



# Helius

MEDICAL TECHNOLOGIES

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A Revolution in Mind

April 2018

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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; 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 the preliminary prospectus supplement for the offering and the Company’s Annual Report on Form 10-K for the period ended December 31, 2017, 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.

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No securities regulatory authority has expressed an opinion about these securities and it is an offense to claim otherwise.

# Helius Leadership Team



**Philippe Deschamps**  
**President and CEO; Chairman and Director**

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



**Joyce LaViscount**  
**CFO and COO**

- 29 years in the health sciences industry
- Accomplished pharmaceutical/healthcare public company CAO
- Former Executive Director/group controller at Aptalis Pharmaceuticals
- Former Chief Operating Officer and CFO at MM Pharmaceutical Solutions



**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

*Experienced management team with expertise in health sciences and commercialization*

# Cap Table

**Tickers: HSM:TSX, HSDT:OTCQB**

Market Cap 3/31/18: US\$ 210 M CAD\$ 268M	Shares Outstanding as of 3/31/17: 20.8 M
Price: 3/31/18      HSDT – US\$ 10.11 HSM.T - CAD\$12.87	Shares Incl. Warrants & Options as of 3/31/17: 25.0 M
52 Week High/Low: HSDT-US\$ \$20.70/\$6.45 HSM.T-CAD \$25.45/\$8.60	Management Ownership as of 12/31/17: 25%
Avg Daily Volume: HDST 6.3K HSM 12.46K	12/31/2017 Cash & Equivalents: US\$5.6 M; No Debt; 12/17 PP Gross Proceeds: \$6.3 M

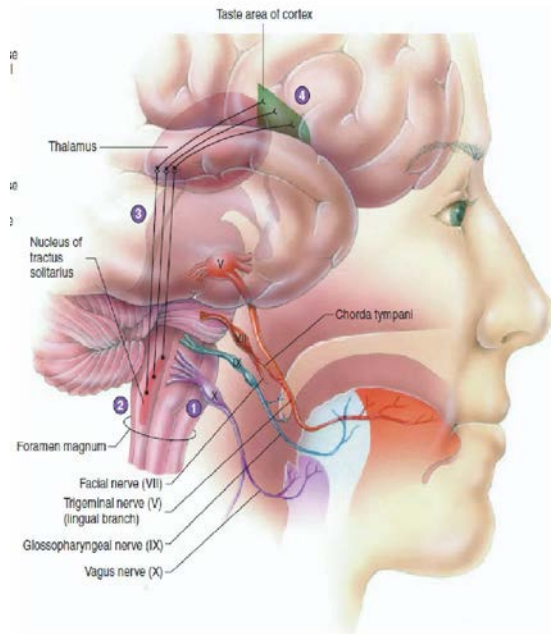
- Company founded in 2014
- Raised \$60M through registered offerings and private placements since June 2014
- 13 employees – 35 FTEs on a variable cost basis

# Investment Highlights

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- First in class, non-invasive PoNS<sup>®</sup> technology addressing symptoms of neurological disease or trauma
- Clear regulatory pathway (de novo to 510K, class II non-significant risk)
- Multiple large, underserved markets the first of which is TBI - a \$5 billion + indication in US alone
- Established, well-characterized commercialization model
- Data in over 275 subjects in six clinical trials supporting safety and efficacy of PoNS<sup>®</sup>
- Significant barriers to competitor entry with comprehensive IP portfolio
- Potential to generate revenue in 2018

# PoNS<sup>®</sup> Designed to Stimulate the Trigeminal and Facial Nerves Through the Tongue



## Portable Neuromodulation Stimulator (“PoNS<sup>®</sup>”)

- Non-invasive investigational technology
- Delivers specially-patterned nerve impulses to the lower brainstem through disposable appliance placed on the tongue
- Combined with physical or cognitive therapy, demonstrated to treat patients with chronic neurological symptoms caused by disease or trauma
- 6 clinical trials performed in 275+ total patients, including a 120 person registrational trial
- Clinical results demonstrated statistically significant safety and efficacy over baseline in all trials



# PoNS<sup>®</sup> Clinical Progress and Opportunities

## Indication and Target Patient Population - US\*



<b>Traumatic Brain Injury (5M patients)</b>
<b>Multiple Sclerosis (1M patients)</b>
<b>Cerebral Palsy (764K patients)</b>
<b>Stroke (7M patients; 795K new each year)</b>
<b>PTSD (25M patients)</b>
<b>Facial Nerve Palsy (75K patients)</b>
<b>Depression (15.7M patients)</b>
<b>Parkinson's Disease (1M patients; 60K new each year)</b>

