



## Corporate Backgrounder

Helius Medical Technologies (Helius) is a United States-based medical device company focused on neurological wellness. The company is committed to leading the advancement of unique and non-invasive platform technologies designed to amplify the brain’s powerful ability to heal itself. Helius intends to submit for FDA, Health Canada and CE Mark and TGA regulatory approval of the Portable Neuromodulation Stimulator (PoNS®) device, in 1H 2018.

<b>Founded</b>	2014
<b>Headquarters</b>	Newtown, Pennsylvania
<b>Public Offering</b>	Reverse merger June 2014 with NeuroHabilitation Corporation
<b>Stock/Exchanges</b>	Helius Medical Technologies is traded on the Toronto Stock Exchange (symbol: HSM) & Over-the-Counter Bulletin Board in the U.S. (symbol: HSDT) with a goal to be listed on a US national securities exchange
<b>Employees</b>	10
<b>Website</b>	<a href="http://www.heliusmedical.com">http://www.heliusmedical.com</a>
<b>Contact Information</b>	Helius Medical Technologies, Inc. 642 Newtown Yardley Rd., Suite 100 Newtown PA 18940 215-944-6100

### **Mission:**

Develop, license and acquire unique, non-invasive platform technologies designed to help patients affected by neurological symptoms caused by disease or trauma.

### **Product Platform:**

- The PoNS device is an investigational non-invasive wearable medical device being studied for the treatment of neurological symptoms caused by disease or trauma. The first targeted application of the PoNS is for balance disorder in mild to moderate TBI.
- The PoNS device represents the first of a series of non-invasive devices – based on the PoNS Therapy platform -- designed to amplify the brain’s powerful ability to heal itself. This is part of a new approach to “symptom treatment” for the rising number of patients today who have experienced loss of function as a result of neurological disease or trauma.
- The PoNS Therapy is currently being evaluated in a completed, pivotal, multicenter, clinical trial in subjects with a chronic balance deficit due to mild to moderate Traumatic Brain Injury (TBI). This trial was deemed a non-significant risk trial by the FDA.
- The PoNS Therapy is also being evaluated in the treatment of symptoms related to other neurological diseases including Multiple Sclerosis (MS) and Cerebral Palsy (CP).
  - A feasibility study of chronic balance and gait deficit due to MS was completed at McGill University’s Montreal Neurological Institute and Hospital and Concordia University PERFORM Center.
  - Results from a pilot study, investigating the benefits of the PoNS with physiotherapy in treating symptoms of pediatric CP, have been accepted for publication in a rehabilitation peer reviewed journal.
  - In MS, a registrational trial for the treatment of chronic gait deficit, is scheduled to start in 2018.

- Helius is the only company focused on commercializing the first, non-invasive means for delivering neuromodulation through the *tongue* – the use of external stimulation to intentionally change or regulate the internal electrochemical environment of the brain. The PoNS™ induces neuromodulation by stimulating brain structures through the cranial nerves connected to the tongue. Researchers believe that using the tongue as a gateway to the brain is a natural, non-invasive and direct way to stimulate the brain.<sup>1</sup> Stimulation of the brain and brain-stem via cranial nerve innervation of the tongue is hypothesized to encourage neuroplasticity, or a “re-routing,” enabling the damaged brain to compensate for lost function due to trauma or disease, by recruiting existing working neurons.
- Through its first wholly-owned subsidiary, NeuroHabilitation Corporation, Helius is building upon almost 40 years of scientific research on neuromodulation, pilot studies and case studies performed at the Tactile Communication and Neurorehabilitation Laboratory (TCNL) at the University of Wisconsin-Madison.
- More than 260 patients in the U.S. have been treated under IRB approval and achieved positive outcomes through multiple pilot and case studies on the PoNS device. Based on the positive results of these proof of principle studies, Helius is moving forward with a robust clinical development plan that includes registrational clinical trials in pursuit of FDA, Health Canada and CE Mark and TGA regulatory approval.
- The PoNS Therapy platform is protected by over 40 patents including proprietary methods, as well as design and utility of therapeutic delivery mechanisms.

### **Company History:**

- Early 1990s: The Tactile Communications and Neurorehabilitation Laboratory (TCNL) was founded at the University of Wisconsin-Madison
- Late 2000s: TCNL developed and built the PoNS device and principals formed Advanced NeuroRehabilitation, LLC (ANR)
- 2013: ANR and MPJ Healthcare (medical device commercialization experts) formed NeuroHabilitation Corporation, which signed a Collaborative Research and Development Agreement (CRADA) with the U.S. Department of Defense
- 2014: Helius was founded and acquired NeuroHabilitation in a reverse merger and became a publicly traded company on the Canadian Stock Exchange
- 2016: Helius began trading on the Toronto Stock Exchange

### **Partnerships for Success:**

The clinical research and development path for the PoNS represents an innovative private-public approach and the company has established several major collaborations that highlight its potential:

