UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

March 20, 2019
Date of Report (Date of earliest event reported)

HELIUS MEDICAL TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**001-38445**	**36-4787690**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

642 Newtown Yardley Road, Suite 100
Newtown, Pennsylvania, 18940
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (215) 944-6100

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a12 under the Exchange Act (17 CFR 240.14a12)
- ☐ Precommencement communications pursuant to Rule 14d2(b) under the Exchange Act (17 CFR 240.14d2(b))
- ☐ Precommencement communications pursuant to Rule 13e4(c) under the Exchange Act (17 CFR 240.13e4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☑

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☑

Item 7.01 Regulation FD Disclosure

The management of Helius Medical Technologies, Inc. (the “Company”) will give a presentation at the Oppenheimer Annual Healthcare Conference in New York, NY on Wednesday, March 20, 2019 at 2:10 p.m. ET.

A copy of the presentation slide deck that will be presented at the conference is being furnished as Exhibit 99.1 to this Report on Form 8-K. A live webcast of the presentation may be accessed by visiting the Investor Relations section of the Company’s website at https://heliusmedical.com/index.php/investor-relations/events/upcoming-events.

The information in this Report, including Exhibit 99.1 hereto, is furnished pursuant to Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing. The Company’s submission of this Report shall not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

This Report and Exhibit 99.1 hereto contain forward-looking statements within the meaning of the federal securities laws. These forward looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibit 99.1 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Corporate Presentation, dated March 2019

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HELIUS MEDICAL TECHNOLOGIES, INC.

Dated: March 20, 2019

By: /s/ Joyce LaViscount
Joyce LaViscount
Chief Financial Officer

Exhibit 99.1

Helius
MEDICAL TECHNOLOGIES

A Revolution in Mind

March 2019

Legal Disclaimers

This presentation contains forward-looking statements, including statements about: uncertainties regarding the FDA regulatory approval process, including whether the results of our clinical trials will be sufficient to support an FDA approval of the PoNS™ device for marketing or whether the FDA may require that the Company conduct future clinical trials; future economic, competitive, reimbursement and regulatory conditions; new product introductions; ability to commercialize its PoNS™ treatment; demographic trends; the intellectual property landscape; financial market conditions; continued availability of capital and financing, including its ability to continue as a going concern; and future business decisions made by the Company and its competitors. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Factors that may cause actual results to differ materially from any future results expressed or implied by any forward looking statements include the risks described in the "Risk Factors" section of Company's Annual Report on Form 10-K for the period ended December 31, 2018, as well as those set forth from time to time in the Company's other SEC filings, available at http://www.sec.gov. The forward-looking statements in this presentation represent our views as of the date of this presentation. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation.

Certain data in this presentation was obtained from various external sources. Neither the Company nor its affiliates, advisers or representatives have verified such data with independent sources. Accordingly, neither the Company nor any of its affiliates, advisers or representatives make any representations as to the accuracy or completeness of that data or commits to update such data after the date of this presentation. Such data involves risks and uncertainties and is subject to change based on various factors.

We are a neurotech company in the medical device industry focused on neurological wellness.

Helius Leadership Team:

Experienced Leadership With Healthcare and Commercialization Expertise

Philippe Deschamps
President, Chief Executive Officer & Chairman

- 30+ years in the health sciences industry
- Former CEO at MediMedia Health
- Former President and CEO at GSW Worldwide (Division of inVentiv Health)
- Former Director of Neuroscience Marketing at Bristol-Myers Squibb

Joyce LaViscount
Chief Financial Officer and Chief Operating Officer

- 29+ years in the health sciences industry
- Accomplished pharmaceutical/healthcare public company CAO
- Former COO and CFO at MM Pharmaceutical Solutions
- Former Executive Director/Group Controller at Aptalis Pharmaceuticals

Dr. Jonathan Sackier
Chief Medical Officer

- 30+ years in the health sciences industry
- Trained surgeon and pioneer of new medical technologies
- Has helped build several companies including medical technology, research and product-design and medical contract sales organizations

Jennifer Laux
Chief Commercial Officer

- 22+ years in the health sciences industry
- Former VP of Commercial at Inovio Pharmaceuticals
- Former VP of Cardiovascular Marketing at Boehringer Ingelheim
- Former Executive Director of Cardiovascular Franchise at Merck

Investment Highlights

Platform Technology	• First in class, non-invasive neurotechnology with broad potential in treating symptoms of neurological disease and trauma
Large Initial Market	• Over 1.5M people in US with chronic balance deficit caused by Mild-to-Moderate Traumatic Brain Injury (mmTBI)
PoNS™ Treatment	• "First mover advantage" with demonstrated safety and efficacy in a market with few viable treatment options
Clinical Pipeline	• Pilot studies completed in Stroke, Multiple Sclerosis, and Cerebral Palsy
Regulatory Progress	• Cleared in Canada. US and EU clearances pending
Robust IP	• Method Patent portfolio coverage extends to 2028; utility and design patents to 2035