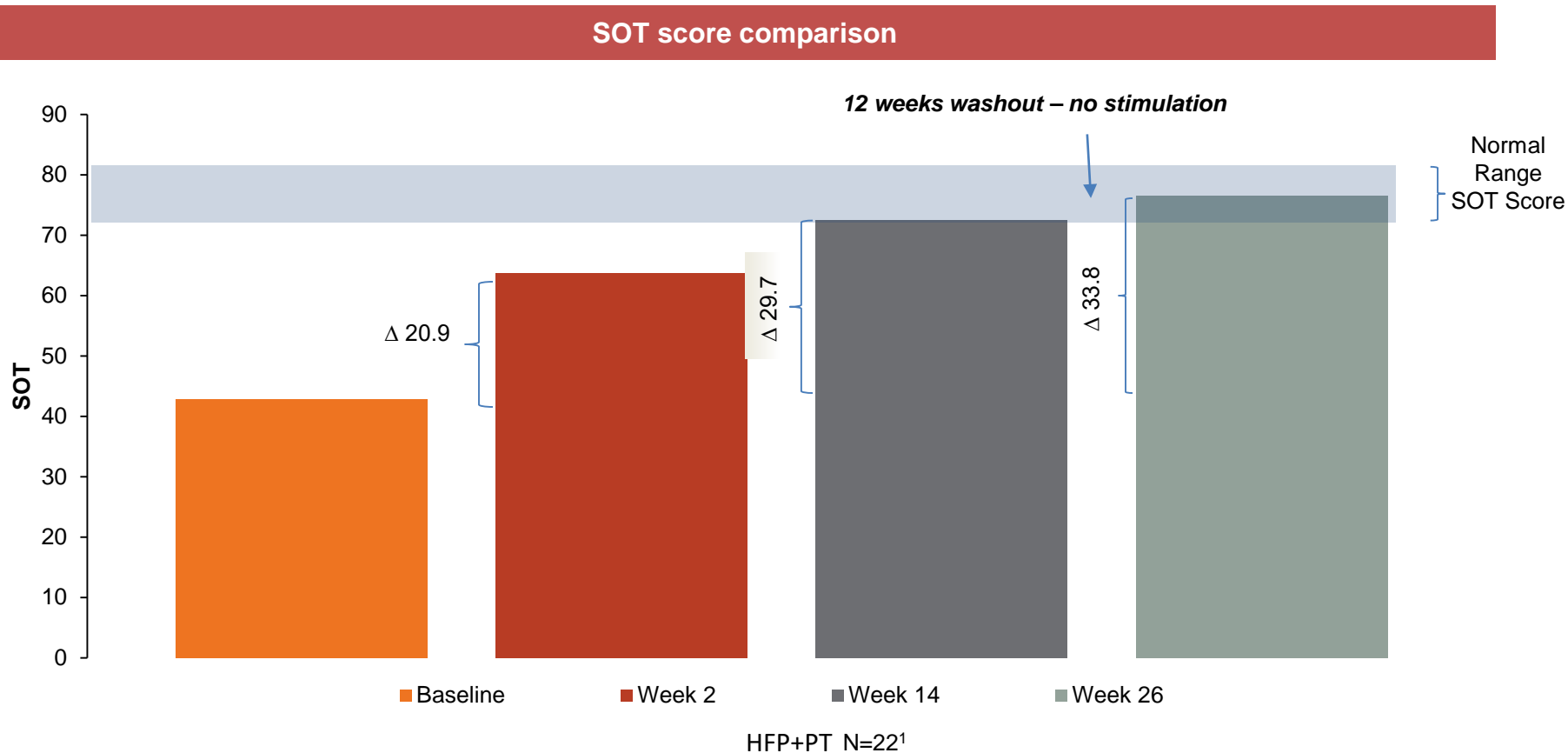
*Completed Registrational  
and Long Term Clinical Trials*

✓ *Pilot Studies Completed*

*Potential for Future  
Development*

\* See appendix references

# Patients Balance was Significantly 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 and normal score was maintained throughout 12 week washout period for all participants*

<sup>1</sup> LFP data not shown since it was not statistically different from HFP



# Clearly Defined Regulatory Pathway – de novo to 510(k)

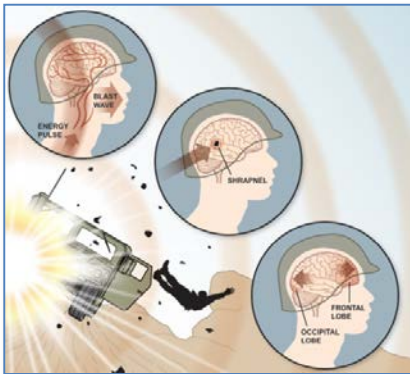
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- **FDA deemed the study of the PoNS<sup>®</sup> for mild-moderate TBI a ‘non-significant risk device study’ under the IDE regulations**
- **FDA confirmed that a request for de novo classification into Class II for the mild-moderate TBI indication would be an appropriate path to seek marketing authorization**
  - **Broad Content for Submission:**
    - ✓ Reasonable assurance of clinical safety in target population
    - ✓ Reasonable assurance of clinical efficacy in target population
    - ✓ Quality management systems – received ISO 13485 Certification in December 2016
    - ❑ Design verification and good manufacturing practices – Forecast to be Completed in 1H, 2018
      - Based on FDA MDUFA performance goal for de novo down classification and 510(k) clearance, 90-150 day review period anticipated
- Contemporaneous applications for marketing clearance from:
  - Health Canada, CE, TGA, Sino-FDA

