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

November 9, 2017
Date of Report (Date of earliest event reported)

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

WYOMING	**000-55364**	**36-4787690**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

(Exact name of registrant as specified in charter)

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

On November 9, 2017, Helius Medical Technologies, Inc. (the "Company") hosted a live webcast to report on data from the Company's completed registrational clinical trial of the PoNS™ device for the treatment of chronic balance deficits due to mild to moderate traumatic brain injury and a recently completed long term treatment study conducted at the University of Wisconsin-Madison (the "Data"). A copy of the slides presented during the webcast is being furnished as Exhibit 99.1 to this Current Report on Form 8-K. A transcript of the webcast is being furnished as Exhibit 99.2 to this Current Report on Form 8-K. On November 9, 2017, the Company issued a press release announcing the Data. The full text of the Company's press release is furnished as Exhibit 99.3 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibits 99.1, 99.2 and 99.3) is being furnished and shall not be deemed "filed" for the 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 references in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Slide Presentation, dated November 9, 2017.
99.2	Transcript of webcast, dated November 9, 2017.
99.3	Press Release, dated November 9, 2017 titled "Helius Medical Technologies Announces Positive Results from its Registrational Clinical Trial for Traumatic Brain Injury (TBI)."

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: November 9, 2017

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

Helius
MEDICAL TECHNOLOGIES

A Revolution in Mind

November 9, 2017

Legal Disclaimers

This presentation includes certain statements that may constitute "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Canadian securities laws. All statements contained in this presentation, other than statements of historical facts, that address events or developments that the Company expects to occur, are forward-looking statements. These statements are based on management's expectations at the time the statements are made and are subject to risks, uncertainty, and changes in circumstances, which may cause actual results, performance, financial condition or achievements to differ materially from anticipated results, performance, financial condition or achievements. All statements contained herein that are not clearly historical in nature are forward-looking and the words "anticipate," "believe," "calls for," "could" "depends," "estimate," "expect," "extrapolate," "foresee," "goal," "intend," "likely," "might," "plan," "project," "propose," "potential," "target," "think," and similar expressions, or that events or conditions "may," "should occur" "will," "would," or any similar expressions are generally intended to identify forward-looking statements.

The forward-looking statements in this presentation include but are not limited to statements relating to: progress, reports and interpretation of results from clinical studies, clinical development plans, product development activities, future product candidate success, plans for U.S. Food and Drug Administration ("FDA") filings and their subsequent approvals, the safety and effectiveness of the PoNS™ device and the Company's ability to commercialize the PoNS™ device.

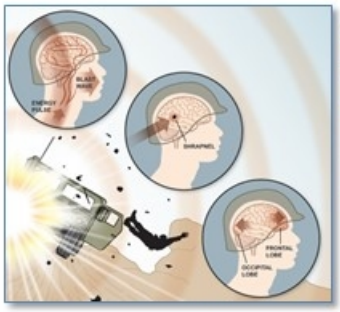
Although the Company believes the expectations expressed in such forward-looking statements are based on reasonable assumptions at the time they were made, they are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. Factors that could cause the actual results to differ materially from those in the forward-looking statements include: 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; demographic trends; the intellectual property landscape; financial market conditions; continued availability of capital and financing; and future business decisions made by the Company and its competitors. These and additional risks and uncertainties are more fully described in the Company's Transition Report on Form 10-K/T for the period ended December 31, 2016 filed with the Securities and Exchange Commission ("SEC") on April 3, 2017 and the Company's other public filings with the SEC and the Canadian securities regulators, which can be obtained from either www.sec.gov or www.sedar.com.

Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. Except as required by applicable securities laws, the Company undertakes no obligation to update or alter these forward-looking statements (and expressly disclaims any such intention or obligation to do so) in the event that management's beliefs, estimates, opinions, or other factors should change.

Traumatic Brain Injury

- **Large Population:** 2.1 million people with balance disorder related to non severe TBI
- **Unmet Need:** Current treatment paradigm offers few viable therapeutic options

Military



Common Types of TBI due to Military Activity:

- Explosive blast injury
- Penetrating injury
- Diffuse axonal injury

- 30,000/year active duty soldiers with TBI
- 200,000 retired soldiers diagnosed with TBI
- 20-30% of new cases result in chronic symptoms

Athletic / Civilian

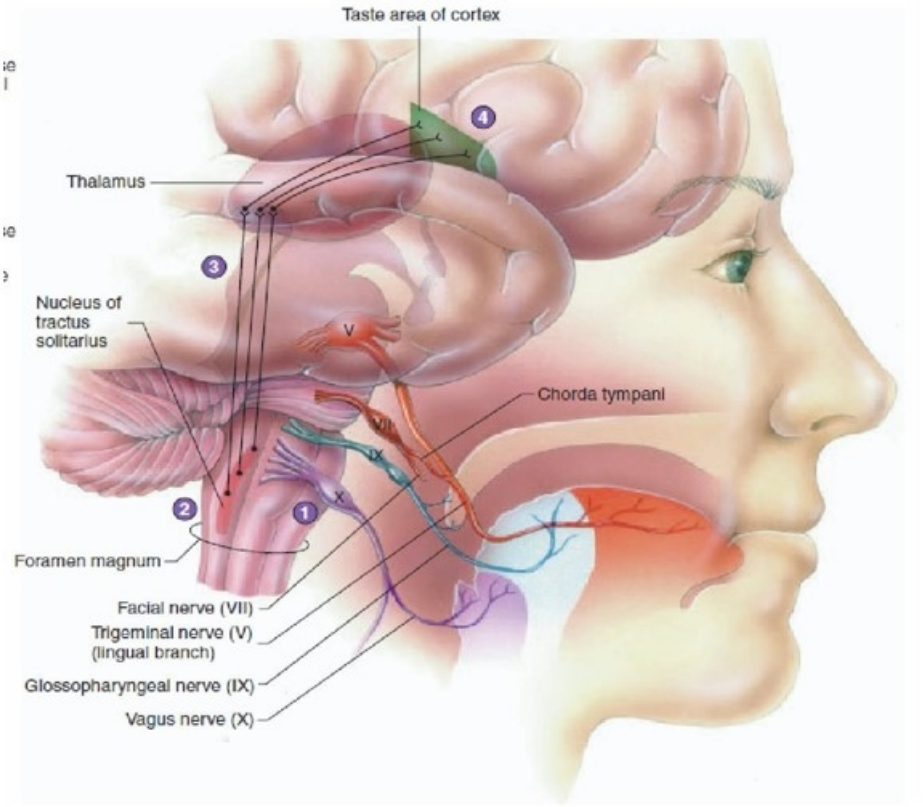
Causes of Civilian TBI:

- Blunt trauma
- Motor vehicle accident
- Sports related injury
- Violence/Assaults
- Falls

- 1.7M new cases of TBI reported in U.S. each year
- 20-30% of new cases result in chronic symptoms
- 3.2 - 5.3M living with TBI related disability

[1,2,3,4,5,6] *see appendix*

PoNS™ Designed to Stimulate the Trigeminal and Facial Nerves Through the Tongue



Neuroprotective Effects of Trigeminal Nerve Stimulation in Severe Traumatic Brain Injury

Nature Scientific Reports, Chiluwal A, Narayan R, Chung W et al. July 28, 2017

- Rat model of TBI
- Standardized injury
- With or without trigeminal nerve stimulation
- Improved blood flow
- Smaller lesion
- Better blood brain barrier
- Less edema
- Lower pro-inflammatory markers

"These data provide strong early evidence that activation of the trigeminal nerve system affords neuroprotection following brain damage."
"If the benefits of TMS in TBI can be replicated in ... humans, it could have tremendous impact in trauma resuscitation and TBI management."
Professor Raj Narayan, Chairman of Neurosurgery and TBI expert, chose to join our SAB in the wake of this publication

What is the Sensory Organization Test (SOT)

The Sensory Organization Test (SOT):

- Uses computerized posturography to quantify a patient's use of sensory input: vision, vestibular and somatosensory cues to maintain postural stability
- The SOT utilizes six "conditions" to interpret a patient's degree of sway, with a score of 100 implying excellent balance and 0 demonstrating none
- A change in score of ***8 points*** is deemed clinically significant (Wrisley, D. et al. 2007)
- SOT is referenced, reliable, reproducible and accepted as a metric for measurement tool for TBI it is the primary effectiveness endpoint for our trial
- In our studies, patients with TBI-induced balance issues scored approximately 40, at which point they may require walking aids and are at increased risk of further falls.

FIGURE 1. Smart Balance Master System. Picture provided courtesy of NeuroCom International, Inc, Clackamas, OR.

Effect of Physical Therapy Alone in Treatment of Balance Disorder in TBI

Dr. Deborah Backus, PhD

Director of MS Research at the Shepherd Center and President of the American Congress of Rehabilitation Medicine has more than 30 years of experience in neurological rehabilitation and research says:

"Most clinicians recognize that functional gains are significantly limited with physical therapy alone in treating balance deficits in TBI"

- Pattern of vestibular recovery for PT alone in TBI subjects:
  - In the literature, we observe a typical change of 8-13 points on the SOT Composite Score following vestibular rehabilitation therapy, and is usually progressively accomplished over a period of 6 to 9 months (Brown et al., 2001 and Badke et al., 2004)

Neuromodulation, Neuroplasticity and Trigeminal Nerve Stimulation

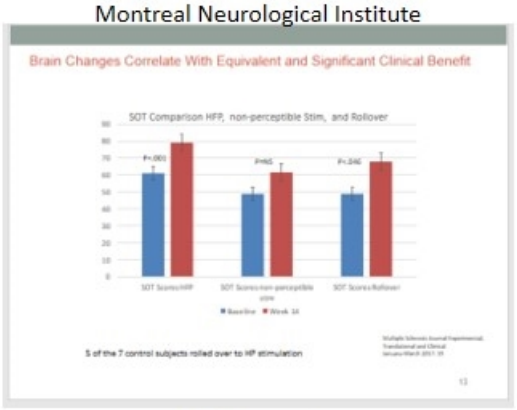
- Neuromodulation is the application of external stimuli to provoke changes in brain activity
- It occurs through two mechanisms: acute changes to how existing synapses work, and chronically by the creation of new synapses
- The trigeminal and facial nerve innervate the tongue, and stimulating these nerves sends impulses into the brain.
- PoNS™, the portable neuromodulation stimulator is a wearable investigational medical device that noninvasively stimulates the trigeminal and facial nerve (cranial nerve V, VII) though stimulation of the tongue
- Two iterations of the PoNS™ device were developed (through adjusting software), one delivering 25,740,000 pulses (High Frequency Pulse (HFP)) during a 20 minute treatment and the other, 13,728 (Low Frequency Pulse (LFP)). Despite these varying "pulse frequencies," a user can detect pulses from both devices.
- Study conducted in Surrey BC, Canada in ten healthy volunteers who were examined with 64 lead electroencephalography (EEG)
    - **Results demonstrated that in both groups the brain activity at baseline was comparable, but both LFP and HFP stimulation showed increased activity above baseline during stimulation. This led to the hypothesis that both pulse frequencies may have the potential to produce a therapeutic effect.**