Large and Growing Addressable Market

Chronic balance deficit is a long-term disability associated with neuro trauma and disease[2]

Gait speed, cadence, stride length and time spent on double-limb support are frequently affected in individuals with balance deficit

People worldwide experience new TBI cases annually[1]

People living with chronic balance deficit following an mmTBI in the U.S. alone[3]

New cases annually of chronic balance deficit caused by mmTBI[4] in the U.S. alone

After the initial medical event, TBI can present significant long-term disabilities and challenges to the individual, family, and society

Clinical Support for PoNS™ Treatment:
RCT Enrollment Criteria for Mild-to-Moderate TBI with Chronic Balance Deficit

- Safety and efficacy of PoNS Treatment demonstrated in two double-blind randomized controlled trials (RCTs)
- Enrollment criteria included patients with persisting balance deficit, despite treatment with physical therapy (PT), the current standard of care

Inclusion Criteria	Exclusion Criteria
Aged 18-65 years at screening	Neurological disorders unrelated to TBI
Balance disorder as a result of TBI	Penetrating injury, craniotomy, or subdural hematoma
≥ 1-year since TBI	Oral health problems or history of oral cancer
Plateaued in recovery with current PT rehabilitation regimen	Experienced a loss of consciousness > 24 hours from TBI
SOT score < 16 points below normal	Other cause for balance disorder

PT = physical therapy; SOT = Sensory Organization Test; TBI = traumatic brain injury.

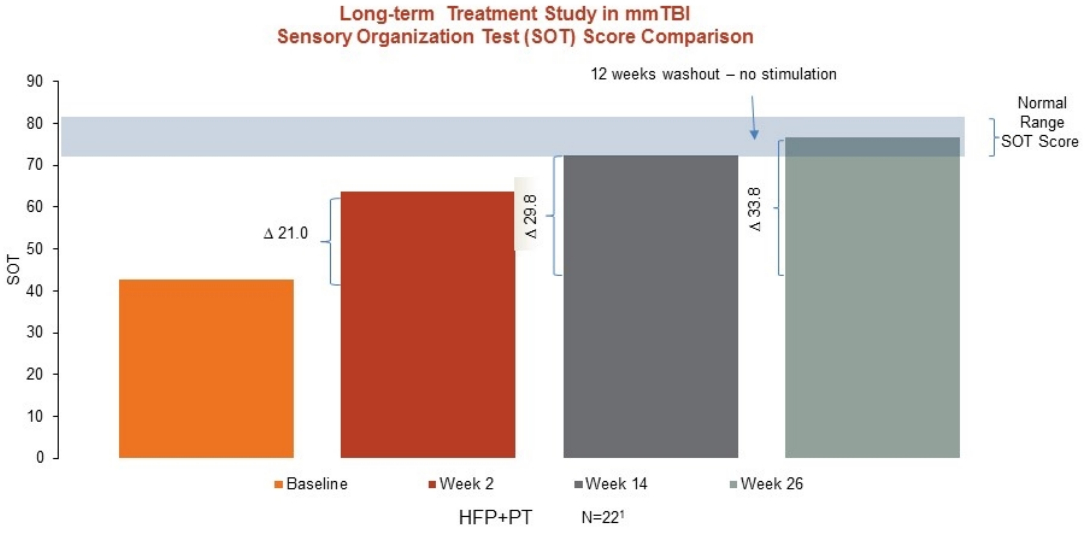
1. Helius Medical Technologies data on file. Executive summary of TBI-001; 2. US National Library of Medicine. Noninvasive Neuromodulation for Treatment of Symptoms Due to Mild or Moderate Traumatic Brain Injury. Available at https://clinicaltrials.gov/ct2/show/NCT02158494?term=PoNS&cond=Traumatic+Brain+Injury&rank=4. Accessed December 10, 2018.

Clinical Support for PoNS™ Treatment:

Significant, Sustained Improvement

In patients with mmTBI balance was significantly better at **2 Weeks, 14 Weeks and 26 Weeks**

On average patients with mmTBI improved from an impaired SOT score to normal SOT score in 14 weeks of treatment with HFP. Normal SOT score was maintained throughout the 12 week washout period for all patients.



[1] Patients treated with high frequency pulse (HFP) device.
Low frequency pulse (LFP) data not shown since it was not statistically different from HFP.

Global Regulatory Strategy

US:

- De novo to 510(k) pathway
- Submitted for de novo classification and 510(k) clearance on August 2018
- Received AI letter January 2019; submitted response March 2019

OUS:

- Canada: Health Canada clearance received 10/17/18
- EU: Submitted CE Mark application 12/7/18
- Australia: TGA filing anticipated in Q2, 2019
- China: providing regulatory support to CMS in preparation for NMPA filing

Commercializing PoNS™ Treatment in Canada (Slide 1/2)

