30% to account for the risks of development stage products. For companies that are well established with mature products and revenues, we typically will use a 10% risk rate. For companies in the early stages of product commercialization, we typically choose a higher risk rate of 15%. For Brainstorm, we use our maximum risk rate of 30% as the company does not yet have an approved therapeutic product. Regarding the company's financials, we estimate that today Brainstorm has approximately \$11M in cash on the balance sheet. However, we note the company is receiving support from CIRM and the Israel Innovative Authority for up \$16 and \$2M respectively. Our model does assume a capital raise, and our valuation is based on a fully-diluted out-year share forecast.

Exhibit 11. Discounted Free-Cash-Flow Model

| | | |
|--------------|----|-------|
| Average | \$ | 12.00 |
| Price Target | \$ | 11.00 |
| Year | | 2019 |

DCF Valuation Using FCF (mln):

| units ('000 - Cnd\$) | 2016A | 2017A | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E |
|-------------------------------------|--------------|---------|----------|---------|---------|--------|---------|---------|---------|---------|---------|---------|---------|
| EBIT (Earnings before income tax) | (4,982) | (4,952) | (10,226) | (6,435) | (1,178) | 63,640 | 156,916 | 255,764 | 360,438 | 471,198 | 588,316 | 712,075 | 799,208 |
| Tax Rate | 0% | 0% | 0% | 0% | 0% | 5% | 10% | 15% | 20% | 25% | 30% | 35% | 37% |
| EBIT(1-t) Earnings after income tax | (4,982) | (4,952) | (10,226) | (6,435) | (1,178) | 60,458 | 141,224 | 217,400 | 288,350 | 353,398 | 411,821 | 462,849 | 503,501 |
| CapEx (equipment) | (103) | (180) | (261) | - | - | - | - | - | - | - | - | - | - |
| Depreciation | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Change in NWC | - | - | - | - | - | - | - | - | - | - | - | - | - |
| FCF | (5,085) | (5,132) | (10,487) | (6,435) | (1,178) | 60,458 | 141,224 | 217,400 | 288,350 | 353,398 | 411,821 | 462,849 | 503,501 |
| PV of FCF | (11,172) | (8,673) | (13,633) | (6,435) | (906) | 35,774 | 64,280 | 76,118 | 77,661 | 73,216 | 65,630 | 56,740 | 47,480 |
| Discount Rate | 30% | | | | | | | | | | | | |
| Long Term Growth Rate | 1% | | | | | | | | | | | | |
| Terminal Cash Flow | 1,753,574 | | | | | | | | | | | | |
| Terminal Value YE2023 | 165,361 | | | | | | | | | | | | |
| NPV | 654,920 | | | | | | | | | | | | |
| NPV-Debt | - | | | | | | | | | | | | |
| Shares out ('000) | 62,185 2023E | | | | | | | | | | | | |
| NPV Per Share | \$ 10.53 | | | | | | | | | | | | |

Source: Dawson James estimates.

Exhibit 12. EPS Model

| | |
|-------------------|----------|
| Current Year | 2019 |
| Year of EPS | 2023 |
| Earnings Multiple | 10 |
| Discount Factor | 30% |
| Selected Year EPS | \$ 3.57 |
| NPV | \$ 12.49 |

| | | Discount Rate and Earnings Multiple Varies, Year is Constant | | | | | |
|-------------------|----------|--|---------|---------|---------|---------|---------|
| | | 2023 EPS | | | | | |
| Earnings Multiple | 12.5 | 5% | 10% | 15% | 20% | 25% | 30% |
| | 0 | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| 5 | \$14.67 | \$12.18 | \$10.20 | \$8.60 | \$7.30 | \$6.24 | \$6.24 |
| 10 | \$29.34 | \$24.36 | \$20.39 | \$17.20 | \$14.61 | \$12.49 | \$12.49 |
| 15 | \$44.01 | \$36.54 | \$30.59 | \$25.80 | \$21.91 | \$18.73 | \$18.73 |
| 20 | \$58.68 | \$48.72 | \$40.78 | \$34.40 | \$29.22 | \$24.98 | \$24.98 |
| 25 | \$73.36 | \$60.90 | \$50.98 | \$43.00 | \$36.52 | \$31.22 | \$31.22 |
| 30 | \$88.03 | \$73.08 | \$61.18 | \$51.60 | \$43.83 | \$37.46 | \$37.46 |
| 35 | \$102.70 | \$85.26 | \$71.37 | \$60.20 | \$51.13 | \$43.71 | \$43.71 |

Source: Dawson James estimates.