Regulatory Science vs Clinical Science

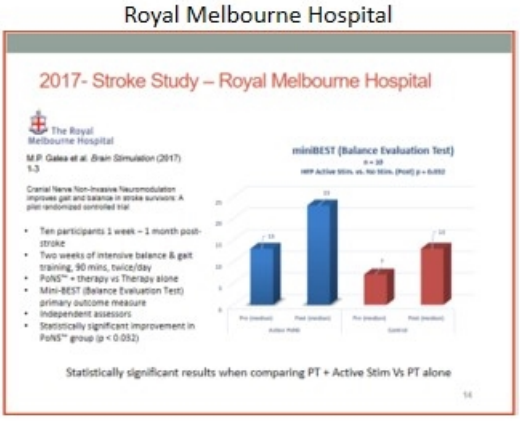
- Regulatory science is done to satisfy the need for regulatory authorities to determine the safety and efficacy of an intervention (Drug or medical device)
- Regulatory submissions require reliable data from randomized, controlled multicenter studies as standard for safety and efficacy i.e., study needs to have placebo or sham device
- In the medical device industry the "placebo" is very difficult to establish since medical devices are by definition a noticeable intervention
- In our case, we developed a Low Frequency Pulse (LFP) PoNS™ ***intended*** to be a non-therapeutic control
- Since we did not know whether it would be non-therapeutic or not we:
  - Ensured that patients participating in the trial would have done vestibular rehabilitation and plateaued in their recovery prior to inclusion
    - Would allow us to determine if LFP PoNS is clinically active
  - Prospectively decide in our statistical analysis plan how to evaluate the data if LFP PoNS showed clinical effect.

Independent Controlled Clinical Trials to Date Demonstrate

Montreal Neurological Institute

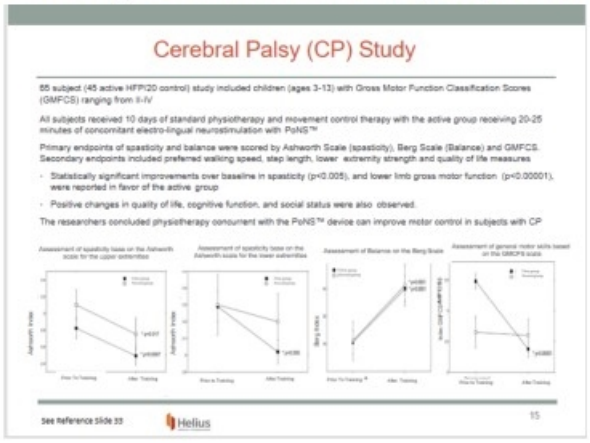


Royal Melbourne Hospital



- 3 independent randomized controlled clinical trials demonstrate statistically significant improvements in SOT scores when PT + High Frequency Pulse PoNS is compared to PT + no stimulation in multiple disease states

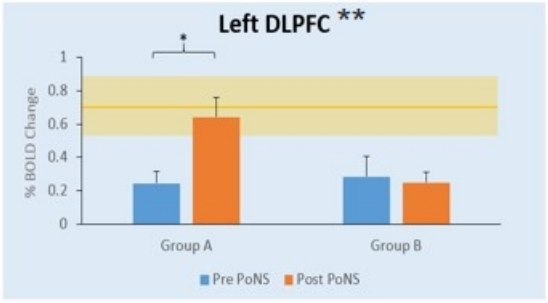
St. Petersburg State Health Institution «City Hospital №40»

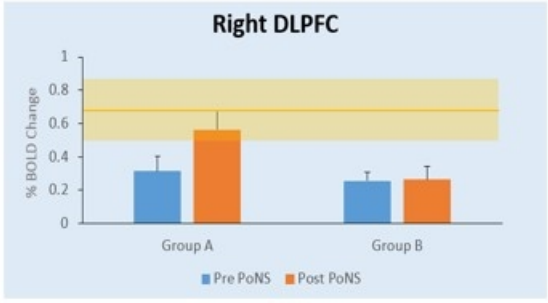


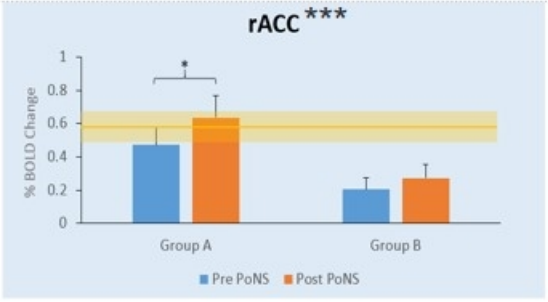
Results from Multiple Sclerosis Study
fMRI Changes in Group A, B vs Healthy Controls

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

VOIs BOLD signal vs. Healthy Controls







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

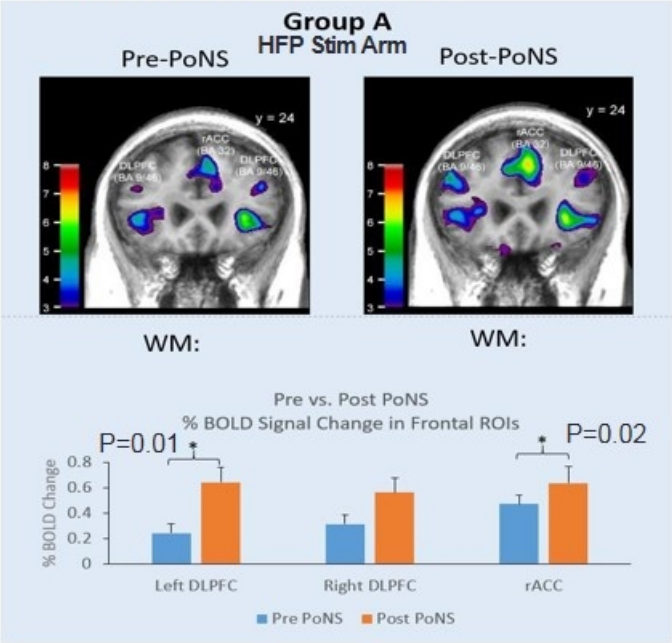
***dorsolateral prefrontal cortex (DLPFC)*
****rostral anterior cingulate cortex (rACC)*

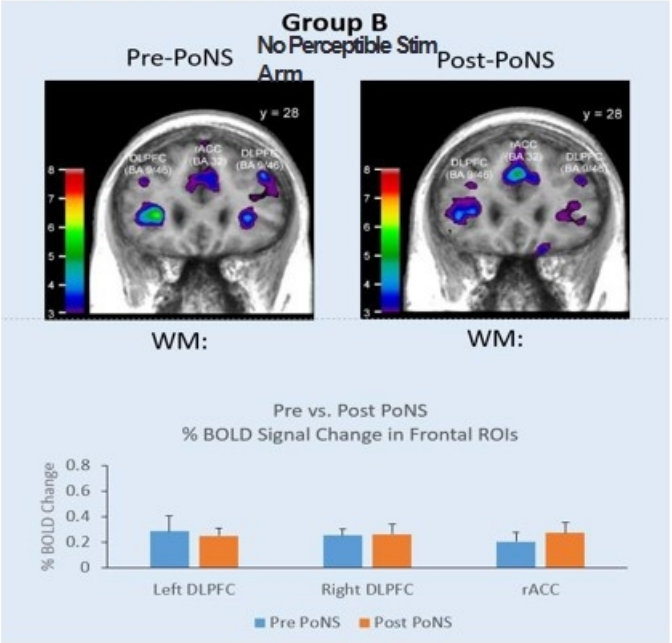
Mean and 95% quantile of healthy control's BOLD signal change

Results from Multiple Sclerosis Study
Working Memory fMRI

Group A: Post PoNS™ device training fMRI shows significant increase in BOLD signal in the left DLPFC** (t=3.55, p=0.01), rACC*** (t=3.057, p=0.02) and a trend for significance in the right DLPFC (t=2.3, p=0.06).

Group B: Baseline as well as post-PoNS™ fMRI shows sub-threshold peaks in bilateral DLPFC and rACC. Paired-t tests comparing pre and post PoNS™ scans did not reveal any significant changes.





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

Clearly Defined Regulatory Pathway

FDA deemed the study of the PoNS™ for mild-moderate TBI a 'non-significant risk (NSR) device study' under the IDE regulations

- Assessed the study as not posing a significant risk to human subjects
- FDA guidance points to 120-day regulatory review upon submission for de novo clearance for Class II

FDA indicated that a request for de novo classification into Class II for the mild-moderate TBI indication would be an appropriate path to seek marketing authorization

- Balance disorder related to non-severe TBI
- FDA reviewed and provided feedback on the registrational trial protocol

Concurrent with FDA filing, seeking EU CE Mark, Health Canada MDL and TGA approval

ISO 13485 received in December 2016 from LRQA an independent organization to review companies quality systems; Passed Surveillance Audit 1 – 9/7/17

So, what does an SOT of 40 look like?

- The mean baseline SOT in our clinical trial was approximately 40 (42.1 and 41.1 in HFP and LFP respectively)
- This video is of a patient that did not participate in our clinical trial
- It is shown to demonstrate the clinical presentation of a person with an SOT score of 40
- Every subject is different and there are many different potential contributions to an SOT result. This is just one example.

What does an SOT Score of 40 look like?