- **Initial Focus on Canada:**
  - Clearance by Health Canada October 17, 2018
    - Over 350K people living with chronic balance deficit due to mmTBI
    - Regulatory, Quality and Distribution infrastructure for PoNS™ Treatment built
    - Established Heuro Canada to develop neuroplasticity clinics
      - Heuro Canada, formed by HTC, as an operating entity to deliver PoNS™ Treatment
      - 2 neuroplasticity clinics established, first patients began treatment in Q1, 2019
      - Expect to add three new neuroplasticity clinics in Canada during 2019

Focused on building infrastructure and treating patients in Canada

[1] Estimate based upon Acquired Brain Injury (ABI) data from the Brain Injury Association of Canada (BIAC) <http://braininjurycanada.ca/wp-content/uploads/2007/05/BIAC-Fact-Sheet-2014.pdf>

Commercializing PoNS™ Treatment in Canada (Slide 2/2)

- **Deploy geographically targeted campaign to activate patients in proximity of certified PoNS™ neuroplasticity centers to inquire about PoNS™ Treatment**
  - Targeted patient segments at launch are cash pay and workers compensation
  - Tactics include direct-to-patient digital campaign and partnership with patient advocacy groups

- **Build KOL and professional society advocacy, with goals to:**
  - Incorporate PoNS™ Treatment into Canadian guidelines
  - Reinforce the scientific basis for PoNS™ Treatment and supporting evidence to build the value proposition
  - Pave the way to reimbursement among commercial and government payers

Planned Commercial Launch Summary
PoNS™ Treatment in US

PoNS™: For the treatment of chronic balance deficit due to mmTBI

Focus targeted promotion on:
- Top 25 high-volume, early adopter neurorehabilitation networks
- Proactive chronic balance deficit patients & caregivers
- KOLs, professional societies, patient advocacy
- Workers compensation payers

Launch Success Factors

Build network of early adopter PoNS™ Tx centers	Activate self pay and workers compensation patients	Establish value proposition and treatment guidelines

Targeted promotion and scientific engagement to build advocacy, adoption, & experience
Significant potential market opportunity and longer-term growth

Commercialization of PoNS™ Treatment

Pre-Regulatory Clearance US Activities

- **Established Helius-sponsored Clinical Experience Programs (CEPs)**
  - Partnering with leading, early-adopter, neurorehabilitation centers:
    - Partnerships in place with five neurorehabilitation centers (Northwell, OSU, OHSU, Kessler & Baylor)
    - Patient recruitment and enrollment began in Q4'18 and continues in 2019
    - Plans to add Helius NeuroRehab as a sixth CEP site

- **CEPs enable Helius to:**
  1. Build relationships with target neurorehabilitation centers and key opinion leaders
  2. Gain real-world experience in the clinical setting to validate commercial model for PoNS™ Treatment
  3. Generate clinical evidence and health outcomes data to support reimbursement coverage discussions with payers

Building commercial infrastructure, evidence and advocacy to support a successful targeted launch

Commercialization of PoNS™ Treatment

Post-Clearance US Commercial Strategy

- **Build network of early adopter, high-volume PoNS™ Treatment centers**
  - Begin treating patients immediately following FDA clearance in Helius Neuro Rehab Center in Newtown, PA
  - Convert CEP clinics into PoNS™ Treatment centers
  - Deploy Strategic Account Executives to target top 25 high-volume, early adopter private cash pay neurorehabilitation network clinics

- **Manage growth to ensure that PoNS™ experience is of the highest quality**

- **Generate real-world evidence to support development of the payer value proposition and health economic analyses**

Post-clearance, establish targeted high-volume PoNS™ Treatment network and drive cash pay and workers compensation patients into PoNS™ clinics

Raising Awareness of the PoNS™ Treatment

Establishing Thought Leadership at Key Medical Meetings

- **American Physiotherapy Association- January 23-26 Washington, DC**
  - KOL meetings / peer insight dinner
- **North American Neuromodulation Society- January 17-20 Las Vegas, NV**
  - KOL meetings / peer insight dinner- podium presentation - Alain Ptito - Dinner Session - Presentation: Treatment of Chronic Symptoms of Mild/Moderate Traumatic Brain Injury with the PoNS
- **International Brain Stimulation Conference- February 24-27 Vancouver, BC**
  - Workshop "Teach In" for PoNS Treatment
- **World Congress on Brain Injury- March 13-16 Toronto, ON**
  - Platinum sponsor
  - Hosted Plenary Panel discussion
- **TBI Conference- May 15-17 Washington, DC**
- **International Neuromodulation Society- May 25-30 Sydney, AU**