Exhibit 13. Sum-of-the-Parts Model

| Brainstorm Cell Therapeutics, Inc (BCLI) | LT Gr | Discount Rate | Yrs. to Mkt | % Success | Peak Sales MMs | Term Val |
|--|-------|---------------|-------------|-----------|----------------|----------|
| Nurown | 1% | 30% | 2 | 70% | \$750 | \$2,586 |
| ALS | | | | | | \$12.06 |
| Nurown | 1% | 50% | 5 | 50% | \$500 | \$1,020 |
| Pre-Clinical Pipeline | | | | | | \$0.76 |
| Net Margin | | | | | | 70% |
| MM Shrs OS | | | | | | 62 |
| Total | | | | | | \$12.06 |

Source: Dawson James estimates.

Exhibit 14. Income Statement

| Brainstorm Cell Therapeutics, Inc.: Income Statement (\$'000) | | | | | | | | | | | | | | | | | | | | |
|---|---------|---------|---------|---------|---------|----------|---------|---------|---------|---------|---------|---------|---------|---------|---------|-----------|-----------|-----------|-----------|-----------|
| Brainstorm Cell Therapeutics: YE Dec. 31 | 2017A | 1Q18A | 2Q18A | 3Q18A | 4Q18E | 2018E | 1Q19E | 2Q19E | 3Q19E | 4Q19E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E |
| Nurown™ (U.S. sales) | | | | | | | | | | | | - | 75,052 | 193,296 | 298,700 | 410,294 | 528,356 | 653,175 | 762,621 | 924,297 |
| Nurown™ (EU sales) | | | | | | | | | | | | 61,474 | 158,325 | 326,213 | 504,097 | 692,428 | 891,674 | 1,102,323 | 1,287,028 | 1,559,878 |
| Supportive Development Grant Revenue | | | | | 1,500 | 1,500 | 1,500 | 1,500 | 1,500 | 1,500 | 6,000 | | | | | | | | | |
| Total Product Sales | | | | | 1,500 | 1,500 | 1,500 | 1,500 | 1,500 | 1,500 | 6,000 | 61,474 | 233,377 | 519,509 | 802,797 | 1,102,722 | 1,420,030 | 1,755,498 | 2,049,649 | 2,484,175 |
| Expenses | | | | | | | | | | | | | | | | | | | | |
| Cost of goods sold | | | | | | | | | | | | 46,105 | 151,695 | 337,681 | 521,818 | 716,769 | 923,020 | 1,141,074 | 1,332,272 | 1,614,714 |
| COGS % of Revenue | | | | | | | | | | | | 75% | 65% | 65% | 65% | 65% | 65% | 65% | 65% | 65% |
| Research and development | 977 | 977 | 1,481 | 1,975 | 1,500 | 5,933 | 1,501 | 1,632 | 1,566 | 1,827 | 6,526 | 6,657 | 6,790 | 6,926 | 7,064 | 7,206 | 7,350 | 7,497 | 7,647 | 7,800 |
| R&D % of Revenue | | | | | | | | | | | | | | | | | | | | |
| SG&A | 4,022 | 1,330 | 1,606 | 1,257 | 1,600 | 5,793 | 1,359 | 1,418 | 1,477 | 1,654 | 5,909 | 10,000 | 18,000 | 18,360 | 18,727 | 19,102 | 19,484 | 19,873 | 20,271 | 20,676 |
| SG&A % of Revenue | | | | | | | | | | | | | | | | | | | | |
| Total expenses | 4,999 | 2,307 | 3,087 | 3,232 | 3,100 | 11,726 | 2,860 | 3,050 | 3,044 | 3,482 | 12,435 | 62,762 | 176,485 | 362,967 | 547,610 | 743,077 | 949,853 | 1,168,444 | 1,360,190 | 1,643,190 |
| Oper. Inc. (Loss) | (4,999) | (2,307) | (3,087) | (3,232) | (1,600) | (10,226) | (1,360) | (1,550) | (1,544) | (1,982) | (6,435) | (1,288) | 56,892 | 156,542 | 255,187 | 359,645 | 470,177 | 587,054 | 689,460 | 840,985 |
| Financial income expenses, net | 47 | (9) | 4 | 56 | | | | | | | | | | | | | | | | |
| Taxes on income | | | | | | | | | | | | | | | | | | | | |
| Other income | | | | | | | | | | | | | | | | | | | | |
| Pre-tax income | (4,952) | (2,298) | (3,091) | (3,176) | (1,600) | (10,226) | (1,360) | (1,550) | (1,544) | (1,982) | (6,435) | (1,288) | 56,892 | 156,542 | 255,187 | 359,645 | 470,177 | 587,054 | 689,460 | 840,985 |
| Income Tax Benefit (Provision) | - | - | - | - | - | - | - | - | - | - | - | - | 2,845 | 15,654 | 38,278 | 71,929 | 117,544 | 176,116 | 241,311 | 311,165 |
| Tax Rate | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 5% | 10% | 15% | 20% | 25% | 30% | 35% | 37% |
| GAAP Net Income (loss) | (4,952) | (2,298) | (3,091) | (3,176) | (1,600) | (10,165) | (1,360) | (1,550) | (1,544) | (1,982) | (6,435) | (1,288) | 54,047 | 140,888 | 216,909 | 287,716 | 352,633 | 410,938 | 448,149 | 529,821 |
| GAAP-EPS | (0.26) | (0.12) | (0.16) | (0.15) | (0.08) | (0.51) | (0.04) | (0.03) | (0.03) | (0.03) | (0.12) | (0.02) | 0.89 | 2.32 | 3.56 | 4.70 | 5.74 | 6.66 | 7.24 | 8.52 |
| Non GAAP EPS (dil) | (0.26) | (0.12) | (0.16) | (0.15) | (0.08) | (0.51) | (0.04) | (0.03) | (0.03) | (0.03) | (0.12) | (0.02) | 0.89 | 2.32 | 3.56 | 4.70 | 5.74 | 6.66 | 7.24 | 8.52 |
| Wgtd Avg Shrs (Bas) - '000s | 18,777 | 19,047 | 19,505 | 20,692 | 20,713 | 19,989 | 30,715 | 45,718 | 45,722 | 45,727 | 41,970 | 45,738 | 45,757 | 45,775 | 45,793 | 45,812 | 45,830 | 45,848 | 45,867 | 45,885 |
| Wgtd Avg Shrs (Dil) - '000s | 18,777 | 19,047 | 19,505 | 20,692 | 20,899 | 20,036 | 37,920 | 59,958 | 60,018 | 60,078 | 41,970 | 60,228 | 60,469 | 60,711 | 60,955 | 61,199 | 61,444 | 61,690 | 61,937 | 62,185 |