PoNS™ Registrational Trial in TBI

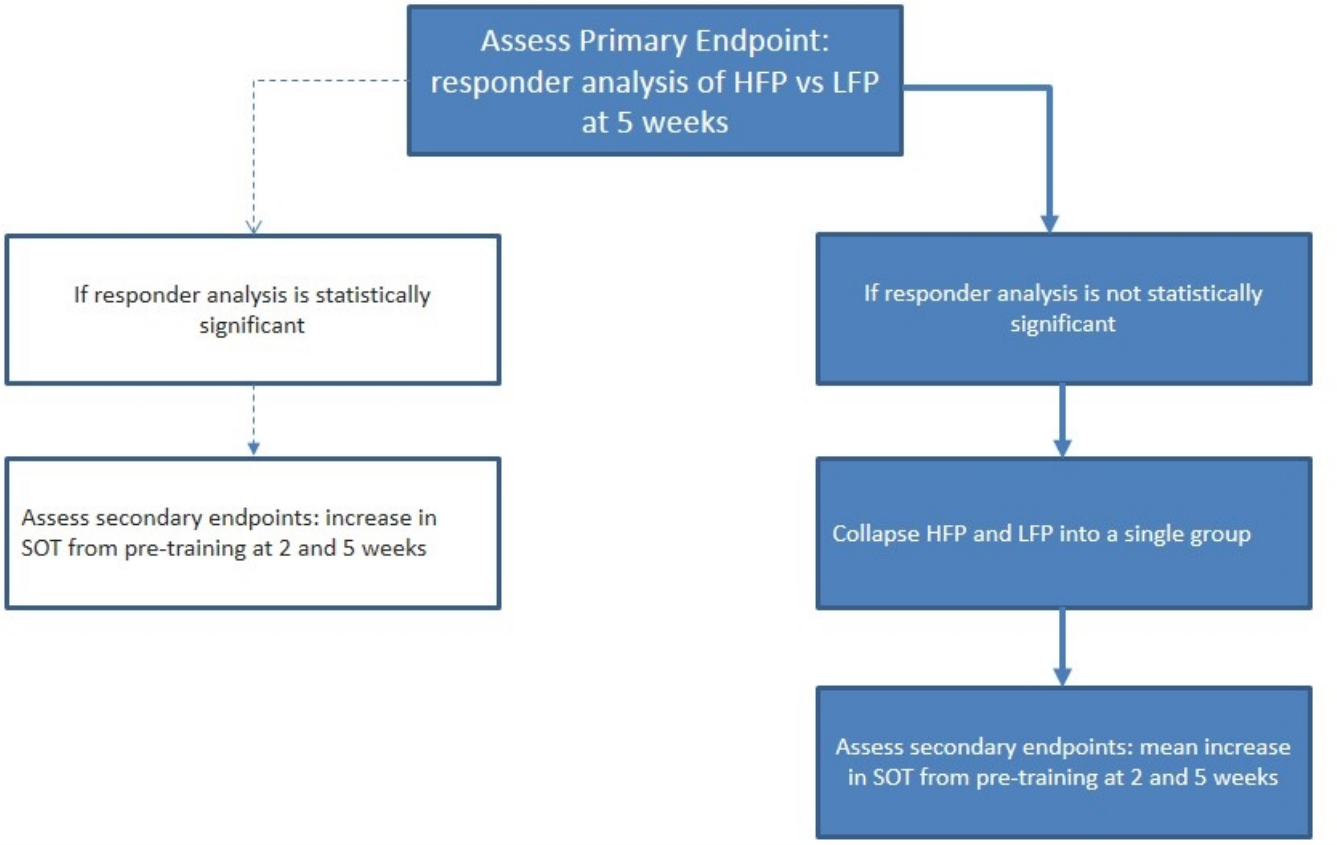
Clinical Study	**A double-blind, randomized, controlled* study of the safety and effectiveness of the PoNS™ device for translingual noninvasive neuromodulation stimulation ("TLNS") training in subjects with a chronic balance deficit due to mTBI.**
Indication	Chronic balance deficit due to non-severe TBI
Start Date	August 2015
Treatment Completion	August 18, 2017
Description	Helius as sponsor launched a Pivotal clinical trial in conjunction with US Army Medical Research and Material Command at: • Montreal NeuroFeedback Centre (Montreal, QB) • Oregon Health and Science University (Portland, OR) • Orlando Regional Medical Center (Orlando, FL) • HealthTech Connex (Surrey, BC) • VCU (Richmond, VA) • MedStar National Rehabilitation Center (Washington, DC) • University of Wisconsin (Madison, WI)
Study population and Endpoints	• 120 patient double-blind, controlled study (HFP vs LFP) • Primary endpoint is improvement comparison HFP Vs LFP of responders SOT ≥15 at 5 weeks. Responder = increase in SOT ≥ 15 • Secondary Endpoints are improvement in SOT scores from baseline at week 2 and week 5

***- PoNS 4.0 versus same device with low perceivable stimulation *intended* to be ineffective.**

Important Inclusion 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 for their TBI related balance disorder and have been deemed by the treating clinician to have reached a plateau
  - still have significant balance issues as they entered the study

Statistical Analysis Plan for TBI Study

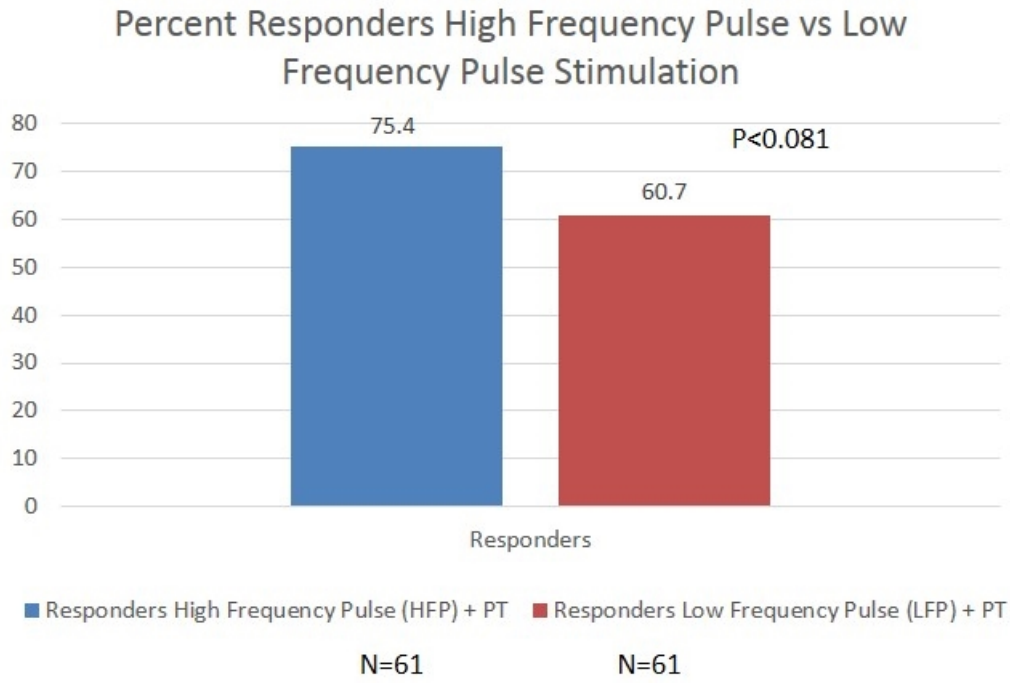


Statistical Analysis Safety Endpoints

- **Primary:** Frequency of falls, as determined by daily event recording on the subject data case report form during the in clinic phase. Fall is defined as an episode where a subject lost his or her balance and fell or would have fallen, were it not for another intervention, such as stabilization on the back of a chair or the wall. Stabilization to restore balance during therapy will not be considered a fall.

- **Secondary:** Frequency of headache, as measured by the Headache Disability Index (HDI) at baseline and at the end-of-treatment (5 weeks).

PoNS Responder Analysis – Primary Endpoint

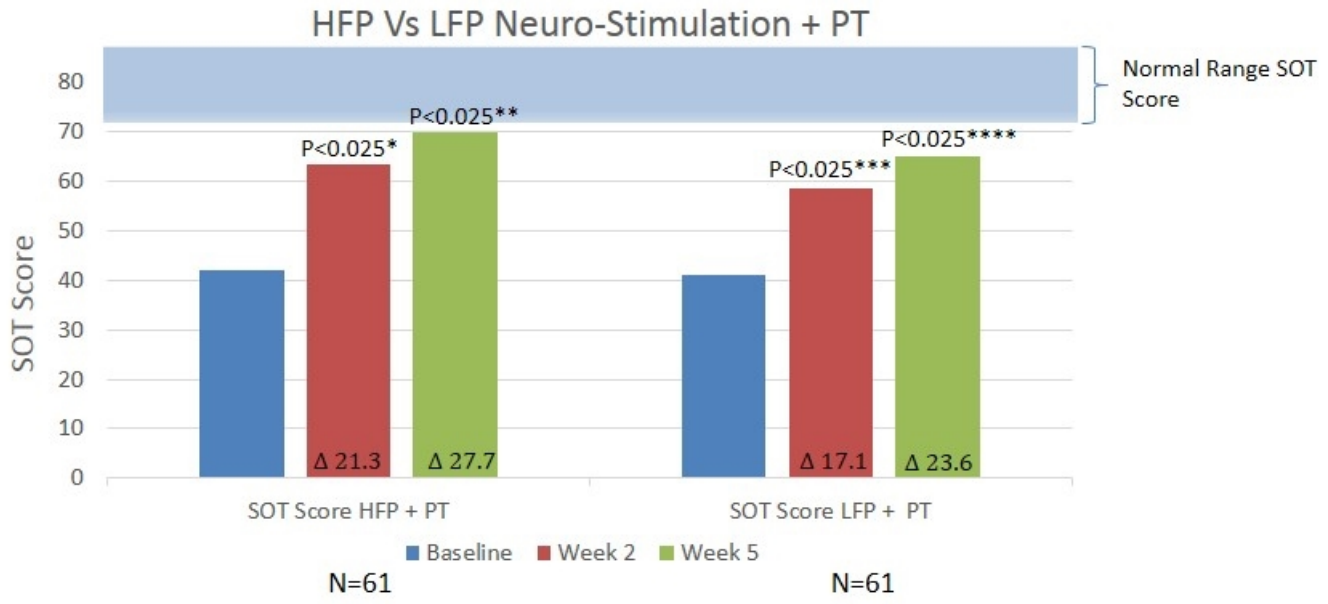


N=61 N=61

Responders = 15 point improvement in SOT above baseline

HFP PoNS group response showed a trend to significant change vs response of LFP PoNS Group

PoNS Study Data Efficacy



*HFP: Mean increase over baseline at end of Week 2 = 20.9 with 95% lower confidence limit of 16.6, p< 0.025
**HFP: Mean Increase over baseline at end of Week 5 = 27.3 with 95% lower confidence limit of 23.1, p<0.025
***LFP: Mean Increase over baseline at the end of Week2 = 15.7 with 95% lower confidence limit of 11.4, p<0.025
****LFP: Mean Increase over baseline at the end of Week5 = 21.7 with 95% lower confidence limit of 16.7, p<0.025

Is the LFP Device Demonstrating Therapeutic Activity?

- It was prospectively contemplated that LFP device might potentially have a therapeutic effect.
- Thus, in the statistical analysis plan it was proposed that if secondary effectiveness endpoints did not generate p-value of less than 0.05, (data showed $p<0.087$, $p<0.081$ respectively for both secondary endpoints), subjects in the HFP and LFP groups would be analyzed vs the baseline to determine if the LFP had therapeutic activity.
- **The results showed that the HFP PoNS had** Mean Increase at the end of Week 2 = 20.9 with 95% lower confidence limit of 20.9. Increase in SOT score from baseline at the end week 2 is significantly greater than zero with p-value < 0.025.
- **Control**: Mean Increase at the end of Week 2 = 15.7 with 95% lower confidence limit of 11.4. Increase in SOT score from baseline at the end week2 is significantly greater than zero with p-value < 0.025.
- **This indicates that the LFP PoNS is not a pure placebo, but has activity, which may be not as strong as in HFP.**
- The analysis was also performed for the data at the end of week 5 with very similar results.

