

NeuroSigma Pursues Multi-Pronged Strategy in Neurological Disorders Market

by James Cavuoto, editor

NeuroSigma Inc., the Los Angeles, CA manufacturer of neuromodulation devices, has adopted a unique strategy for competing in the market for treating neurological disorders. While many startup firms pin their hopes on a single device platform, NeuroSigma has elected to pursue three or four simultaneously. Their platforms include both surface stimulation and implanted versions of trigeminal nerve stimulation systems, plus deep-brain stimulation. Down the road, the company is looking at new materials that may herald a new class of implanted brain devices.

The first embodiment of NeuroSigma's TNS platform is the Monarch system, which uses surface stimulation (the company calls it eTNS). A subcutaneous version (which the company calls sTNS and uses an implantable pulse generator) is under development. TNS stimulates branches of the trigeminal nerve, which are located very close to the surface of the skin in the forehead. The low-energy stimulus is confined to the soft tissues of the forehead without direct penetration into the brain.

The trigeminal nerve is the largest cranial nerve, offering a high-bandwidth pathway for signals to enter the brain. The trigeminal nerve projects to specific areas of the brain, such as the locus coeruleus, nucleus tractus solitarius, thalamus, and the cerebral cortex, which are involved in epilepsy, depression, PTSD, ADHD, and other disorders. PET imaging studies confirm that eTNS activates or inhibits key regions implicated in these disorders and the changes were observed within minutes of therapy. The company believes that many patients will elect to be treated with the eTNS at first, but once approved by regulatory agencies, patients who respond well to eTNS may opt for the implantable sTNS system.

Trigeminal nerve stimulation was invented at UCLA [NBR Mar09 p1] and is exclusively licensed to NeuroSigma. Both Boston Scientific and Advanced Bionics helped fund some of the early research at UCLA on TNS applications in epilepsy.

Leon Ekchian is NeuroSigma's president and CEO. Prior to co-founding NeuroSigma in 2008, he served as president of Arrowhead Research Corp., a publicly-traded company that commercializes innovative nanotechnologies in the electronic and biotech industries. Leon received a B.S., M.S., and Ph.D. in electrical engineering from MIT and an MBA from UCLA's Anderson School of Management.

Earlier this year, NeuroSigma announced that it received CE Certification for the external Monarch device for the adjunctive treatment of epilepsy and major depressive disorder, for adults and children 9 years and older. The eTNS system will be sold under prescription from a physician in the European Union. It is composed of an external pulse generator and disposable electric patches placed on the forehead that are replaced daily. The patches can be worn primarily in the evening while asleep. In clinical studies, eTNS was well tolerated and has been shown to substantially reduce seizures in patients with epilepsy and improve mood in patients with depression.

NeuroSigma is planning to introduce this treatment at major EU epilepsy and depression centers and is establishing a marketing, sales, and distribution infrastructure for a fourth quarter 2012 product launch in the EU. Epilepsy and depression are major health concerns in the EU, with approximately 4 million people suffering epilepsy and 20 million experiencing clinical depression.

"As a company, we are committed to making eTNS affordable and widely available in the EU," said Ekchian. "We are excited to begin the rollout of our commercialization strategy for patients suffering from epilepsy and depression. Simultaneously, we will seek to obtain approvals in other parts of the world. In the U.S., we will be submitting a request to the FDA for an Investigational Device Exemption to commence a multi-center eTNS pivotal trial in epilepsy. Over 30 major centers in the U.S. and Europe have expressed interest in being part of this pivotal trial."

Christopher DeGiorgio, vice-president of neurology at NeuroSigma and professor of neurology at the UCLA School of Medicine, spearheaded clinical development of eTNS for epilepsy. Clinical and human mechanism of action studies of eTNS in major depression were led by Ian Cook, a senior medical advisor to NeuroSigma and a professor-in-residence at the UCLA School of Medicine's department of psychiatry, where he serves as director of the UCLA Depression Research and Clinic Program. "As a noninvasive neuromodulation therapy, trigeminal nerve stimulation may represent a paradigm shift in the way we treat major depression and offers the potential to significantly improve the lives of millions of people without the side-effects common to medication treatment," said Cook.

NeuroSigma is looking at two novel indications for DBS: obesity and post-traumatic stress disorder. The company has sponsored pre-clinical work in this area at VA facilities.

Apart from its efforts with TNS and DBS, NeuroSigma is developing thin-film nitinol-covered stents for endovascular applications through its majority-owned subsidiary, NSVascular, Inc. Nitinol is a superelastic nickel and titanium alloy with unique properties that allow deformation and subsequent full recovery of the original shape upon exposure to body heat. Recently, the company was awarded a Phase I NIH-STTR grant from the National Institute of Neurological Disorders and Stroke for the further development of its stent for the treatment of brain aneurysms. Mayo Clinic is the sponsored research institution in this STTR grant.

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Market: Trigeminal nerve stimulation and DBS
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