Reimbursement Strategy

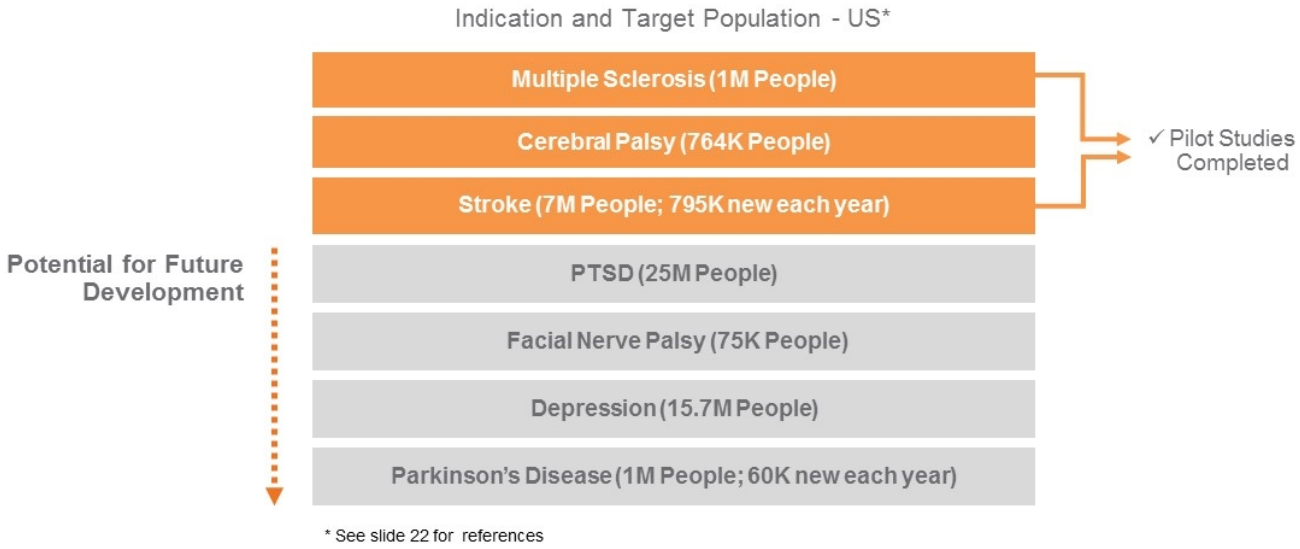
- **Multi-year effort to secure broad-based reimbursement coverage:**
  - Focused on accumulating health economic data to support pursuit of coverage and payment
  - Near-term priority: establishing clinical data to secure dedicated procedure codes with Workers Compensation payers (US and Canada)
  - Long-term strategies to engage with federal (Medicare), VA & commercial payers in US and Canada

- **Following Regulatory clearances, initial customers expected to be private pay pending broad-based reimbursement coverage in respective geographies**

Focused on obtaining health economic and treatment durability data to facilitate reimbursement coverage

PoNS™ Treatment

Additional Clinical Progress and Potential Opportunities



* See slide 22 for references

Financial Overview

- **$25.6M cash and no outstanding debt as of December 31, 2018**
- **November 2018: Completed registered public offering with net proceeds of $18.3M at price of $8.25, led by BTIG and Oppenheimer**
- **Full Year 2018 Summary:**
    - **Reported First Company Revenue:** $0.5M, licensing fee for Canadian rights granted to Heuro
    - **Operating Expenses:** $27.2 million in 2018 vs. $22.9 million in 2017 increase of $4.3M
        - Year-over-year increase driven primarily by an increase of $8.7 million in G&A expenses due primarily to higher stock-based compensation expense, which was primarily the result of the change in the Company's functional currency*
        - Year-over-year increase offset partially by a decrease of $4.4 million in research and development expenses, primarily due to reduced clinical trial and product development expenses
    - **Total Other Expense:** $1.9M in 2018 vs. $5.2M in 2017, a decrease of $3.2M
        - Year-over-year decrease driven primarily by a foreign exchange gain of $1.6M in 2018 versus a foreign exchange loss of $1.7M in 2017
- **Net Loss:** $28.6M in 2018 vs. $28.0M in 2017
- **Net Cash Used in Operating Activities:** $19.6M in 2018 vs. $19.3M in 2017
- **Net Cash Provided by Financing Activities**: $40.0M in 2018 vs.$22.2M in 2017.

*Note: Changed functional currency from $CAD to $USD, effective April 1, 2018.
Financial statements prior to and including the period ending March 31, 2018 have not been restated for the change in functional currency.

Full Year 2019 Outlook

2019 Guidance:

- For 2019, we expect total revenue in a range of $1.6 million to $2.0 million U.S. dollars.

Assumptions Supporting 2019 Guidance:

- 2019 revenue guidance assumes an exchange rate of $1 Canadian dollar to $0.75 US dollars.
- We expect all revenue will be generated only from contributions by the two founding neuroplasticity clinics that are operational and treating patients in Canada.
- We anticipate generating revenue of approximately $18,000 Canadian dollars per device delivered to the Canadian clinics in 2019.
- We expect to engage three additional neuroplasticity clinics in Canada during the course of the year, one in each of the last 3 quarters of the year, to end 2019 with a total of 5 clinics.

