

NDI Medical's Spin-Off Model for Neurostimulation

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Written By Mary Stuart
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Summary: The neurostimulation market is becoming electric for many large companies looking for major growth opportunities. Worth \$1.3 billion in the US in 2009, the neurostimulation market is expected to grow to \$2.7 billion by the year 2014. Those robust figures take into account some fourteen different clinical product categories, some of the largest being Alzheimer's disease, chronic pain, depression, epilepsy, obstructive sleep apnea, obesity, and stroke. In fact, that's the beauty of neurostimulation for medical device companies: it offers a single platform technology that can be leveraged over multiple, large product areas. But what model most efficiently helps a company with core expertise in neurostimulation - the knowledge of impulse generators and leads and their interface with nerves, power sources, and controllers - leverage that knowledge over numerous product areas? NDI Medical has its own strategy with a for-profit incubator solely focused on neurostimulation.

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NDI Medical's Spin-Off Model for Neurostimulation

The neurostimulation market is becoming electric for many large companies looking for major growth opportunities. Worth \$1.3 billion in the US in 2009, the neurostimulation market is expected to enjoy a 16% compound annual growth rate over the next five years, reaching \$2.7 billion by the year 2014, according to "US Markets for Neurostimulation Products," a report recently issued by the Medtech Insight division of Elsevier Business Intelligence. (*See Exhibit 1.*) Those robust figures take into account some 14 different clinical product categories, some of the largest being Alzheimer's disease, chronic pain, depression, epilepsy, obstructive sleep apnea, obesity, and stroke. In fact, that's the beauty of neurostimulation for medical device companies: it offers a single platform technology that can be leveraged over multiple, large product areas. But what model most efficiently helps a company with core expertise in neurostimulation – the knowledge of impulse generators and leads and their interface with nerves, power sources, and controllers – leverage that knowledge over numerous product areas?

NDI Medical LLC, a privately held company founded in 2002 in Cleveland, OH, has its own strategy. NDI Medical is a for-profit incubator solely focused on neurostimulation. It vets and develops new concepts until they are ready for spin-off and independent support with external financing. This idea of shepherding early-stage medical technology from inception to company creation is fairly typical of device incubators. (*See "Device Incubation: Challenges in Making the Model Work," START-UP, March 2010 [A#2010900063].*) But NDI's unique spin is its focus on a single technology platform, neurostimulation.

Geoff Thrope founded NDI Medical in 2002 with \$200,000 in private funding from friends and family and some non-dilutive NIH SBIR grants. The company is located in Cleveland, which is somewhat of a "center of excellence" for neurostimulation. Cleveland is home to **Case Western Reserve University**, the **Cleveland Clinic**, the **Cleveland Functional Electrical Stimulation Center**, and perhaps the earliest independent neurostimulation company, NeuroControl Corp. where Thrope was once the national sales manager and director of new business development. NeuroControl (now inactive) operated in functional neurostimulation, the use of electrodes and pulse generators to directly cause muscle contractions, and once offered products for the paralysis that accompanies stroke and quadriplegia, as well as for chronic pain. In fact, Thrope says he has spent his entire career in the neurostimulation field, half of it on the academic side, at Case Western.

NDI Medical's model is to select product areas that meet the following criteria: large markets where there is at least one validated product, but where large clinical needs still exist. What NDI doesn't want to do, says Thrope, is to take on the risk of trying to create a new market where none ever existed before. "I don't want to compare ourselves to Apple, but they have looked at existing markets and said that there are better ways to do the things that people already want to do, and that is our goal." Thrope also notes that the goal of NDI is to serve its shareholders by providing them with good returns, which he hopes they will reinvest in the company and its spin-outs. Thrope says the team at NDI has looked at 87 different opportunities in neurostimulation, "all of which could benefit the human condition," he says, "but when we line up all of our criteria for investment, there is only a small number where we would place our focus."

NDI's first product was a pacing device for the bladder. "We saw that there were a lot of people chasing the urinary incontinence market with devices and drugs. We looked at their mechanisms of action, and we understood why turning on a specific nerve would allow one to be continent, and that became a source of IP." That IP became the basis for NDI's first spin-out, Pelvic Health, developing a product called *MedStim*. MedStim treated incontinence by stimulating the dorsal genital nerve. In April 2008, soon after the spin-out, **Medtronic Inc.** acquired MedStim for \$42 million.

