

## **[385] BRAINSGATE: SPHENO PALATINE GANGLION STIMULATION FOR TREATMENT OF ACUTE ISCHEMIC STROKE**

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### **Investment Rational**

BrainsGate developed the ISS (Ischemic Stroke System) medical device to stimulate the Spheno palatine ganglion (SPG). The recently concluded pivotal study, ImpACT-24B, demonstrated the SPG stimulation is safe and effective in treating acute ischemic stroke patients in a 24 hour window. The unmet need of ischemic stroke patients offers a very significant potential for SPG stimulation therapy.

### **Business Strategy**

The current recanalization therapies are extremely limited due to strict eligibility criteria and complex operational requirements resulting in only 5%-15% of patients receiving active therapy. BrainsGate's solution is simple and fast to apply allowing its use in most medical facilities where acute stroke patients are first admitted. The therapy can serve as stand alone, or complementary treatment to recanalization therapies.

#### ○ **Core Technology**

SPG stimulation is achieved using a miniature proprietary injectable neurostimulator to deliver a personalized stimulation regime. SPG stimulation augments collateral blood flow and protects the integrity of the blood brain barrier, which can serve multiple central nervous system applications. Injecting the neurostimulator to the patient is a less than 5 minutes bedside procedure performed under local anesthesia.

#### ○ **Product Profile/Pipeline**

Following the completion of the ImpACT-24B pivotal study, the company is now seeking regulatory approvals both in the US (preparing a PMA application) and in Europe (obtaining CE certification for the ISS).

#### ○ **What's Next?**

Regulatory approvals (FDA, CE)

A new clinical trial to evaluate the ISS in hyper acute time window. The hyper acute application further expands market potential and the synergy with recanalization therapies