Extensive IP Portfolio

Exclusively licensed from inventors (4% royalty):
- 8 US Medical Method Patents Issued
- Patents expire 2028

Patents owned by Helius (no royalty):
- 27 US Patents Issued
- 20 Foreign Patents Issued
- Patents expire 2035

Helius Patents Transferred to China Medical System Holdings (CMS):
- 3 Chinese Design Patents

Independent Verification of Patents and Freedom to Operate Opinion – September 2017

A Significant Barrier to Competitor Entry

References

Slide 6: Traumatic Brain Injury

1. *Maas et. Al. (2017). Traumatic brain injury: integrated approaches to improve prevention, clinical care, and research. The Lancet Neurology. 16. 10.1016/S1474-4422(17)30371-X. https://www.researchgate.net/publication/320898726_Traumatic_brain_injury_integrated_approaches_to_improve_prevention_clinical_care_and_research [accessed Jul 22 2018].
2. Addressable market: 5.3 million people with chronic disability multiplied by 40% having a balance disorder tied to TBI;
   5.3 million – see reference 5 below;
   40% https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4936800/;
3. Selassie AW, Zaloshnja E, Langlois JA, Miller T, Jones P, Steiner C. Incidence of long-term disability following traumatic brain injury hospitalization, United States, 2003. J Head Trauma Rehabil. 2008;23(2):123 131.
4. Taylor CA, Bell JM, Breiding MJ, Xu L. Traumatic brain injury-related emergency department visits, hospitalizations, and deaths - United States, 2007 and 2013. MMWR Surveill Summ. 2017;66(9):1-16. Calculations 2.8M x 33% of chronic symptoms sufferers x 40% who suffer Chronic balance disorder (2.8 x .30 x .40)= 333K

References

Slide 17: Disease State Prevalence

- Multiple Sclerosis - http://www.nationalmssociety.org/About-the-Society/MS-Prevalence
- Cerebral Palsy: http://www.cerebralpalsy.org/about-cerebral-palsy/prevalence-and-incidence
- Stroke – http://www.strokeassociation.org/STROKEORG/LifeAfterStroke/Life-After-Stroke_UCM_308546_SubHomePage.jsp
  - https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_stroke.htm
- PTSD – http://www.ptsdunited.org/ptsd-statistics-2/
- Bells Palsy: https://www.news-medical.net/health/Bells-Palsy-Epidemiology.aspx - US rate of 23 cases per 100,000 persons – (326 Million US Population /100,000 * 23 = 75,000)
  - US Population: http://worldpopulationreview.com/countries/united-states-population/
- Depression - http://www.nimh.nih.gov/health/statistics/prevalence/major-depression-among-adults.shtml
  - http://www.cdc.gov/nchs/fastats/depression.htm
- Parkinson's - http://parkinson.org/Understanding-Parkinsons/Causes-and-Statistics/Statistic

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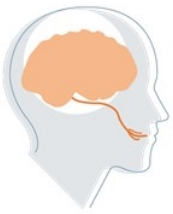
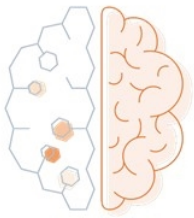
Tongue Based Neuromodulation



The nerves in the tongue are directly connected to the brainstem, which is the body's control center. It is dense with nerve endings in a warm, dark environment making it ideal for stimulation

A mild-to- moderate TBI damages a part of the brain, reducing the ability of the brain's neural impulses to communicate clearly with the body



To restore balance and function, the brain needs to be "rewired" to work around the damaged area and reestablish neural impulses to the body. This "rewiring" is called neuroplasticity.

We achieve this change by **neuromodulation.**

The PoNS® investigational medical device gently stimulates the trigeminal nerve through the tongue to activate neuroplasticity in the brain and unlock its ability to restore lost function.

One Smart Device

The PoNS device is a smart technology that tracks frequency, duration and intensity of use

Data captured is uploaded to cloud to be analyzed to drive PT and HCP treatment decisions and provide details on compliance for payer reimbursement opportunities

PoNS® Registrational Trial in TBI

Important Criteria For the Study

- 120 subjects
- Response criteria was set at 15 point improvement in Sensory Organization Test (SOT), an objective measure used in balance research
  - 15 point SOT score improvement is 50% higher than the expectation in the medical literature for physical therapy alone.
- All subjects had to:
  - Have participated in a focused physical rehabilitation program and have reached a plateau
  - Still have significant balance issues as they entered the study
- All subjects were at least one year post-injury
  - Further spontaneous recovery unlikely

Pre-Treatment Video

Post-Treatment

Helius
MEDICAL TECHNOLOGIES

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References

Slide 6 Traumatic Brain Injury

1. *Maas et. Al. (2017). Traumatic brain injury: integrated approaches to improve prevention, clinical care, and research. The Lancet Neurology. 16. 10.1016/S1474-4422(17)30371-X. https://www.researchgate.net/publication/320898726_Traumatic_brain_injury_integrated_approaches_to_improve_prevention_clinical_care_and_research [accessed Jul 22 2018].
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3. Selassie AW, Zaloshnja E, Langlois JA, Miller T, Jones P, Steiner C. Incidence of long-term disability following traumatic brain injury hospitalization, United States, 2003. J Head Trauma Rehabil. 2008;23(2):123 131.
4. Taylor CA, Bell JM, Breiding MJ, Xu L. Traumatic brain injury-related emergency department visits, hospitalizations, and deaths - United States, 2007 and 2013. MMWR Surveill Summ. 2017;66(9):1-16. Calculations 2.8M x 33% of chronic symptoms sufferers x 40% who suffer Chronic balance disorder (2.8 x .30 x .40)= 333K
5. Thurman DJ, Alverson C, Dunn KA, Guerrero J, Sniezek JE. Traumatic brain injury in the United States: a public health perspective. J Head Trauma Rehabil.1999;14(6):602-615.

