

Unique Neurostimulation for an Underserved Market

The objective of Silere Medical Technology, Inc. is to design, manufacture, and bring to market electrical neural stimulators to treat hearing, balance and perceptual disorders. The initial product offering targets the treatment of Tinnitus, a condition that results in an auditory perception experienced in either the ears or the head when external auditory stimulation is absent. The condition is characterized by ringing, crackling, buzzing, whistling, or pulsing sounds. There is currently no standard treatment for tinnitus.

Large unmet clinical need

The number of individuals afflicted with tinnitus in North America exceeds 50 million. In the U.S., more than 13 million of these seek medical treatment. Silere's target market is the 2.7 million patients with symptoms that are highly debilitating and which severely affect their ability to function. This reflects a large unmet clinical need, representing 1% of the population. Based on human data the potential benefits of electrical stimulation for the treatment of tinnitus indicates that between 50 and 60% of severely afflicted subjects would gain relief. A product that treats this population has the potential to benefit between one million and 1.62 million patients. Silere estimates that demand for its products could reach 70,000 units per year in the fifth year of commercial distribution. This corresponds to annual sales of \$400 million per year. The American Neuro-Otology Society (ANS) has 700 members, all of whom are qualified as Silere's customer group. Anecdotal discussions and clinical record reviews with practicing neuro-otologists indicate that 10 to 20 patients a week report tinnitus as their main complaint.

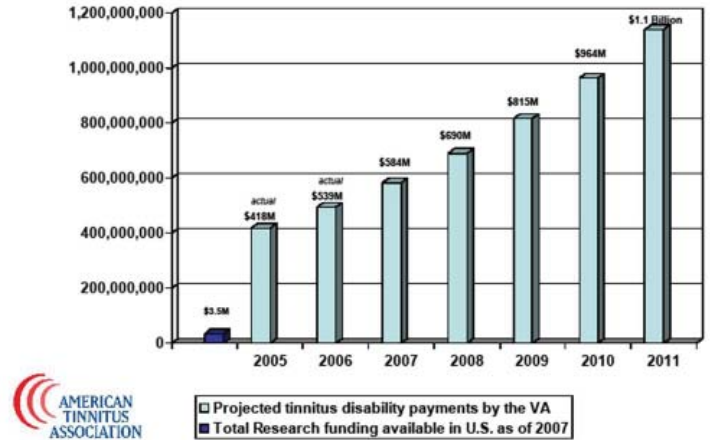
Familiar surgical approach

The technology used to build Silere's proposed products is equivalent to the technology used to design and build a cochlear implant. The product architecture is conceived and defined to allow the use of software to modify, upgrade and expand the clinical benefits of Silere's technology and stimulation paradigms. It is Silere's intent to develop and sell software products that can increase the therapeutic utility of its systems as tinnitus treatment experience and knowledge is developed and refined.

Demonstrated clinical effectiveness

While the clinical effectiveness of Silere's approach has been demonstrated in multiple clinical settings, additional validation of the technology will be accomplished with single center and multi-center trials. Silere anticipates submitting a PMA application to the FDA during its fourth year of operations. Silere will apply to the FDA for a category B device assignment during the early phase of development and to the AMA for a Category III coding assignment.

Projected Cost to VA for tinnitus disability compensation
Projection based on five-year trend data



Source: Compensation & Pension Services, Veterans' Benefits Association.
Projected Dollar amounts do not include inflation.

Experienced leadership

Silere was co-founded by a group of industry veterans including Chief Medical Officer Jay T. Rubinstein, MD, PhD, a professor at the University of Washington and director of the Virginia Merrill Bloedel Hearing Research Center, a leading Neuro-otologist and Otolaryngologist, and pioneer in the treatment of hearing disorders utilizing electrical neurostimulation. William 'Van' Harrison, Executive Chair and CTO, whose prior work with neurostimulation technology at Advanced Bionics led to the development of the most technologically advanced neurostimulation device ever developed and commercially distributed; Mrs. Dorcas Kessler, MA, Vice President, Clinical Research and Regulatory Affairs, a highly regarded and well-known contributor to the development and growth of the cochlear implant industry. Mrs. Kessler defined and managed the original clinical trials that resulted in FDA approval of the first cochlear implant system developed in the US.

Management



President & CEO: Michael F. Langhout, MBA

Mr. Langhout has over 20 years of senior executive experience in both Lifesciences and other manufacturing companies. Previously he was Founder and President of AUDIENT LLC, an international hearing health care services company distributing digital hearing instruments to over 1,000 medical providers. His interest in auditory processing disorders and neural stimulation originated with his oldest daughter, who became profoundly deaf at an early age. For the past 25 years he has developed many beneficial business relationships with Silere's targeted international customer group.

Contact

CEO: Michael Langhout

www.silere.com
Tel: (425) 269-3000