

# Intelect Medical Inc.

## *Deep brain stimulation for TBI and stroke*

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**Contact:** Vincent P. Owens, President & CEO

**Industry Segment:** Neurostimulation

**Business:** Deep brain stimulation implants

**Founded:** April 2005

**Founders:** Ali Rezaei, MD (Cleveland Clinic Foundation); Nicholas D. Schiff, MD (Weill

Medical College of Cornell University)

**Employees:** 10

**Financing to Date:** \$17.5 million

**Investors:** Greatbatch Inc.; Boston Scientific Corp.; Ohio's Third Frontier Project

**Board of Directors:** Joseph Hahn, MD (Cleveland Clinic); Michael O'Boyle (Cleveland Clinic); Thomas Hook (Greatbatch Inc.); Ali Rezaei; Wendelin Maners (Boston Scientific Inc.); Vincent P. Owens

**Scientific Advisory Board:** Ali Rezaei; Nicholas D. Schiff; Alim Louis Benabid, MD (Joseph Fourier University Hospital, Grenoble), Andre Machado, M.D. (Cleveland Clinic)

incubator Bioenterprise Corp. helped the company find its first home and a \$7.5 million grant to the Cleveland Clinic from the Ohio Third Frontier program provided the initial funding for the deep brain stimulation technology. (See "The New Device Incubators," *START-UP*, June 2007.) Owens' first task was to focus the company's efforts by sorting out, from a large array of potential applications for deep brain stimulation, the initial addressable markets. He settled on stroke rehabilitation, an emerging market in which **Northstar Neuroscience Inc.** has already broken ground with an implantable cortical stimulation device, and also traumatic brain injury, a poorly understood condition in which there is great deal of federal interest at the moment because of the number of traumatic brain injury sufferers returning from the military conflicts in Iraq and Afghanistan. (See "Northstar's Buzz," *IN VIVO*, September 2005 and "Treating Traumatic Brain Injury," *START-UP*, January 2007.)

In the process of conducting a strategic assessment of the portfolio, Owens contacted Steve LaPorte, the former head of the neuroventures division of Medtronic. LaPorte had some familiarity with the technology; Rezaei, it turns out, had already pitched his portfolio to Medtronic as a potential investor or acquirer. LaPorte did more than advise Owens; he decided to join Intelect Medical as chief technology officer on a part-time basis after retiring from Medtronic. Likewise, James Mellor, Intelect's VP of business and therapy development, who worked with Owens

They came, they saw, they became convinced. It was the vision of Ali Rezaei, a neurosurgeon at the **Cleveland Clinic Foundation**, for a future in deep brain stimulation that lured several medical device executives to Cleveland. Vincent Owens came from a career in the design and manufacture of implantable leads and pulse generators for cardiac rhythm and neuromodulation devices, first, at Biomec Cardiovascular Inc. (BCI), which is now part of **Greatbatch Inc.** (by way of Greatbatch's acquisition of BCI acquirer Enpath Medical Inc.), and then at Texcel LLC, a contract manufacturer of neurostimulators and implantable defibrillators based in Massachusetts. Owens says that when he was running the implantable leads company in Minneapolis back in 2003, Rezaei contacted him about developing a prototype of a new type of deep brain stimulation lead for primate studies.

Rezaei, whose clinical areas of expertise include the neurosurgical management of patients with severe movement disorders such as Parkinson's disease and dystonia, psychiatric conditions such as depression and obsessive compulsive disorder, chronic pain, and traumatic brain injury and stroke, came and talked to the staff of BCI. "The team was blown away by his vision of the neuromodulation field," Owens says.

When Cleveland Clinic Innovations, the commercialization arm of the Cleveland Clinic, was ready to spin out Rezaei's IP into a start-up, along with deep brain stimulation therapies licensed from the **Weill Medical College of Cornell University**, Owens and two of his colleagues from BCI and Texcel, both former development engineers at the Medtronic Neurological division of **Medtronic Inc.**, came to Cleveland to help start up new company **Intelect Medical Inc.** Regional

at BCI, had previously defected from Medtronic after 15 years in its cardiac rhythm management group. While searching for clinical and regulatory support, Owens and Mellor came across Linda Johnson, an industry veteran who spent six years at Medtronic's cardiac rhythm management division. Johnson recently signed on as Intelect's VP of clinical and regulatory affairs.