NDI's second spin-out, **Checkpoint Surgical LLC**, is a good example of how the incubator operates. The idea for Checkpoint had been incubating for years, says Thrope. "We first set out to find out if there was a regulatory pathway. Then we made a prototype and ran comprehensive internal clinical validation. We had a

dozen surgeons giving us feedback on the device and we accordingly revised it." Checkpoint Surgical was spun out of NDI in 2009 with feasibility data, IP, and NDI's VP of strategic initiatives Len Cosentino serving as Checkpoint's CEO. In 2009, Checkpoint raised about \$1.25 million from regional venture firm JumpStart and individual investors. [W#200930604] The spin-out raised an additional \$250,000 in April 2010 from angel group Medical Growth Fund, to expand its commercial launch nationwide for the company's 510(k)-cleared product.

Checkpoint's device, the *Checkpoint* stimulator/locator, is a disposable nerve stimulator that can be held in one hand to prospectively help orthopedic, plastic and ENT surgeons test, locate and preserve nerves during surgeries, as an alternative to large, console-based devices. "A tool like this raises the bar for surgical outcomes. Where once a surgeon might have had to offer patients a reduction in functionality, not being able to raise their shoulder as much as they once could, for example, in exchange for pain relief, [as a result of nerve damaged during the procedure] now surgeons are telling us that their patients are getting results that are better than ever."

For its third product, NDI took an alternative approach to a validated market, with a neurostimulation device that works on peripheral nerves to treat chronic pain. **SPR Therapeutics** was spun out in 2009, supported by approximately \$1.5 million in funding from the NIH. Maria Bennett, NDI's VP of clinical affairs, a biomedical engineer who had also worked at NeuroControl, and is the inventor of the SPR technology, is the spin-off's president & CEO.

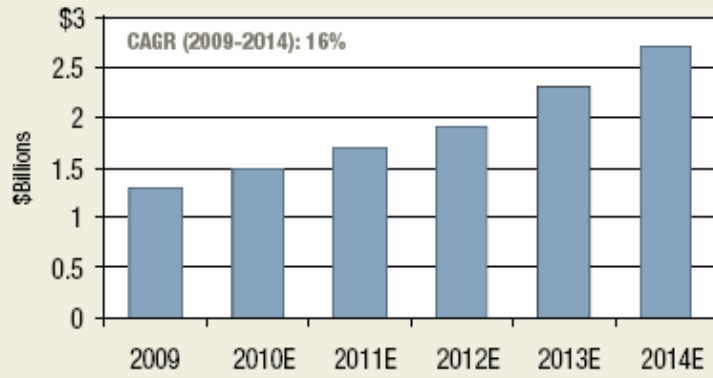
Chronic pain is one of the most established clinical areas for neurostimulation. (See "*Device Investors Look for Gains in Pain*," START-UP, February 2010 [A#2010900033].) As an alternative to the spinal cord stimulators on the market, which act on the central nervous system to broadly dampen pain, companies have long sought to develop site-specific devices that stimulate peripheral nerves, but this goal presents several challenges. Says Thrope, "People have attempted to put the tip of the electrode in, on, or around the peripheral nerve, which requires dissection and some method of stabilization, because it is difficult to keep devices in place." SPR's concept is to more stably anchor neurostimulation leads into muscles. "There are lots of nerves running through muscular tissue. Instead of taking a lead and, with intimate dissection, placing it onto a nerve, on a variation of a theme, we place a lead in a muscle and stimulate the nerves round it." Thrope claims that SPR creates the anesthetic effect, but from a stable location. The stimulation dosage is below the threshold for muscle activation. SPR recently received FDA approval to begin its commercialization trial. Thrope notes that the response from the SPR device is "rapid, and the onset of pain relief is within one week." That has allowed the company to devise a "stage 1" approach to ensure that a patient can benefit from the SPR device before it is ever implanted, a feature that payors are bound to appreciate. SPR has developed a percutaneous stimulator called *NeuroPill*, a patch applied to the lead, and will dose the patient for a period of up to three weeks. If the temporary therapy provides the patient with benefit, the patient can go on to have the permanent implant. In May, NDI received approximately \$1.2 million from a Phase II SBIR grant for the further development of *NeuroPill*.

NDI operates with a staff of 25-30; the number is smaller immediately after a spin-off, Thrope notes, since staff will go with the new company to get it through the next gate.

Thrope emphasizes that as a small company trying to reward shareholders, NDI isn't venturing into territory that is either uncharted or too complex. Obesity, one area where other neurostimulation companies have ventured (and failed), is one such overly complex area, where multiple factors – genetic, metabolic, psychological and social – impact the efficacy of any therapy. Nor "are we going to invent a visual neuralprosthesis. Other companies are working on it, and if they cure blindness, they should get a Nobel Prize!" As it has done so far, NDI will focus on what it can reasonably accomplish and on "what we need to get it through the gate and sell quickly. "

--Mary Stuart

Exhibit 1
US Neurostimulation Market, 2009-2014



NOTE: Totals include implantable and transcutaneous electrical nerve stimulation.
Original report includes break-out.

SOURCE: Report A579, Medtech Insight, March 2010