Secondary Effectiveness Endpoint Combined Data Analysis at Week 2

Device	N	Mean	SD	SE	95% Conf. Interval		p-value
HFP	61	20.9	16.66	2.13	16.6	25.2	
LFP	61	15.7	16.65	2.13	11.4	20.0	
Combined*	122	18.3	16.79	1.52	15.3	21.3	P<0.0005

- When mean of the combined data set is significantly greater than zero, it indicates that results for both devices combined demonstrate statistically significant improvement in SOT scores.

Secondary Effectiveness Endpoint Combined Data Analysis at Week 5

Device	N	Mean	SD	SE	95% Conf. Interval		p-value
HFP	61	27.6	17.42	2.23	23.1	32.1	
LFP	61	21.7	19.58	2.51	16.7	26.7	
Combined*	122	24.6	18.69	1.69	21.3	28.0	P<0.0005

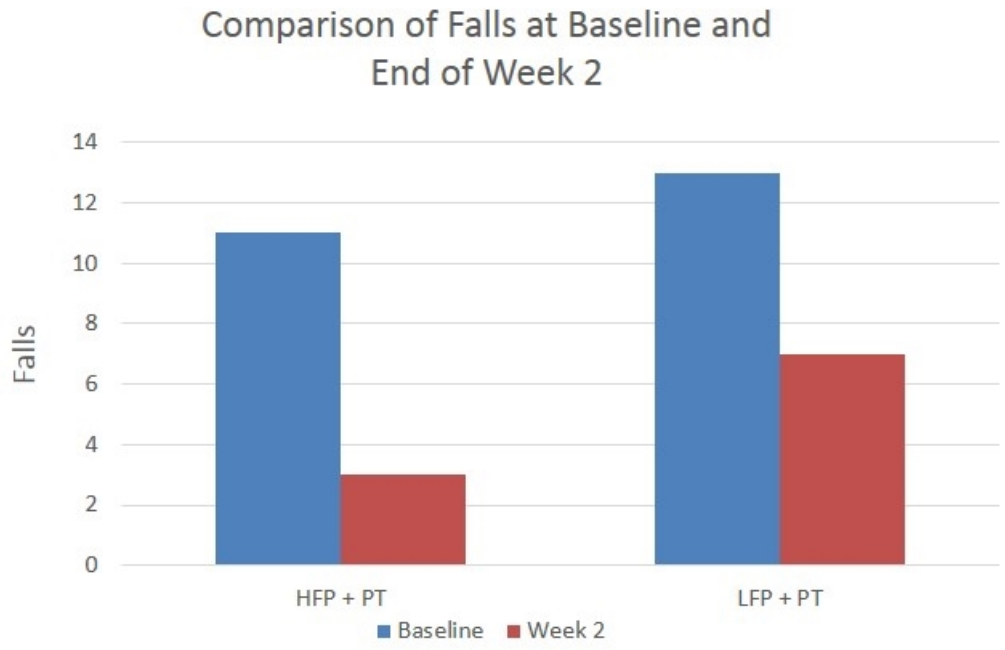
- When mean of the combined data set is significantly greater than zero, it indicates that results for both devices combined demonstrate statistically significant improvement in SOT scores.

IP Portfolio Covers all forms of Stimulation

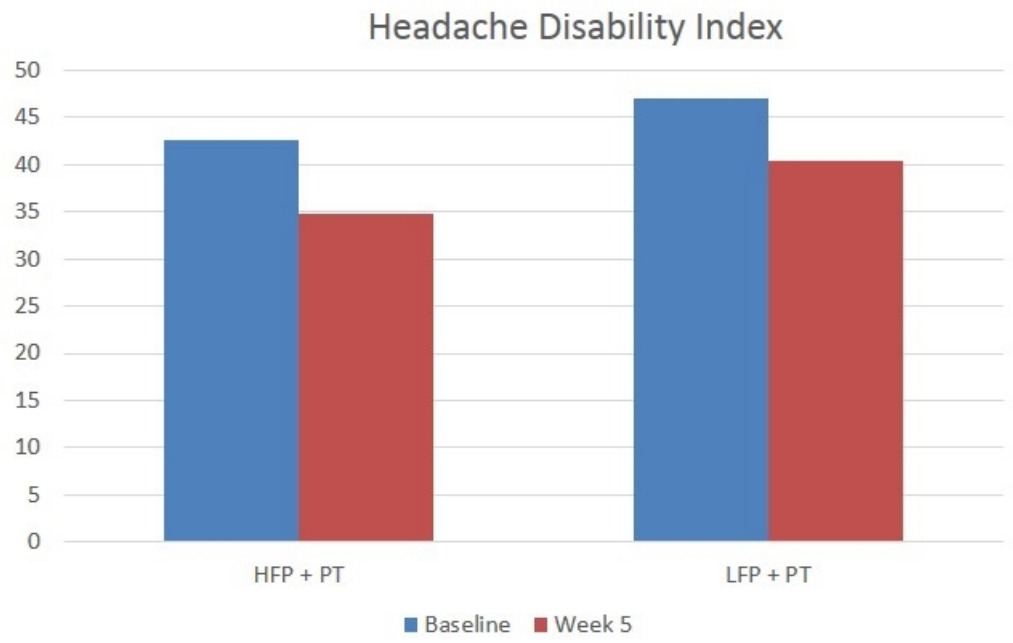
- 7 US Medical Method Patents Issued
  - ❖ Skin Stimulation + Physical Therapy = Therapeutic Outcome
  - ❖ Skin Stimulation + Cognitive Therapy = Therapeutic Outcome
  - ❖ Oral Cavity Stimulation + Physical Therapy = Therapeutic Outcome
  - ❖ Oral Cavity Stimulation + Cognitive Therapy = Therapeutic Outcome
  - ❖ Oral Cavity Stimulation with Pulse Generator + Exercise = Therapeutic Outcome
  - ❖ Oral Cavity Stimulation + Cognitive Therapy = Treatment of Tinnitus and other Neurological Disorders
  - ❖ Oral Cavity Stimulation + Exercise = Enhanced Human Performance

- **Our independently validated Medical Method patents cover all forms of skin or oral cavity stimulation.**

Primary Safety Endpoint Met – Decrease in Number of Falls



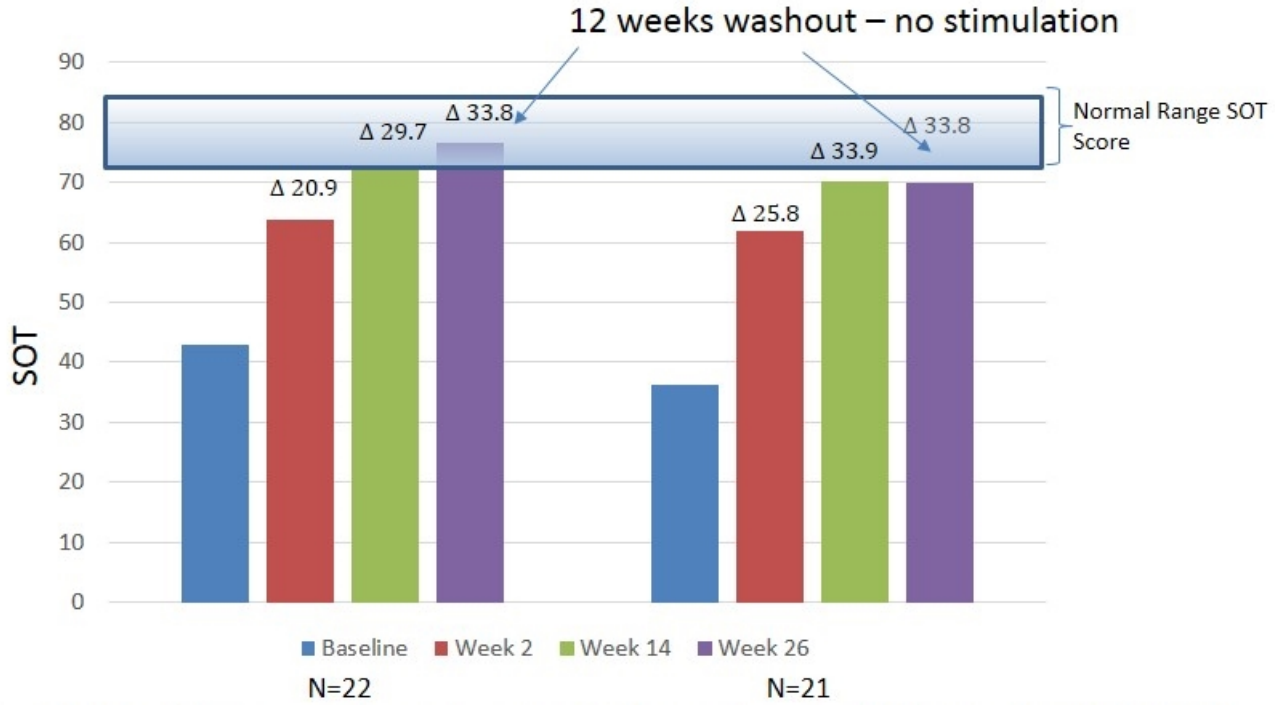
Secondary Safety Endpoint Met - Headache Disability Index Showed a General Lowering in Both Groups