Source: Dawson James estimates.

Companies mentioned in this report:

Sanofi-Aventis (SNA) – Not Covered

Risk Analysis

In addition to the typical risks associated with development stage specialty pharmaceutical companies, potential risks specific to Brainstorm are as follows:

Partnership risk. Brainstorm is in discussions with possible partners today, but there can be no assurances that the company will be able to secure a favorable partnership.

Commercial risk. There are no assurances that the company will be able to achieve significant market share and become profitable.

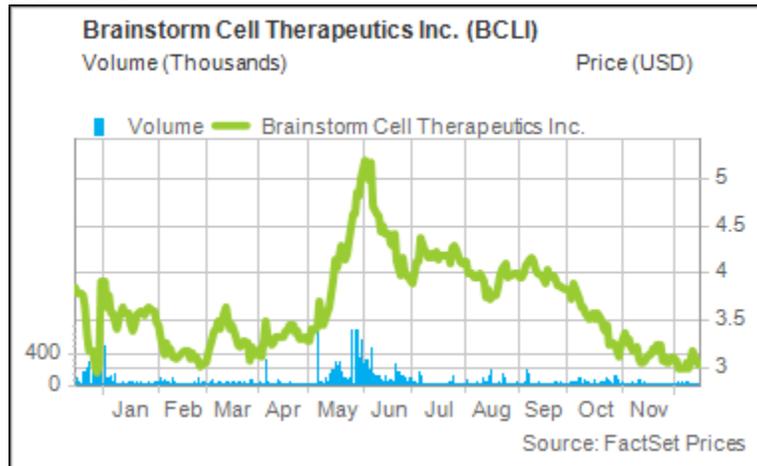
Clinical and regulatory risk. Lead products have to complete clinical trials. Trials may not produce results sufficient for regulatory approval.

Financial risk. The company may need to raise capital in the marketplace, and there can be no assurances that the company will be able to successfully raise capital and/or do so, at favorable terms.

Legal and intellectual property risk. The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and/or that the company may infringe on third parties' patents.

Important Disclosures:

Price Chart:



Price target and ratings changes over the past 3 years:

Initiated – Buy – December 18, 2018 – Price Target \$12

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- 1) **Buy:** the analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** the analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** the analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

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| Rating Distribution | Company Coverage | | Investment Banking | |
|----------------------------|------------------|------------|--------------------|------------|
| | # of Companies | % of Total | # of Companies | % of Total |
| Market Outperform (Buy) | 39 | 89% | 10 | 0% |
| Market Perform (Neutral) | 5 | 11% | 0 | 0% |
| Market Underperform (Sell) | 0 | 0% | 0 | 0% |
| Total | 44 | 100% | 10 | 23% |

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