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Start-Up News

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Silere Medical Technology: Neurostimulation for Tinnitus Relief

Start-up **Silere Medical Technology Inc.** is focused on relief for patients who suffer from tinnitus—a constant ringing or buzzing in the ear that can be debilitating—and the company has a unique reason to push for success in this effort, as two of the firm's five founders have the condition.

"I have pretty severe tinnitus, so I'm excited that we can likely solve my problem and preserve hearing," says William "Van" Harrison, CTO and executive director at Silere Medical. Michael Langhout, Silere Medical's president and CEO, also suffers from tinnitus and has a daughter with a profound sensorineural hearing loss who is the recipient of a cochlear implant. Langhout previously founded and was president of Audient LLC, a company focused on hearing health care and digital hearing instruments.

Founded in June 2008, Kirkland, WA-based Silere is developing neurostimulation for the suppression of chronic tinnitus, adapting cochlear implant technology (used to restore hearing to the profoundly deaf) for this application. The company's *T-Stim* implantable neurostimulation device consists of an internal component that is surgically inserted under the skin behind the ear, and an external component that sits behind the ear. Silere anticipates CE Mark approval for the device in Europe by 2012. In the US, the firm has already identified several clinical sites for feasibility and pivotal studies, although no studies have yet been initiated.

The company pegs the US market for the *T-Stim* at $13 billion and the worldwide market at nearly $60 billion. "These are patients experiencing chronic, debilitating tinnitus," Harrison notes. "Our target market is the neurotologist, who is already active with the cochlear implant. But our device is less complex and less invasive."

According to estimates from the American Tinnitus Association, approximately 50 million people in the US are affected by tinnitus, and last year, 12 million people visited physicians complaining of tinnitus, according to a survey of otolaryngologists who practice in the field of hearing impairment. As many as three million are considered chronic sufferers and would be candidates for this device. Tinnitus can occur gradually as a result of hearing damage accumulated over the years, or it can develop suddenly following exposure to loud noises, such as those encountered on the battlefield. "The Veterans Administration is expected to pay over $1 billion in tinnitus-related benefits to nearly 400,000 vets next year alone," Harrison says.

Harrison, who served as a senior vice president of R&D at cochlear implant manufacturer Advanced Bionics Corp. from 1996 to 2006, "stumbled" upon the application for tinnitus. He then discussed the idea of applying the stimulation therapy to tinnitus with Jay Rubinstein, MD, PhD, a professor in the department of otolaryngology at the **University of Washington, Seattle,** and director of the University's Virginia Merrill Bloedel Hearing Research Center.

"Dr. Rubinstein is a unique individual in that his medical specialty is neurotology (ear and temporal bone disorders) and he has a PhD in electrical engineering," Harrison says. "Dr. Rubinstein developed a computational model for hearing and neurostimulation. Based on that model, he came up with a theory of restoring hearing with cochlear implants. All three manufacturers of cochlear implants use an electrode placed inside the cochlea to deliver electrical stimulation to the auditory nerve. A similar yet less invasive technique also seems to treat tinnitus."

"Dr. Rubinstein was able to achieve suppression of the tinnitus after five minutes of electrical stimulation using the signal he developed."

–William Harrison

In a healthy cochlea, the auditory nerve functions normally, which the brain interprets as a "code for silence." When hearing loss occurs, however, the auditory nerve no longer produces normal random fluctuations. The brain responds to the absence of this spontaneous activity by amplifying other signals from the central processing system and this causes the noise typically classified as tinnitus. The *T-Stim* produces a pseudo-spontaneous neural stimulation "in such a way that we restore those spontaneous firings that have stopped as a result of hearing loss when the cochlea can no longer perform normally," Langhout explains.

The internal component of the *T-Stim* consists of a small titanium, hermetically sealed electronic package that conveys processed electric signals to a single electrode. The package is about the diameter of a penny and the thickness of about three pennies. An antenna, housed in flexible silicone and roughly the diameter of a quarter, is placed on the side of the head behind the ear and conforms to the shape of the skull.

The processor is worn externally behind the ear and is modeled after a large, high-powered hearing aid. This component powers the device and produces electrical radiofrequency signals that transmit data to the internal component, so it can provide the correct stimulation to the cochlear neurons.

Initially, the implantation procedure will take 45 to 60 minutes under general anesthesia. "However, we believe it can eventually become an outpatient procedure as we refine the technology and train physicians," Langhout says. "For the neurotologist, the procedure is less invasive than implanting a cochlear implant. The one area that is different is the electrode, which is designed to be very atraumatic and also preserve residual hearing, a critical end point to our clinical trials."

Two human clinical studies of the technology were conducted by Dr. Rubinstein at the **University of Iowa** in 2003, comprising 14 patients total. Three of the 14 subjects had previously been implanted with a cochlear implant for a profound hearing loss, but they also had chronic tinnitus. "Dr. Rubinstein was able to achieve suppression of the tinnitus after five minutes of electrical stimulation using the signal he developed," Harrison says. The other 11 patients did not have a cochlear implant, but had some level of hearing loss with chronic tinnitus. Overall, tinnitus was reduced by over 80% in 10 of the 14 patients, a 71% success rate.

Going forward, a mini-trial of the prototype *T-Stim* is scheduled to begin in about two years at the University of Washington. Following that trial, Silere Medical will pursue the CE Mark in Europe. Two clinics in the European Union have already been identified for clinical studies. The *T-Stim* is projected to have an average selling price of $8,000 through a direct sales force, and new diagnosis-related group (DRG) codes will be needed in the US.

Silere Medical has four pending patents and three other patents licensed from the University of Iowa Research Foundation. To date, the company has raised $350,000 through the five founders, and expects to close a Series A round of approximately $8.5 million by late summer, with several venture capital firms interested in forming a syndication. The start-up is also in discussions with potential strategic partners.

As for the competition, Harrison and Langhout believe Silere Medical is in a class of its own. None of the three established cochlear implant manufacturers—Advanced Bionics, **Cochlear Corp.** (a division of **Ansell Ltd.**), and **MED-EL Corp.**—are currently producing a device that would suppress tinnitus. As for other devices to treat tinnitus, "none of them suppress tinnitus; rather, they mask it," Langhout points out. "They are noise makers that basically present an auditory signal, whether music or white noise, to cover up the sound of the tinnitus." Several hearing-aid companies provide masking devices and **Neuromonics Inc.** offers music therapy. "Many patients attempt to create the masking effect by turning up the radio or TV, but masking does not suppress the tinnitus," Langhout says.