

Neuros Medical: An Electrical Nerve Block for Chronic Pain

Neuros Medical has been working in the field of neuromodulation for chronic pain since 2008, and in that length of time the company has raised \$34 million, including



its recent \$20 million Series AA round in August 2017, led by US Venture partners and with the participation of **Boston Scientific Corp.**, Aperture Venture Partners, Osage University Partners, and JumpStart. The company has also advanced its *Altius System High Frequency Nerve Block*, originally licensed from Case Western Reserve University, into a pivotal trial. But most importantly, says Jon Snyder, founder and Chief Business Officer of Neuros, the company has answered two key questions: in its initial target application of chronic post-amputation pain, its technology works. That was demonstrated by a pilot trial completed in 2013, in which

seven out of nine subjects experienced a greater than 50% reduction in pain, with an average 83% reduction in pain score. As for the second important unknown: yes, there is market demand. "We are now in our pivotal study, a randomized controlled trial designed to yield a PMA level data set, and in our recruitment efforts, many patients for whom, going forward, there is no long-term option, reached out directly to us."

Chronic post-amputation pain (phantom limb pain or pain in the residual limb or stump) is very common, affecting half of the two million people in the US who undergo amputation of major limbs. This number is expected to increase in coming years because of the prevalence of peripheral artery disease and diabetes.

Pain persists even after the amputation site has healed, because of damage to nerves which scar over, attempt to regrow, and generally continue to fire in an unpredictable fashion. Taking its cue

from the nerve block lidocaine, Neuros has developed a neuromodulation platform that uses a high frequency signal (5-10 kHz) applied to particular peripheral nerves to block them. (This is in contrast to neurostimulation, for example, which stimulates nerves to activate them).

The components of Neuros' *Altius* system are similar to those of spinal cord stimulation; there are cuff electrodes that are coiled around nerves of interest (for a below the knee amputation, electrodes are placed on the common peroneal and tibial nerves, and for above the knee patients, on the sciatic nerve). These are connected by lead wires to an implantable pulse generator (IPG) with a rechargeable battery, placed in a surgically created pocket in the abdomen. Finally, there is an external hand-held controller that patients use to activate the therapy, which, once the patient pushes the button, runs for 30 minutes, a process that can be repeated as often as the patient feels pain

as a result of the activities of daily life.

Before the surgical procedure, which can be accomplished by a vascular, neuro- or orthopedic surgeon, patient response can be gauged using injected lidocaine to block the nerve. If the nerve block doesn't relieve the patient's pain, then there is no use in doing the surgical implantation procedure. This process is much simpler than spinal cord stimulation trials, which involve implanting the electrode and lead, but not the IPG, which remains outside the body during the trial.

As noted, the company is now conducting its pivotal study, a 180-patient, randomized, double blind trial. The primary endpoint is a 50% reduction in pain scores at three months post implant for more than 50% of all pain episodes. Snyder notes that as a brand new therapy, "We have chosen to do the robust, large-patient, PMA-type study with long-term follow-up for safety."