Long Term Treatment Study

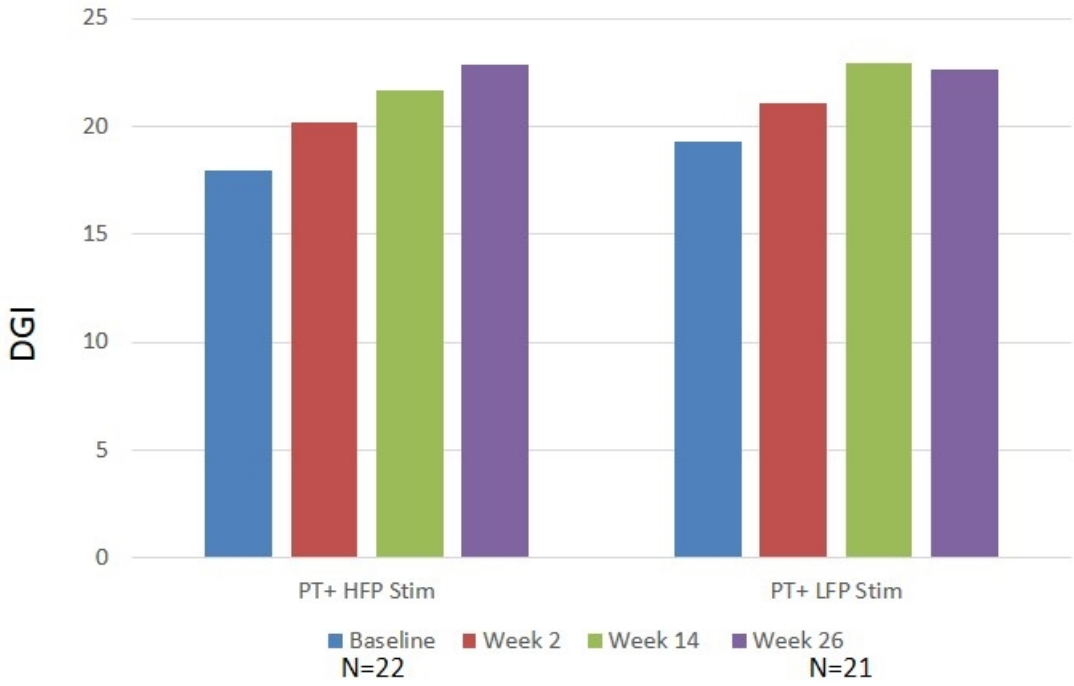
- Study completed May 28th, 2017
- Tactile Communication Neurorehabilitation Laboratory at University of Wisconsin-Madison
- Sponsored by US Army
- Double blind randomized controlled trial in patients with mild to moderate TBI
- 22/21 patients High Frequency Pulse stimulation Vs Low Frequency Pulse stimulation
- 14-weeks active treatment, 12-week washout
- Study designed to determine what happens after chronic treatment (14 weeks) if subjects discontinue therapy
- Study included a 12 week washout period following 14 weeks of active treatment

Patients in both Groups were Significantly Clinically Better at 2 weeks, 14 weeks and 26 weeks



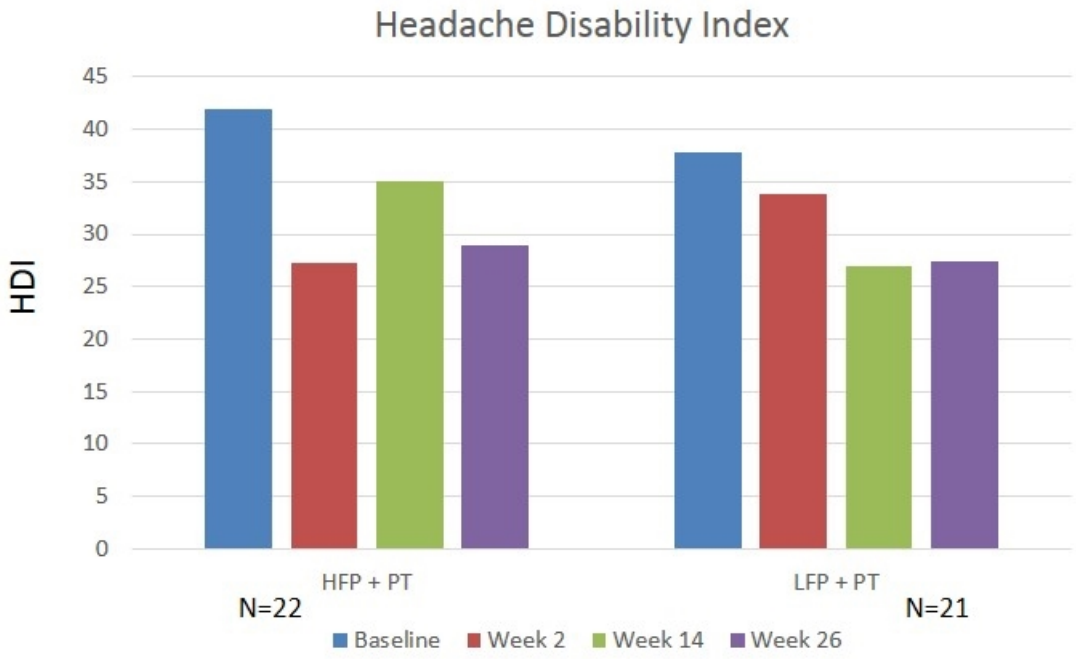
- On Average Patients improved from an impaired SOT score to normal SOT Score in 14 weeks of treatment with HFP
- Normal Score was maintained throughout 12 week washout period for HFP

Dynamic Gait Index



- Both treatment groups had baseline scores in the 'elevated risk of fall category' (≤ 19; normal=24)
- By the end of participation, the scores for both groups approached normal levels (Active: 22.82; Control: 22.65)

Patients in both Groups Demonstrated an overall Reduction in Headaches



So, what does a normal SOT score look like?

- This video is of a patient that did not participate in our TBI clinical trials but had previous experience with the therapy
- It is shown to demonstrate the clinical presentation of a person with a Normal SOT score
- Every subject is different and there are many different potential contributions to an SOT result. This is just one example.

Video of Subject with SOT Score in Normal Range

Overall Conclusion

In three previously published independent controlled clinical trials:

- PT + HFP PoNS therapy has been observed to be statistically significantly superior to PT with no stimulation in SOT scores
- HFP PoNS therapy produced FMRI confirmed statistically significant neuro plastic change to the brain, while PT alone + non stimulating PoNS did not produce any changes to the brain.

In registrational trial:

- Response Rate of High Frequency PoNS (75.4%) showed a trend to be superior to Low Frequency PoNS ($p<0.081$)
- We did not reach our primary endpoint because the LFP treatment had a significant therapeutic effect
- Achieved secondary efficacy endpoint: HFP and LFP PoNS therapy resulted in a highly statistically significant improvement vs baseline measurement at all measurement timepoints ($p<0.0005$)
- PoNS therapy achieved the primary safety endpoint, reduction in falls at week 2
- There were no device-related serious adverse events

In long term treatment trial:

- HFP PoNS therapy subjects achieved normal SOT scores at the end of 14 weeks of treatment which was sustained over 12 weeks of washout

- These results provide encouraging evidence of PoNS Therapy in the treatment of balance disorder in patients with mild to moderate TBI and we look forward to discussing the data with FDA to secure marketing clearance for the device. We now anticipate that our 510(K) application to the US FDA will be submitted in the first half of 2018, with clearance expected in the second half of 2018.

Company Name: Helius Medical Technologies (HSDT)
Event: Results From The Traumatic Brain Injury Trial
Date: November 9, 2017

Operator: Ladies and gentlemen, welcome to the Helius Medical Technologies Reports Results From The Traumatic Brain Injury Clinical Trial. My name is Cammy and I will be your operator for today’s call. At this time, all participants are in a listen-only mode.

I’d now turn the call over to Phil Deschamps. The line is yours.

<<Phil Deschamps, President, Chief Executive Officer & Chairman>>

Good morning, everyone. Boy, it’s such an exciting day for us. Now, welcome to our presentation regarding the recent clinical results. By now, you should have seen the press release that we issued this morning available on our website at www.heliusmedical.com and following today's presentation you may also review the slides and listen to a replay of today's call on the Investor section of our website.

Before I begin, I want to remind you that statements made on today's call regarding matter that are not historical facts are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Canadian securities laws. Examples of these forward-looking statements include statements concerning progress, reports and interpretation of results from clinical studies, clinical development plans, product development activities, future product candidate success, plans for FDA filings and their subsequent approvals, the safety and effectiveness of the PoNS Device and our ability to commercialize the PoNS Device.

These forward-looking statements are subject to risk and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. Including those risks include in the risk factors section of our SEC and Canadian security file.

Before I walk through the presentation, I really want to thank our staff and our investors and I’d like to thank all of the scientists, the researchers, the physical therapists, the patients and our board of directors and all of our advisors, but more specially I wanted to thank Jonathan Sackier, Chief Medical Officer for Helius with our passion, expertise and there we pursued a perfection, we would have never completed this clinical trial with the rigor and precision it received.

So let me introduce you to the good Dr. Jonathan Sackier.

<<Jonathan Sackier, Chief Medical Officer>>

Thank you very much, Phil, and good morning everyone listening in or watching the webcast. We're very pleased to be announcing the results of our registrational traumatic

brain injurym or TBI trial, as well as the results from a long-term TBI trial performed at the University of Wisconsin, Madison, with our investigation of Portable Neuromodulation Stimulator, the PoNS Device.

Before I get to the results that important background information that we need to share to provide everyone with context to understand the trial results. First a few words about our target population. There are, according to Health and Human Services, approximately five million patients suffering from the chronic symptoms of the TBI at any given time in the United States.

TBI has produced a whole host of symptoms including headache, sleep and cognitive disturbances, but most commonly in about 43% of patients according to the literature, a TBI is accompanied by a chronic balance disorder. That means that in the general population today, there are 2 million to 3 million people that suffer balance symptoms from a mild to moderate TBI in the U.S. alone.

In the civilian population unfortunately, approximately 1.7 million people were suffered this year, roughly two thirds of them will spontaneously recover. But this means that likely another 600,000 people will experience chronic symptoms of TBI every year. In the military, 30,000 service members suffer TBI each year, which are mostly due to training exercises rather than actual combat. Unfortunately today there are very few if any therapeutic options for the treatment of balance disorder in patients with TBI.

<<Phil Deschamps, President, Chief Executive Officer & Chairman>>

So, Jonathan, what we're saying here is there's a huge medical unmet need here that we certainly hope to be able to satisfy, right.

<<Jonathan Sackier, Chief Medical Officer>>

It's a massive need and awareness of that need is growing. So the PoNS treatment that generated the results presented today is a combination of physical therapy, or PT as we will call it, and the use of a device that stimulates the trigeminal and facial nerves that you can see on this slide. These important cranial nerves terminate in the tongue and tied to the lower brain.

Recent work done by Dr. Raj Narayan team at Northwell Medical Center in Long Island showed in an animal model of traumatic brain injury that stimulating the trigeminal nerve resulted in improved blood flow, smaller lesions, less edema or swelling and lower bloodborne marker of inflammation when compared to no stimulation of the trigeminal nerve following the induced TBI. Dr. Narayan was encouraged by these results and suggested that if these results can be replicated in humans, it could have tremendous impact in trauma resuscitation and on TBI management.

<<Phil Deschamps, President, Chief Executive Officer & Chairman>>

It was really interesting, Jonathan, when Dr. Narayan first saw these results from his study, we happened to be in the room the same day and we haven't presented yet and so when he said in order to be able to stimulate the trigeminal nerve in their study, they had to open the brains of rats and put an electrode in there and we just said well Dr. Narayan in humans you can actually just use the tongue to send impulses to the trigeminal nerve. And that's when he said okay this rocks. And he said I need to join your Scientific Advisory Board because I think we have something here that might be pretty cool.

