[224] SAFETY AND EFFICACY OF TRANSPLANTATION OF NUROWN (AUTOLOGOUS MESENCHYMAL STROMAL CELLS SECRETING NEUROTROPHIC FACTORS) IN PATIENTS WITH ALS: A PHASE 2 RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED STUDY.

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- **Investment**
  BrainStorm (Nasdaq: BCLI) is developing NurOwn®, innovative autologous mesenchymal stem cell therapies for incurable neurodegenerative diseases with unmet need, such as Amyotrophic Lateral sclerosis (ALS). Successfully completed Phase-2 US placebo-controlled clinical trial for ALS, confirming safety and efficacy and reached general agreement with FDA to proceed to Phase 3 trial to support a Biologic License Application for NurOwn® in ALS.

- **Business**
  BrainStorm will establish and maintain fully-equipped cell culture facilities in strategic locations in the US Europe and Israel. Each facility will process bone marrow cells harvested from patients, expanded and differentiated into NurOwn®, which will then be transplanted into the patient via intrathecal injection (IT) by neurologists at leading Medical Centers.

- **Core Technology**
  NurOwn® is BrainStorm's proprietary process for the propagation of autologous Mesenchymal Stem Cells, their differentiation into NeuroTrophic Factor (NTF)-secreting cells, and their transplantation at or near the site of damage (to the cerebrospinal fluid). Designed to halt or reverse the underlying pathology, the technology has a high safety profile with no risk of rejection, tumor formation, or ethical issues.

- **Product Profile/Pipeline**
  BrainStorm's target diseases are relentlessly progressive, with limited treatment options and high unmet need. ALS clinical studies have demonstrated safety, no serious side effects and encouraging indications of efficacy. Pipeline includes Multiple Sclerosis, and spinal cord injury. Orphan Drug Designation for ALS in the US and the EU, and Fast-track designation by the FDA, supports a short time-to-market.

What Next?

BrainStorm has recently completed a Phase 2 FDA-approved US multi-center double-blind placebo controlled clinical trial for ALS. A multinational Phase III trial will start in 2017. The Company is also pursuing additional (Israeli and Canadian) regulatory pathways to provide patients with early access to treatment. The Company is currently seeking an investment to fund clinical activities through Phase 3.