References

Slide 22: Scientific Evidence

1. Shiflett JM, Parent AD, Britz GW, Golanov EV. Forehead stimulation decreases volume of the infarction triggered by permanent occlusion of middle cerebral artery in rats. J Neurol Stroke. 2015;2(5):00067
2. Chiluwal A, Narayan RK, Chaung W, et al.Neuroprotective effects of trigeminal nerve stimulation in severe traumatic brain injury. Sci Reports. 2017;7:6792

Slide 18: Disease State Prevalence

- Multiple Sclerosis - http://www.nationalmssociety.org/About-the-Society/MS-Prevalence
- Cerebral Palsy: http://www.cerebralpalsy.org/about-cerebral-palsy/prevalence-and-incidence
- Stroke – http://www.strokeassociation.org/STROKEORG/LifeAfterStroke/Life-After-Stroke_UCM_308546_SubHomePage.jsp
  - https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_stroke.htm
- PTSD – http://www.ptsdunited.org/ptsd-statistics-2/
- Bells Palsy: https://www.news-medical.net/health/Bells-Palsy-Epidemiology.aspx - US rate of 23 cases per 100,000 persons – (326 Million US Population /100,000 * 23 = 75,000)
  - US Population: http://worldpopulationreview.com/countries/united-states-population/
- Depression - http://www.nimh.nih.gov/health/statistics/prevalence/major-depression-among-adults.shtml
  - http://www.cdc.gov/nchs/fastats/depression.htm
- Parkinson's - http://parkinson.org/Understanding-Parkinsons/Causes-and-Statistics/Statistic

Other Science

Scientific Basis that Trigeminal Nerve Stimulation Positively Impacts Brain Physiology

Journal of Neurology and Stroke, Shiflett J.M. et al 2015[1]

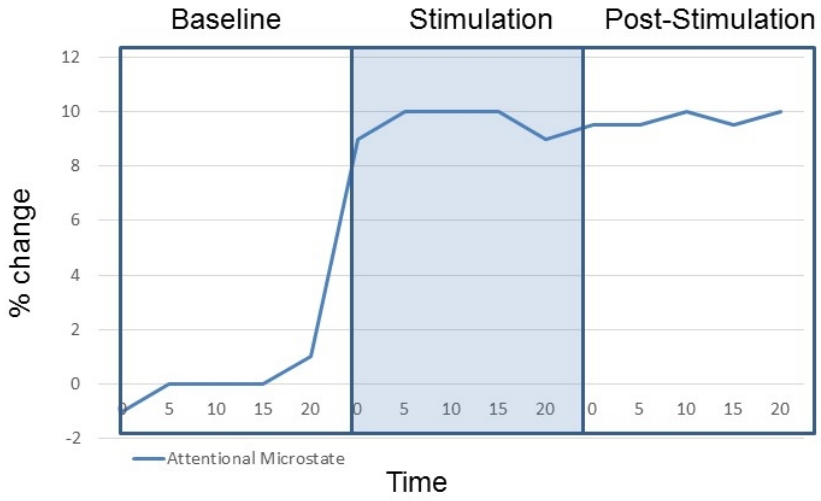
- Standard rat model of middle cerebral artery occlusion
- Indirect TNS led to 31% reduction in stroke
- Direct TNS led to 65% reduction in stroke
- Mediated by diving reflex
- Implications for stroke recovery, acute treatment or prevention?

Nature Scientific Reports, Chiluwal A., Narayan R., Chung W. et al. 2017[2]

- Rat model of TBI
- Improved blood flow
- Smaller lesion
- Better blood brain barrier
- Less edema
- Lower pro-inflammatory markers

[1,2] see appendix

In an independent EEG study, stimulation showed increased activity above baseline during and after stimulation for the attention microstate