There are other signs that Intelect is really onto something. Major neurostimulation force **Boston Scientific Corp.** was also drawn to the start-up by the intellectual heft of its founders, which also include Nicholas Schiff, the director of the Laboratory of Cognitive Neuromodulation at the Weill Medical College. Boston Scientific participated, along with Greatbatch, in Intelect's \$7 million Series B round in June 2007, and took a board observer seat. GreatBatch, a worldwide manufacturer of components for implantable medical devices, holds Biomec's Series A round investment in Intelect; Biomec had invested \$3 million in the start-up in September 2005.

Intelect believes it offers technological advances over the deep brain stimulation devices of predecessors. According to Owens, the company's proprietary external waveform generators and directional stimulation leads could improve device effectiveness and longevity as well as reduce stimulation side effects.

Intelect began work in traumatic brain injury (TBI). There are five million TBI patients in the US today, and the number grows by 1.4 million each year, as people suffer falls, traffic accidents, and assaults. The company will implant its deep brain stimulators to stimulate specific brain targets in the thalamus, based on neurobehavioral criteria and overall patterns of cortical injuries. Rezai has an approved IDE for a 12-patient TBI study and has already implanted one patient who was in a minimally

conscious state (MCS). To the layperson, this type of patient appears to be in a persistent vegetative state, but MRI and functional MRI scans reveal that many of the brain networks are intact in such individuals. The goal of the clinical trial will be to see if neurostimulation protocols succeed in resynchronizing or reactivating intact neural networks and improving cognitive function.

Intelect estimates that this deep brain stimulation market segment includes more than 110,000 individuals in the US with chronic severe cognitive disability, including MCS patients.

Researchers have reported, anecdotally, on the results of one patient—a 38-year old man who had been in a minimally conscious state for six years. Surgeons at the Cleveland Clinic implanted electrodes in the thalamus of the brain, left them there, inactivated, for six weeks following the procedure, and then for a six-month trial period, intermittently activated the stimulators in a blinded manner, so that study investigators didn't know when stimulation was on or off. There was a significant improvement in the man's abilities to move, communicate, and function, the researchers reported, and these gains endured even when the stimulation was turned off. A one-patient study is merely a hint of things to come, but Owens says the investigators are applying to the FDA to broaden patient inclusion criteria and expand the study to different sites to accelerate enrollment.

It is very early in Intelect's validation of the technology and very early in a new field as well. Owens says, "we are investing the proper amount of time to understand what the reimbursement and regulatory landscapes look like, clinically relevant outcomes measures, and all of the factors that will be so important in doing this the right way." The company will have a lot of new turf to plough as it

nears commercialization; TBI care pathways are fragmented, if such patients are under the care of any physician at all. Intelect will initially approach the market through specialized brain injury centers and patient advocacy groups, but again, it will take advantage of renewed government interest in the condition.

It's also early, but not quite as early, in Intelect's second target market, ischemic stroke rehabilitation therapy, for which it plans to pursue an IDE for a pilot study later this year. Intelect's deep brain stimulation for stroke is based on the work of Rezai and Dr. Andre Machado, a Cleveland Clinic neurosurgeon. There are 5.5 million stroke survivors in the US and as many as 85% have some degree of upper extremity motor impairment. Intelect estimates its potential market at approximately 157,000 patients per year. Northstar Neuroscience has already gone some distance to prepare the market. It just finished enrollment and randomization for its EVEREST pivotal trial of cortical stimulation to restore hand or arm impairment in stroke survivors. Intelect's deep brain stimulation approach is more invasive than Northstar's cortical stimulator, but Intelect believes it has the potential to enhance neural plasticity and to perhaps achieve a longer duration of effect and promote greater recovery following a stroke. Of course this remains to be determined, as the company completes the necessary human clinical studies. The company is finishing preclinical studies for ischemic stroke rehabilitation and has a lot of work ahead of it, but it has the intellectual and financial capital to do it. Intelect is today a tiny company, but it is a powerhouse of neurostimulation expertise on both the device and clinical sides of the equation. It looks like it might be just the company to pioneer these new applications and crack Medtronic's hegemony in deep brain stimulation. —**Mary Stuart**