<<Jonathan Sackier, Chief Medical Officer>>

Absolutely, sometimes life is about timing and in science very often people are working in separate silos unaware of what the other is doing. So to receive that kind of experimental independent verification was wonderful. So the primary measurement tool in both the studies being reported on today was the Sensory Organization Test, or SOT, and you can see that illustrated in the slide here, one patient call this is the phone booth from hell.

You'll hear the acronym SOT frequently during this discussion. The SOT uses computerized posture analysis to quantify a patient's use of sensory input, a vision, vestibular or the inner ear and somatosensory quiz to maintain their balance. The SOT create six conditions to interpret a patient's degree of sway or how solid they are on the ground with a score of 100 implying excellent balance and zero demonstrating none. A changing score of eight points is deemed clinically significant according to Wrisley, D. et al. in 2007. The SOT is referenced, reliable, reproducible and accepted as a metric for measurement tool for TBI and the primary effectiveness end point for our trial.

<<Phil Deschamps, President, Chief Executive Officer & Chairman>>

So, Jonathan, eight points, when you say eight points is clinically significant, that means that patients notice a change in eight points.

<<Jonathan Sackier, Chief Medical Officer>>

So my SOT is 79 and if my SOT declined by eight points to 71 I would not be able to do the activities that I so enjoy. We – if you think about standing on the deck of a rocking ship or having an alcoholic beverage, it can impair your balance. These people have impaired balance. In an eight point difference, yes, it is clinically significant and noticeable by patients.

<<Phil Deschamps, President, Chief Executive Officer & Chairman>>

Okay, so everyone on the phone when you see that eight point difference is noticeable. When we see our results, make sure that you compare those with what you see our results to be.

<<Jonathan Sackier, Chief Medical Officer>>

Absolutely, so in both treatments on to our study, subject followed and identical vestibular balance rehabilitation program in other words physical therapy to help restore their balance. Unfortunately, PT alone in the treatment of balance disorder has not proven to be particularly effective in TBI. Dr. Deborah Backus, PhD, Director of MS Research at the Shepherd Center in Atlanta and President of the American Congress of Rehabilitation Medicine, who has more than 30 years of experience in neurological rehabilitation and research shared with us the following statement. Most clinicians recognize that functional gains are significantly limited with physical therapy alone in treating balance deficits in TBI.

Further, the literature shows that the change of eight to 13 points in the SOT score, note that level of change. It is going to be important later. Usually, progressively accomplished over six to nine months is the norm for physical therapy alone. This is going to be very important, when you look at the pattern of recovery in our clinical trials.

Another term you need to know is neuromodulation. This is the application of external stimuli to provoke changes in the brain or nervous system. This change is known as neuroplasticity and it occurs through two mechanisms. Huge changes to how existing synapses those are the electrical connections in the nervous system if you will, to ascertain how those synapses work and chronically by the creation of new synapses.

PoNS, the Portable Neuromodulation Stimulator is a wearable investigational medical device that is designed to non-invasively naturally and elegantly stimulate the trigeminal and facial nerves through stimulation of the tongue. There are two iterations of the PoNS device that were developed through a simple adjustment of the software.

One delivering approximately 26 million pulses, which we refer to as the high frequency pulse or HFP is the short, during a 20-minute treatment. And the other approximately 14,000 pulses, which we refer to as the low frequency pulse or LFP.

Despite these varying pulse frequencies, a user can detect pulses from both devices and the LFP was originally intended to be a non-therapeutic control to maintain blinding of study subjects in the trial.

Clinical signs that is performed with the goal of submitting for a regulatory clearance from health authority, requires reliable data in highly homogenous populations performed in clinical trial that are controlled, meaning that you need to compare a placebo or a sham device, so that the health authorities can understand that an intervention is effective compared to a condition without the intervention.

This is usually done by using a placebo in a DROP-trial or a sham non-therapeutic device, a medical device trials. In the medical device world, however that’s challenging. It can be difficult to create a device that truly blinds both the subject and the clinician to the real device, particularly when they have an active interface with the subject.

In our case, we developed the LFP device which was intended to be non-therapeutic, but we've realized that because it stimulated the same nerve as the HFP, it could potentially be therapeutically active. So we sponsored a study conducted in Surrey, British Columbia in Canada in 10 healthy volunteers, who are examined with 64 lead electroencephalography or EEG.

Results demonstrated that in both groups the brain activity or baseline was comparable but both LFP and HFP stimulation showed increased activity above baseline during stimulation. This was our first inkling that led to the hypothesis that both pulse frequencies may have the potential to produce a therapeutic effect.

We proceeded with the LFP device, so that we could truly have double-blind conditions, which we believe it would live up to the standard of the FDA and other health authorities. The FDA agreed, so we proceeded in that fashion. This decision, that is to make a critical study design decisions that we could respond credibly to the potential situation where the LFP device showed clinical activity.

First, we modified our inclusion criteria in the trial to only include subjects who had done prior physical therapy to address balance and based on the determination by other healthcare professional or themselves that they were no longer receiving benefit from that therapy. This would allow us to confirm that if subjects in the LFP stimulation group derive benefits that was superior to what the literature stipulates from physical therapy alone i.e. you'll recall an eight to 13 point rise in SOT scores, which would suggest that the LFP device provides therapeutic benefit.

We also thought, we needed to prepare for this possibility in our statistical analysis plan to prospectively direct the analysis in such a way that could direct how the analysis is to be performed. We of course recognize that if we were discovered that the LFP device was in fact active but it would be very difficult for us to reach our primary endpoint to the trial, which is a responder analysis between the HFP group versus the LFP group.

As you will see a little later, our statistical analysis plan, prospectively stipulated that if we did not reach statistical significance in our analysis that we would coax the two groups to determine, overall the interventions were statistically different from baseline. I'll show you this in a few minutes when we walk you through the statistical analysis plan.

Before we show you the results of the trial, we wanted to share briefly the published clinical research performed to-date. In three independent randomized clinical trials studying balance disorders in different patient populations, we demonstrated when HFP stimulation was compared to physical therapy alone, all three trials showed a statistically significant difference in favor of PT plus HFP stimulation versus PT alone.

Interestingly, the no-stim groups saw results completely consistent and comparable to the literature for treatment with PT alone i.e. an increase of eight to 13 points in each of these studies. So that was a pretty cool result, right because in all of our clinical trials when we

have the control, that was a no-stim control. So in those cases when we have the high frequency pulse device was the active – we produced statistically significant results in every one of the trial that we did, right.

Absolutely, basically what this demonstrated was our “brand of physical therapy” recapitulated what would be seen in standard, the gold standard, the current gold standard of treatment, which is vestibular rehabilitation therapy. And these studies instantly were in multiple sclerosis, cerebral palsy and stroke. Certainly, different medical conditions to traumatic brain injury but still medical conditions.

And a good confirmation that our studies and our intensive physical therapy protocol when performed without PoNS stimulation produced results that are comparable to the literature. So that was good affirmation.

This slide is interesting, in our MS study with 14 subjects seven with PT and HFP stimulation and seven patients with PT and no placeboable stimulation. We wanted to see if the statistically significant results that we saw in comparison in SOT between the groups in favor of the stimulation group could be tied to changes in the brain.

We’ve outperformed local functional MRI scans in two conditions. The subjects would simulate walking and be tested for their working, memory. Both the baseline and the end of the study, and that’s what you see on this slide. The results were simply put stunning.

As you can see here on this slide, the HFP group which is the group A in the three produced statistically significant changes in bold signals, that’s blood oxygen level dependency. A measure of oxygen, a glucose consumption in areas of the brain associated with walking and working memory. This was strong evidence that when you stimulate the tongue using a HFP device, in combination with PT it does in fact produce changes in the brain compared to PT alone.

We saw no changes in oxygen and glucose consumption in a functional MRI scans. And on this slide, this is – the prior one was the walking condition, this is a short-term memory again on the right of the slide that is just PT and no placeboable stimulation and you see no change from pre to post physical therapy. Whereas, while you have stimulation, but less slide on slide, you can see that there is an increase in the BOLD images that was statistically significant in two of the areas and came close in the third.

So we have a very well characterized and clearly defined regulatory pathway to FDA clearance. The FDA told us that they deemed this protocol to be a non-significant risk. So we did not need an investigational device exemption or IDE for short, to perform this registrational trial. I'm very happy to confirm that no device-related, serious adverse events were reported in either of the two trials that we are reporting today, nor have we seen any device-related serious adverse events in any clinical trial the we've performed with the PoNS Therapy.

A Class 2 application for medical device clearance by the FDA requires several elements. First, a documentation and reported of our quality systems. We received ISO 13485 certification in 2016 and recently passed our one year outed without a single citation. I must credit Joyce LaViscount in our team, who run this, and Kristie Ferris [ph] (0:19:23) the wonderful job they did.

Second, we need to provide the safety data from our clinical trial. We can confirm that our investigational devices demonstrated a favorable safety profile in our clinical trial and we look forward to discussing that data with the FDA.

Third, we need to supply our device verification documentation that demonstrates that we can manufacture the PoNS™ device with a level of demonstrated quality and reproducibility. And finally, we must also demonstrate clinical benefit. The efficacy component is instrumental to instructing the prescribing information for the product if it is cleared.

The subjects in our trial entered the study at an average SOT score of 42.1 and 41.1 in each respective group, that’s the average score. The subject presentation that you are about to see in the video was not a subject in our clinical trial, but she suffered significant balance impairment due to her TBI and scored a 40 on her baseline of 30. Every subject is different and there are many different potential contributions to an SOT result. This is just one example and if you understand the starting point of the typical subject in our trial.

So I’m now going to play this video for you. And this subject was a lady who had suffered a traumatic brain injury as a result motor vehicle accident. She was struck whilst riding bicycle. And the test that you will see her having is about three years later, it's called Dynamic Gait Index. She is walking up and down the hallway. Please note, and our focus is on walking, her Gait is wide, her arms are held out wide and they do not swing, her body moves in an unnatural manner, her whole focus is on walking. She has been given tasks to do by the instructor. You’ll see when she transitions from faster to slower, it’s a difficult and not a smooth transition as it would be for people who do not have this kind of problem.

When she turns to look right, you’ll see that she stumbles towards the right. And likewise, when she turns left she stumbles to her left like she is on deck of a rocking boat. And this of course causes immense distress for patients that have the tendency to fall, likewise when she looks up and looks down. And there she is reaching the stability again notice her arms held out wide to spread out to center of gravity. And again looking up from behind, and this DGI, Dynamic Gait Index is scored and then our trial was scored by independent receptors who were blinded. Stepping over an obstacle requires her entire concentration one step at a time, regaining her center of gravity and her balance. And again you can filmed from behind, this lady has an SOT of 40, I’m living with an SOT of 79. Coming downstairs requires holding on with both hands, her feet almost parallel to the threads and she walks very, very cautiously.