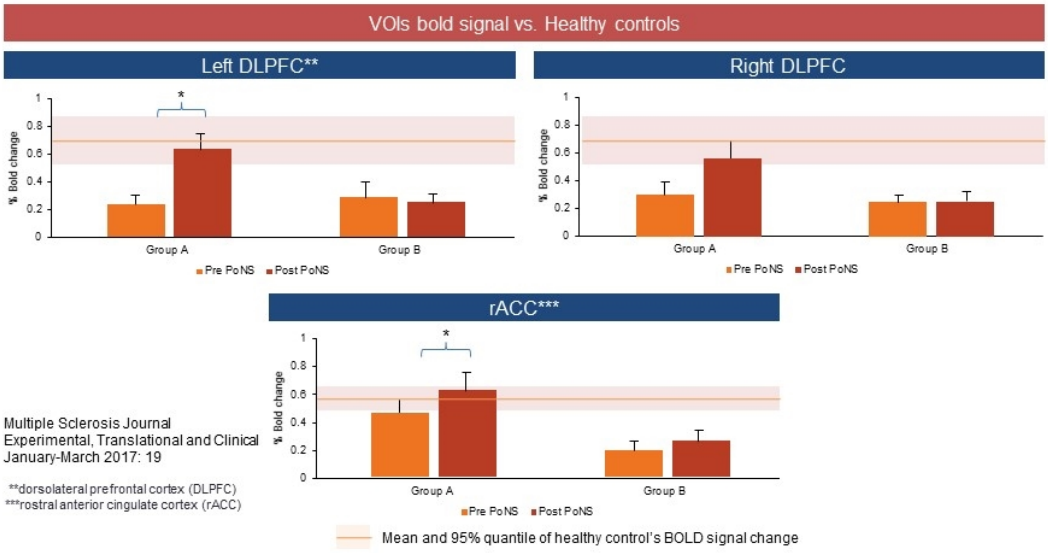


Data on file, Helius Medical 2017

n= 20 neurologically intact volunteers

Results from Multiple Sclerosis Study
fMRI Changes in Group A, B vs Healthy Controls

- 14 subject (7/7) study: All received physiotherapy with Group A receiving HFP PoNS® stimulation and Group B non-perceivable stimulation PoNS®



Multiple Sclerosis Journal
Experimental, Translational and Clinical
January-March 2017: 19

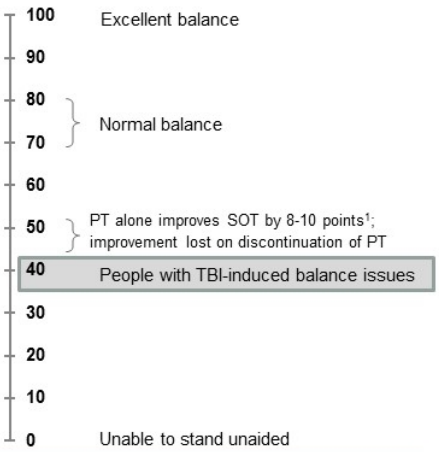
**dorsolateral prefrontal cortex (DLPFC)
***rostral anterior cingulate cortex (rACC)

Sensory Organization Test (SOT) – Standard Clinical Endpoint for Balance

Sensory Organization Test

Computerized posturography using 6 conditions to interpret a person's degree of sway

Scale: Degree of sway



Change of 10 points represents clinically significant change in SOT in TBI[1]

[1] see appendix

PoNS® Registrational Trial in TBI

Clinical Study	A double-blind, randomized, controlled* study of the safety and effectiveness of the PoNS® device for translingual noninvasive neuromodulation stimulation ("TLNS") training in subjects with a chronic balance deficit due to mild to moderate (mTBI)
Indication	Chronic balance deficit due to non-severe TBI

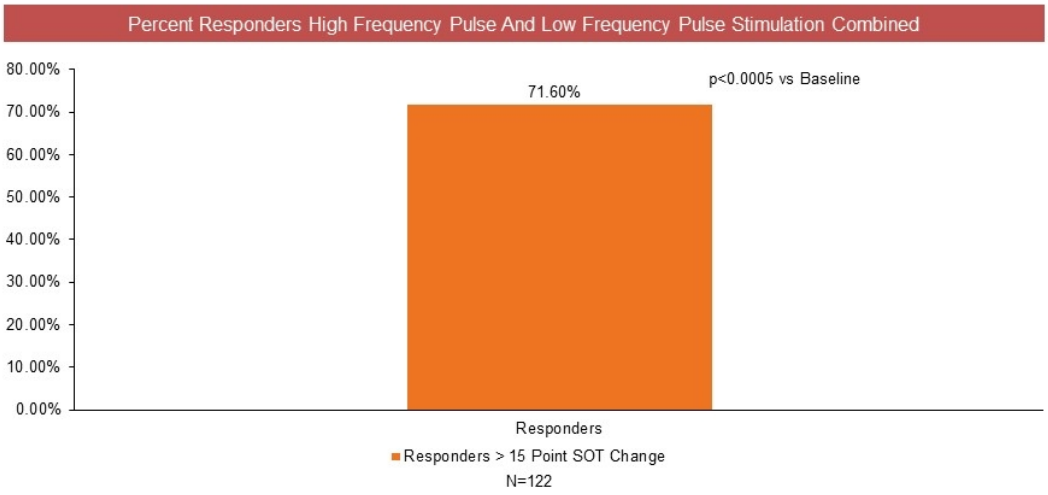
Study Population and Endpoints	• 120 person double-blind, controlled study HFP vs LFP
	• Primary endpoint is improvement comparison HFP vs LFP of responders at 5 weeks. Responder = increase in SOT ≥ 15
	• Secondary Endpoints are improvement in SOT scores from baseline at week 2 and week 5
	• Safety Endpoints
	  • Primary: No increase in frequency of falls
	  • Secondary: No increase in headache disability index