- **U.S. Armed Forces:** Because of its potential application for treating symptoms of Traumatic Brain Injury (TBI) for armed services veterans and members, the United States Army Medical Research and Materiel Command (USAMRMC) holds a Cooperative Research and Development Agreement (CRADA) with NeuroHabilitation, a division of Helius, to fund clinical studies to further evaluate the PoNS device and to work with the FDA to get the PoNS approved for use. Pursuant to the CRADA, U.S. Armed Forces are called to fund, manage and provide regulatory oversight associated with the clinical effort necessary to secure FDA clearance and approval, at which point USAMRMC will transfer such clearance or approval to Helius.
- **TCNL:** TCNL, located at the University of Wisconsin-Madison, studies applied neuroplasticity with the aim of developing solutions for sensory and motor disorders. This is the home laboratory of the scientists behind Helius’ PoNS technology.
- **Manufacturing**

Ximedica is a medical device product development company that designed and manufactured the clinical prototype of the PoNS™ device used in clinical trials. Ximedica is a full-service ISO 13485 certified and FDA registered product development firm with an exclusive focus on medical products. With more than 25 years of experience developing medical devices, combination products and consumer healthcare, Ximedica’s client base spans the globe and ranges from start-ups to the world’s largest medical device manufacturers.

Key Tronic Corporation is an electronic manufacturing services provider who supported Helius in product development, clinical prototype manufacturing and was named Helius' commercial contract manufacturer in 2017. With over 45 years of experience, Key Tronic Corporation specializes in PCBA and full product assembly, plastic molding, precision metal stamping, fabrication and finishing, and engineering services with products ranging from simple consumer devices to complex, high end commercial and industrial electro-mechanical products.

**Market Potential:**

While physicians and patients turn to available options to manage a host of neurological symptoms today, for millions living with these chronic disorders, limited treatment options exist that actually help rehabilitate lost function.

- Industry analysts report that devices are gaining acceptance as therapy alternatives for certain chronic conditions. Positive outcomes with PoNS Therapy, for example, could reduce the cost of pharmaceutical and rehabilitation treatments for patients today.
- The U.S. neurostimulation device market is expected to grow to \$4 billion in 2018. The neuromodulation market is estimated at nearly \$6 billion worldwide by 2020 and is expected to grow in the double digits on a percentage basis annually.
- Fueling the growth of the market is the development of non-invasive neurostimulation devices, which will help increase the adoption of these devices as treatment alternatives.<sup>4</sup>
- Other contemporary forms of neurostimulation are costly and invasive, with the potential for adverse effects. For example, deep brain stimulation (DBS), which uses an implanted pacemaker-like electrical device to decrease tremors in Multiple Sclerosis, carries surgical risks.<sup>5</sup>

**Leadership**

<p><b>Management Team</b></p> <ul style="list-style-type: none"> <li>– Philippe Deschamps, President, Chief Executive Officer and Chairman of the Board of Directors</li> <li>– Dr. Jonathan Sackier, Chief Medical Officer</li> <li>– Joyce LaViscount, Chief Financial Officer and Chief Operations Officer</li> </ul>	<p><b>Board of Directors</b></p> <ul style="list-style-type: none"> <li>– Philippe Deschamps, President, Chief Executive Officer and Chairman of the Board of Directors</li> <li>– Thomas Griffin, Board of Directors, Chairman of Audit Committee</li> <li>– Blane Walter, Board of Directors and Member, Audit Committee</li> <li>– Edward M. Straw, Board of Directors and Member, Audit Committee</li> <li>– Mitch Tyler, Clinical Director of Education/Training at TNLC; co-inventor of the PoNS™ device, Board of Directors</li> <li>– Dane C. Andfreeff, Board of Directors</li> <li>– Huaizheng Peng, PhD, Board of Directors</li> </ul>
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<sup>1</sup> Y.P. Danilov, M.E. Tyler, K.L. Skinner, R.A. Hogle, and P. Bach-y-Rita, *Efficacy of electro tactile vestibular substitution in patients with peripheral and central vestibular loss*, J. Vestib. Res., 16:119-130, 2007; M. Tyler, Y. Danilov and P. Bach-y-Rita, *Closing an open-loop control system: Vestibular substitution through the tongue*, J. Integrat. Neurosci., 2:159-164, 2003; Bach-y-Rita P., Kaczmarek K., Tyler M. and Garcia-Lara J., *Form perception with a 49-point electro tactile stimulus array on the tongue*, J. Rehab. Res. Develop. 35 (1998) pp. 427-431

<sup>2,3,4</sup> Root Analysis Research & Consulting: *Neurostimulation Device Market, 2012-2017*. Gross, R. (2008). "What Happened to Posteroventral Pallidotomy for Parkinson's Disease and Dystonia?" *Neurotherapeutics* 281- 293.

<sup>5</sup> Tyler, M.E., Kaczmarek, K.A., Rust K.L., Subbotin, A.M., Skinner, K.L., & Danoliv, Y.P. (2014). Non-invasive neuromodulation to improve gait and chronic multiple sclerosis, *Journal of NeuroEngineering and Rehabilitation*.