

[311] BRAINSGATE - SPHENO PALATINE GANGLION (SPG) STIMULATION TO TREAT ACUTE ISCHEMIC STROKE

yoram solberg¹, Avinoam Dayan¹, Eyal Shai¹, ¹ 00

- **Investment Rational**
BrainsGate develops a medical device to treat acute stroke. Currently, only up to 15% of patients receive definite treatment, due to time from onset window restrictions. Our technology enhances brain collateral blood flow enabling the treatment to be applied in an extended window of 24 hours from stroke onset and permitting the therapy to majority of ischemic stroke patients.
- **Business Strategy**
BrainsGate is currently running the ImpACT-24b study, a phase 3 international clinical trial. The trial is planned to be finalized within a year. Positive results will lead to FDA PMA and European CE mark submissions. Following regulatory approvals, BrainsGate is planning start its marketing and sales activities worldwide.
- **Core Technology**
BrainsGate proprietary technology involves the electrical stimulation of the Spheno-Palatine Ganglion (SPG). SPG stimulation leads to increase of blood supply to the brain. Our therapeutic platform may serve multiple vascular brain disorders. We currently focus on the development of treatment to acute ischemic stroke in an extended time window which will expose the therapy to majority of patients.
- **Product Profile/Pipeline**
Our device is a small electrode which is implanted via the roof of the mouth to be positioned next to the SPG. The implantation is a minimal invasive, local anesthesia, bed side, 10 minutes' procedure that is carried out by any physician. Our next milestone is to make the implantation even simpler, a 5 minutes injectible device procedure.
- **What's Next?**
BrainsGate's plans for the coming year are to finalize the development of the injectible device and to conclude our phase 3 FDA regulated randomized clinical trial. Positive results will to PMA and CE mark submissions. Additionally, BrainsGate is about to initiate a clinical trial to test SPG stimulation in combination to currently approved therapies: Neurothrombectomy and IV thrombolysis.