PoNS® Registrational Trial in TBI (con't)

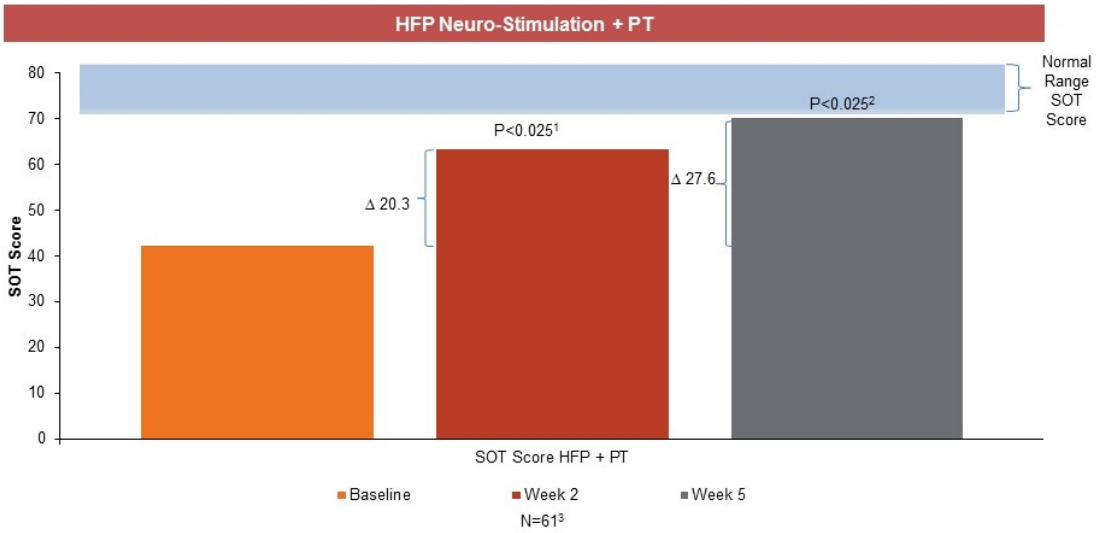
Important Criteria For the Study

- All subjects were at least one year post-injury
  - Further spontaneous recovery unlikely
- All subjects had to:
  - Have participated in a focused physical rehabilitation program and have reached a plateau
  - Still have significant balance issues as they entered the study

PoNS® Responder Analysis



PoNS® Study Efficacy - Time Course Data

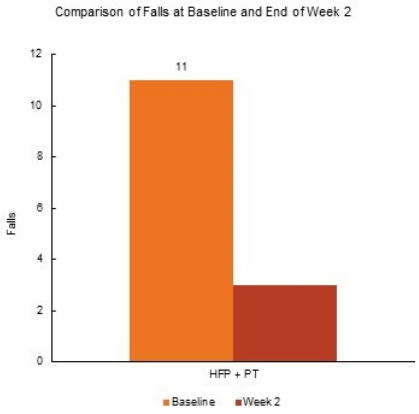


Results at 2 and 5 weeks represent ≈2-3x the clinical efficacy of PT alone

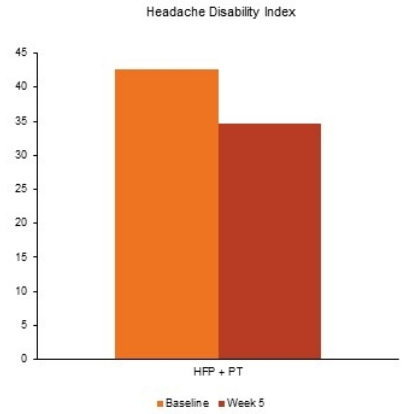
[1]HFP: Mean increase over baseline at end of Week 2 = 20.9 with 95% lower confidence limit of 16.6, p< 0.025
[2]HFP: Mean increase over baseline at end of Week 5 = 27.6 with 95% lower confidence limit of 23.1, p<0.025
[3] LFP data not shown since it was not statistically different from HFP

Primary and Secondary Safety Endpoints Met

Primary Safety Endpoint Met – Decrease in Number of Falls



Secondary Safety Endpoint Met - Headache Disability Index Showed a General Lowering



N=60

Long Term Treatment Study in TBI

Durability of the PoNS Treatment

- Study completed May 28th, 2017
- Tactile Communication Neurorehabilitation Laboratory at University of Wisconsin-Madison
- Sponsored by US Army
- Double blind randomized controlled trial in people with mild to moderate TBI
- 22/21 people with TBI received High Frequency Pulse stimulation and Low Frequency Pulse stimulation
- 14-weeks active treatment followed by a 12-week washout period

People with TBI's Balance was Significantly Better at 2 Weeks, 14 Weeks and 26 Weeks

On average people with TBI improved from an impaired SOT score to normal SOT score in 14 weeks of treatment with HFP and normal score was maintained throughout 12 week washout period for all participants

[1] LFP data not shown since it was not statistically different from HFP