So our clinical trial was a randomized, double-blind, controlled study in patients with mild-to-moderate TBI. It was performed at seven centers across the United States and Canada. As mentioned before, all patients were at least one year post injury, so that they would have any spontaneous recovery possible and all subjects had to receive prior PT for their balance disorder and plateaued, meaning no further improvement was expected from PT alone. And of course they had an ongoing balance disorder to qualify the trial and have to have an SOT score at least 16 points below the normal limit for their age.

As mentioned before, here is a schematic of our statistical analysis plan. We would firsts analyze the study, assuming that the low frequency policy LFP did not produce a clinical benefit. If this analysis resulted in a trend or non-significant results in the primary endpoint, we would collapse the data into one group and determine if the intervention was statistically different from baseline as one group. We would determine whether the LFP therapy was impactful by forming a statistical analysis looking at the p-value of the difference between the baseline SOT measurement ad the SOT scores at the end of week-two and week-five. And we can thus definitively determine whether the LFP therapy was therapeutically effective. Remember a change in SOT of eight points is clinically relevant.

We would also see to confirm this by looking at whether the response of the LFP group exceeded the response expected for PT alone based on both the literature and our three peer reviewed publications who have all brands of the intensive physical therapy alone with no stimulation.

From a safety standpoint the primary safety – yes I'm sorry we are having a little slight less clarity, it looks like it's loading. From a safety standpoint, the primary endpoint was a reduction in force of week-two and the secondary endpoint was reduction in headache visibility index. I just want to say at this point if there is an issue with the slides technology sometimes defeats us it s going to be loaded onto the Helius Medical website, as Phil said at the beginning.

So here are the results. Please stay with us all the way because this is interesting. The primary endpoint of the trial was the comparison in the responder rate between the HFP treatment group and the LFP treatment group. Specifically the number of subjects who improved by over 15 points in their SOT scores we saw 75.4% responded in the HFP group versus a 60.7% response rate in the LFP group. Feel did p-value of 0.081, which is a trend to the superiority of the HFP group versus LFP group, a clear clinically significant improvement for both groups, but is not a statistically significant difference between the groups.

When looking at a change in SOT at week-two, and week-five for the HFP group, we saw an average increase of 21.3 scores in two weeks and 27.1 change at week-five. And for the LFP group, we saw an average increase of 17.1 and 23.6 points at week-two and week-five respectively. At each of the time points two weeks or five weeks in either the HFP therapy or LFP therapy groups, when compared to baseline, increases in SOT this week statistically significant p-values less than the 0.025 at all points with both groups.

Okay, so let’s – there’s lot going on in this slide and it's really important. So a couple of things that everyone needs to notice is you look at from the baseline let's look at the HFP plus PT group. From baseline to the two-week we would expect again over a long period of time about an eight point change, right. If it was PT alone, we are seeing a 21 point change, 21.3 point change in two weeks. And then on the five week, we are seeing a delta of 27.7 again compared to that eight to 13 point that we saw in the literature.

Now in the low frequency pulse group, we also saw a very significant change in the baseline, so from the baseline. So a 17 point so not as much as the high frequency pulse but very significant, compared to the literature. And the same thing at week five, a 23 point change and when we compare statistically the 0.2 – to the baseline from the SOT rise between at 10.2 and 10.5 we saw a statistical difference in both groups at 0.25.

So that's really, really important and this is the reason why so you see the difference between the two of the HFP is a little bit higher than the other one, and that's reflected in what we saw in the response rate in the previous slide, why we saw 75% response point rate in the first one but a very significant 60 point – a 60% response rate in the low. So what we have here are two effective clinical PoNS therapy and that's why we didn't reach – that's why we went to a trend rather than significant in our primary endpoint.

<<Jonathan Sackier, Chief Medical Officer>>

And thank you Phil, to put that into perspective and to restate in a two to five week time period, we are seeing in both groups changes in SOT scores that has double or more what the literature sometimes triple, we predict in a six to nine month period for PT alone.

We perform the statistical analysis, mentioned previously that is looking at the mean increase at the end of week two, the LFP device, which was 15.7 with a 95% lower confidence limit of 11.4. The increase in SOT score from baseline at the end of week two is significantly greater than zero, with a p-value less than 0.025. This indicates that the LFP treatment has a significant therapeutic effect but the HFP treatment in the two week time frame pushes the SOT scores a little higher with the average increase in the HFP group of 20.9 also with a p-value of 0.025. We perform the same analysis for the week five day at a time, a very similar result illustrated in the table.

We didn't reach our primary objective of this endpoint, simply put because the LFP treatment had a significant therapeutic effect and much greater than seen in the literature, eight to 13 points. Since we met the condition that the LFP treatment was shown to be clinically effective and the responder analysis only showed a trend toward significance in the primary effectiveness endpoint, we proceeded with the statistical analysis under the condition dictated by statistical plan.

You see in the table that when we combine the LFP and HFP group, the HFP groups and compare to baseline but the intervention with either the HFP or LFP group yields a mean increase in SOT score of 18.3 that is statistically significant to a p-value of less than

0.0005 for the endpoint at week two. Similarly, the change in mean score of five week time point is 24.6 and statistically significant at a p-value of 0.0005. For those of you who may be concerned whether we have a patent.

<<Phil Deschamps, President, Chief Executive Officer & Chairman>>

Let me take that one, Jonathan. So I could see that some of you might have some questions and say hey, so it looks like we actually might not have just one device we might have two devices here that are clinically effective, our two therapies one with the high and one with the low so just the rest assured everyone that our IP portfolio covers all forms of stimulation. So that's not an issue at all for us, our patents are essentially – our method patents are essentially any kind of skin or oral stimulation combined with physical therapy resulting in any kind of therapeutic outcome.

And by the way, we just had those patents independently validated by a third-party law firm and they came through perfectly clean.

<<Jonathan Sackier, Chief Medical Officer>>

So the FDA is very concerned that this would be with safety, we met our primary safety endpoints through a significant reduction in a number of falls in both groups. We also met our secondary safety endpoint with reduction in the headache disability index, a measure of how people are troubled by headaches, finally there were no device related series adverse events.

In summary, we didn't meet our primary endpoint because the LFP treatment also provided significant therapeutic effect, we did satisfy our two secondary effectiveness endpoints with a p-value of less than 0.0005, this is a statistically significant result. We also met our primary and secondary safety endpoints.

Now that we've observed that LFP treatment has therapeutic effect, it helps us to better interpret data from the long-term treatment trial performed at the University of Wisconsin-Madison, they use the same HFP and LFP devices that we did. So we don't expect to see any statistical differences between the HFP and LFP groups. So let's focus on the magnitude of the change that we're seeing in both these treatment groups.

The study was performed in response to a question posed by FDA during our early – our pre-submission meeting the question was what happens after responders discontinue treatment, do subjects maintain the benefit of the 14 weeks of active therapy in this trial or do they trend back to baseline impairment over a 12-week washout period.

This was not a registrational trial, it was performed to answer the clinical question from the FDA. The study was a randomized controlled clinical trial with 44 patients, 22 randomized to PT plus HFP and 22 randomized to the LFP group. As noted, this study used identical PoNS devices as we did in the registrational trial. This study was also performed with an identical physical therapy protocol as the registrational trial.

The long-term study looked at the results of SOT change between groups of baseline two weeks, 14 weeks and 26 weeks, after the 12 weeks of washout. Subject for an active treatment for two weeks in the clinic and then did that therapy and stimulation at home for a further 12 weeks reporting every week to the clinic. At the end of 14 weeks treatment, all subjects were discontinued and monitored during the washout period, subjects were given no special instructions except to resume life in any way they solve it.

In the long-term study, we saw very similar results as the registrational trial and you can see that on this slide. This supported both the HFP and LFP devices were therapeutically effective, in fact response in both groups, changes in SOT at week two will not statistically different between groups but were highly significantly different. I'm sorry, there’s an announcement at the conference room. Our sincerely apologizes. It’s way beyond our control.

<<Phil Deschamps, President, Chief Executive Officer & Chairman>>

I can’t believe this.

<<Jonathan Sackier, Chief Medical Officer>>

It’s the hotel celebrating our results.

<<Phil Deschamps, President, Chief Executive Officer & Chairman>>

Again, they have flashing lights. So our apologizes for that. So in the long-term study we saw very similar results for registrational trial supporting both the HFP and LFP devices, were therapeutically effective. In fact, response in both groups changes SOT group, as I’ve said, we’re not statistically different between the groups, but we’re highly significantly different in comparison to baseline.

Our Week 2 there was a 20.9 point change in the HFP group versus a 25.8 SOT point change in the LFP group. Again, remember, 8 point is clinically significant. 14 weeks of treatment in the HFP group yielded SOT score change that reached the normal range. This means that on average patients in the HFP group went from being significantly impaired scoring 40 on the SOT just like that lady you saw earlier, to having normal balance.

Subjects in both the HFP and LFP groups maintained the clinical benefit over a 12-week period without directed PT or stimulation, suggesting these subjects had recovered potentially, permanently or very least for the 12 weeks from that balance disorder. Think about that for a second. Chronic symptoms of TBI after a year from injury are often lifelong and we are seeing people on average recover that balance fully over a period of 14 weeks treatment.

The Dynamic Gait Index result was similar to the SOT changes. So remember, SOT is measuring balance, Dynamic Gait Index is indeed measuring gaits, you need balance to be able to walk. Baseline both treatment groups have scores in the elevated risk of all category that is they score less than 19 whereas 24 is considered normal. There were no statistical differences between groups of expected. After 14 weeks completion of treatment both groups saw an increase in Dynamic Gait Index score that put them in a category approaching normal. There was a general decrease in the Headache Disability Index and there were no device related serious adverse events.

To put these results in contacts, we'd like to show you a video of the same subject from the earlier video after she underwent a 5-week course of HFP PoNS treatment. She now has a normal score on the SOT. I want to reiterate she did not have – she did not participate in our clinical trial and this is only shown to illustrate where a person with a normal SOT looks like while performing the Dynamic Gait Index vertical.

You'll notice she's walking smoothly, her arms are swinging, she transitions from fast to slow smoothly. And when she looks to the right she doesn't stumble nor to the left. And you probably won't be surprised that when she locks up and down, no longer that she have that kind of wobbliness that she had, she no longer looks like she's on the deck of a boat. She steps over an obstacle effortlessly, smoothly, and you could imagine she'd be capable of doing more things. And coming downstairs, she doesn't need to hold on and her toes are now right angles to the threads.

In conclusion, I'd like to summarize what we saw in the results of clinical work done today with PoNS therapy. In previous published clinical trials, physiotherapy plus the HFP PoNS therapy has proven to be statistically significantly superior to PT with no stimulation in three independent controlled clinical trials imbalanced conditions outside of TBI. HFP PoNS therapy produced functional MRI, confirmed statistically significant changes to the brain, while PT alone and a non-stimulating device did not produce any changes to the brain.

In the registrational trial the response rate of HFP PoNS treatment was 75% showing a trend to be superior to LFP PoNS treatment that have 60.7% with a p-value of 0.081. And while we did not reach statistical significance between the two groups, both groups got vastly better than baseline and had a far superior increase than the literature would ever suggest is possible with PT alone.

We did not reach our primary effectiveness endpoint because the LFP treatment had a significant therapeutic effect with a p-value of 0.025. We achieved our secondary effectiveness endpoint, HFP and LFP PoNS treatment combined resulted in a highly statistically significant improvement in SOT versus baseline measurement at all measurement time points with a p-value less than 0.0005. PoNS therapy achieved the primary safety endpoint, a reduction in points for Week 2. There were no device-related to serious adverse events.

And in the long-term treatment trial on average HFP PoNS therapy subjects achieved normal SOT scores at the end of 14 weeks of treatment, which was sustained over 12 weeks of washout period, providing a hope that we may have discovered the therapy that restores the vestibular function in subjects treated for 14 weeks.

So we've gone through a lot of really technical days and I can't imagine how that must have sounded to the other end of the phone. What I'd like first of all to do is to have you think about these results in the big picture. Phil, do you want to make some comment on that?

<<Phil Deschamps, President, Chief Executive Officer & Chairman>>

Well, look, for us we're ecstatic with the results. And we certainly look forward to working with the FDA in presenting these results and submitting those results to them. We look forward to the clearance for our device. Obviously, we hope that these device or these results seem to support that we would be able to do that. And by the way, we now anticipate that our five 10-K application to the U.S. FDA will be submitted in the first half of 2018 and clearance is expected in the second half of 2018.

So many thanks everybody. Jonathan, thank you very, very much, you did that very, very well. Again, thank you to all the clinicians. Thank you to all the BCs. We're ecstatic with the results that we've seen today and look forward overtime to answer your questions.

<<Jonathan Sackier, Chief Medical Officer>>

And just one final parting comment, we also have to thank the subjects who participated in this clinical trial. And do not forget that we have a profound and very sincere commitment to trying to improve the health of patients out there, because, remember, sooner or later we're all patients. Thank you very much for your attention, ladies and gentlemen.

<<Phil Deschamps, President, Chief Executive Officer & Chairman>>

Bye now.

Operator: Thank you, ladies and gentlemen. This concludes [Call Ends Abruptly]

Helius Medical Technologies Announces Positive Results from its Registrational Clinical Trial for Traumatic Brain Injury (TBI)

Neurostimulation of the Brain via the Tongue using PoNS™ Therapy Observed to Produce Clinically Significant Improvements to Balance Deficits

Newtown, PA – November 9, 2017 – Helius Medical Technologies, Inc. (TSX: HSM, OTCQB: HSDT) ("Helius" or the "Company"), a medical technology company focused on neurological wellness, announced results from its registrational trial evaluating the safety and effectiveness of the Portable Neuromodulation Stimulator (PoNS™) for the treatment of subjects with chronic balance deficits due to mild-to-moderate TBI.

The multi-center registrational trial titled, ***A double-blind, randomized, sham-controlled study of the safety and effectiveness of the Portable Neuromodulation Stimulator (PoNS™) 4.0 device for cranial nerve noninvasive neuromodulation (CN-NINM) training in subjects with a chronic balance deficit due to mild-to-moderate traumatic brain injury (TBI),*** evaluated a total of 122 randomized subjects (61 active and 61 control). Subjects, age 18 to 65, received 5 weeks of treatment (2 weeks in-clinic and 3 weeks at-home) consisting of physical therapy and either a high-frequency PoNS™ device (active) or a low-frequency PoNS™ device (control).

Endpoints for effectiveness were assessed using the Sensory Organization Test (SOT), measuring balance using computerized dynamic posturography. A responder rate analysis was used for the primary endpoint. A responder was defined as a subject with an improvement of at least 15 points on the composite SOT score compared to baseline after 5 weeks of PoNS™ Therapy.

Secondary effectiveness endpoints were contingent on the outcome of the primary endpoint and determining the clinical effectiveness of the low-frequency device. As the low-frequency device demonstrated, on average, statistically significant improvements on composite SOT scores compared to baseline ($p<0.025$) – the secondary effectiveness endpoints evaluated for the study were the mean change in composite SOT score from baseline at 2 and 5 weeks, for both arms combined.

Endpoints for safety were assessed by frequency of falls, frequency of headaches, and Adverse Events (AEs). Falls and headaches were measured by daily activity logs and the Headache Disability Index, respectively.

Study results highlights:

- Primary effectiveness endpoint demonstrated a trend toward a higher responder rate in the high frequency PoNS™ Therapy group (75.4%) than in the low frequency PoNS™ Therapy group (60.7%), $p<0.081$
    - Primary effectiveness endpoint was not reached because low frequency pulse treatment had a significant therapeutic effect

- Secondary effectiveness endpoints demonstrated statistically and clinically significant increases (at least 8 points) in composite SOT scores:
    - The mean improvement at 2 weeks for combined-arms was 18.3 points, p<0.0005
    - The mean improvement at 5 weeks for combined-arms was 24.6 points, p<0.0005
- Successfully met primary and secondary safety endpoints as measured by a decrease in falls and headaches, in both groups
- There were no serious device related adverse events

“We are very pleased with the findings from our registrational trial that demonstrate that PoNS™ Therapy, deployed independently across our seven study sites, produced statistically significant improvements in balance from baseline, on average over three times the clinically significant amount,” said Helius’ Chief Medical Officer, Dr. Jonathan Sackier. “Achieving the safety endpoints and further growing a positive safety profile continues to build confidence in our technology. With an underserved patient population waiting for improved treatment opportunities, we are eager to move forward with our applications for clearance with the U.S. Food and Drug Administration (FDA) and other foreign regulatory bodies.”

TBI is a serious public health problem in the United States, according to the U.S. Center for Disease Control. A large proportion of TBI patients with chronic balance symptoms are left with limited treatments options. Currently available therapies are minimally effective and focus on teaching patients how to cope with their remaining deficits, rather than improving symptoms.

“We are excited to be on the forefront of research that may bring this novel and exciting therapy to patients in need,” said Dr. Alain Ptito, Director of the Department of Psychology of the McGill University Health Centre and Coordinating Principal Investigator for the study. “The investigators and research teams from the Montreal Neurofeedback Center, Orlando Regional Medical Center, Oregon Health and Sciences University, Health Tech Connex, Inc., Virginia Commonwealth University, MedStar National Rehabilitation Hospital and University of Wisconsin – Madison are pleased with the execution of this study and look forward to further analysis and publication of the results.”

“This is a very exciting and promising milestone for our Company, patients and the healthcare community,” added Helius’ CEO, Philippe Deschamps. “Our next steps include compiling the clinical evidence produced from this registrational trial and previous studies investigating the PoNS™ treatment, as well as verifying and validating product design improvements and manufacturing to be included in our regulatory application. We are working to submit our 510(K) application to the U.S. FDA in the first half of 2018, with clearance anticipated in the second half of 2018.”

Helius is building upon almost 40 years of scientific research on neuromodulation, early pilot projects and case studies performed at the Tactile Communication and Neurorehabilitation Laboratory (TCNL) at the University of Wisconsin in Madison. Most recently, a study at the University was conducted to evaluate what happens when responders to PoNS™ Therapy stop treatment. The results showed that, on average, subjects with compromised balanced who restored vestibular function to normal levels after 14 weeks, maintained their improvements even after 12 weeks of wash-out.

The company will provide a presentation of the data on Thursday, November 9, 2017 at 8:00 AM ET.

- Webcast at http://www.wsw.com/webcast/cc/hsdt
- Dial-in at 1 (866) 939-3921 (US Toll Free) or 1 (678) 302-3550 (US Toll). Please use confirmation number 45986789.
- An archived copy of the webcast will be available at www.heliusmedical.com and http://www.wsw.com/webcast/cc/hsdt

About PoNS™ Therapy

The PoNS™ is an investigational, non-invasive, wearable medical device designed to deliver neurostimulation through the tongue. Clinical research has shown that electrical stimulation of the tongue activates two major cranial nerves – the trigeminal nerve and the facial nerve. Electrical stimulation of these cranial nerves creates a flow of neural impulses that are then delivered directly into the brain stem and cerebellum. PoNS™ Therapy combines the use of the PoNS™ device with physical therapy.

About Helius Medical Technologies, Inc.

Helius Medical Technologies is a medical technology company focused on neurological wellness. Helius seeks to develop, license and acquire unique and non-invasive platform technologies that amplify the brain's ability to heal itself. Helius intends to file for FDA clearance for the PoNS™ device. For more information, please visit www.heliusmedical.com.

The Toronto Securities Exchange has not reviewed and does not accept responsibility for the adequacy or accuracy of the content of this news release.

Cautionary Disclaimer Statement:

Certain statements in this news release and to be made in this morning's presentation are not based on historical facts and constitute forward-looking statements or forward-looking information within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Canadian securities laws ("forward-looking statements").

All statements other than statements of historical fact included in this news release and in this morning's presentation are forward-looking statements that involve risks and uncertainties. Such forward-looking statements include, among others, statements regarding ongoing or planned clinical research, expected future development timelines, regulatory submissions and approvals or other business initiatives and objectives.

Forward-looking statements are often identified by terms such as "estimate" "intend" and similar expressions.

There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated in such statements. Important factors that could cause actual results to differ materially from the Company's expectations include the failure of the Company to achieve its business objectives and other risks detailed from time to time in the filings made by the Company with securities regulators.

The reader is cautioned that assumptions used in the preparation of any forward-looking statements may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties,

and other factors, many of which are beyond the control of the Company. The reader is cautioned not to place undue reliance on any forward-looking statement. Such information, although considered reasonable by management at the time of preparation, may prove to be incorrect and actual results may differ materially from those anticipated. Forward-looking statements contained in this news release and this morning's presentation are expressly qualified by this cautionary statement. Risks and uncertainties about the Company's business are more fully discussed in the Company's disclosure materials, including its Annual Report on Form 10-K and other filings with the United States Securities and Exchange Commission and the Canadian securities regulators and which can be obtained from either at www.sec.gov or www.sedar.com.

The forward-looking statements contained in this news release and to be made on this morning's presentation are made as of the date of this news release and the Company assumes no obligation to update any forward-looking statement or to update the reasons why actual results could differ from such statements except to the extent required by law.

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