# Traumatic Brain Injury (TBI)

- 2.1 million people with balance disorder related to non severe TBI<sup>1</sup>
- **Unmet Need:** Current treatment paradigm offers few viable therapeutic options

## Military



### Common Types of TBI due to Military Activity:

- Explosive blast injury
- Overpressure
- Diffuse axonal injury

- 5 year average of 25,000/year active duty soldiers with TBI<sup>2</sup>
- 200,000 retired soldiers diagnosed with TBI<sup>3</sup>
- 40+% of new cases result in chronic symptoms<sup>4</sup>

## Athletic / Civilian

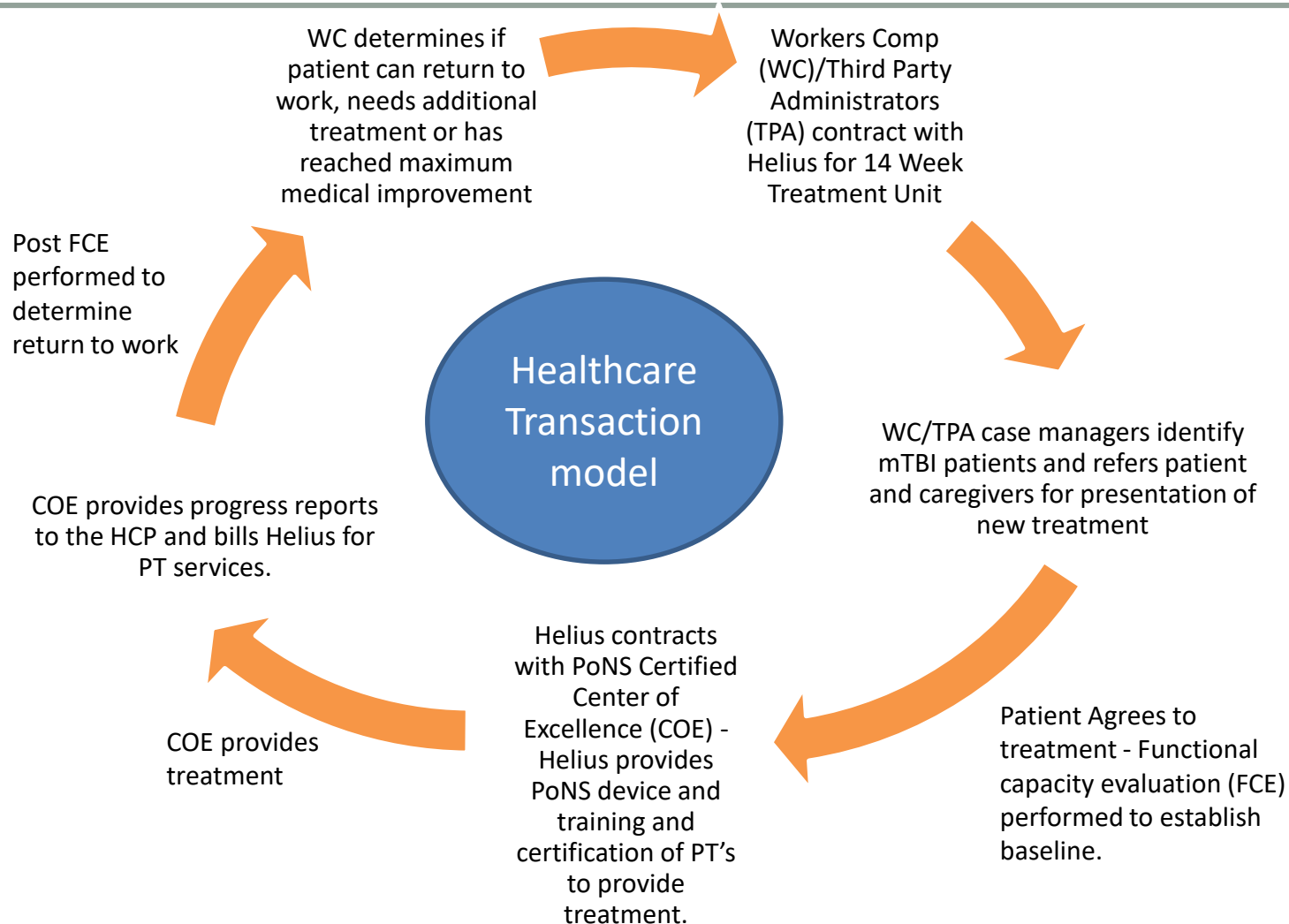


### Causes of Civilian TBI:

- Blunt trauma
- Motor vehicle accident
- Sports related injury
- Assaults

- 2.8M new cases of TBI were reported in the U.S. in 2013<sup>6</sup>
- 40% of those with mild to moderate TBI have gait and balance issues<sup>1</sup>
- 3.2 - 5.3M living with TBI related disability<sup>5</sup>

# Healthcare Transaction – Specialty Network/Workers Comp



# Why Workers Compensation Focus?

- Benefit payments under workers' comp programs totaled \$62.3 billion in 2014<sup>1</sup>
- Well established process of delivering care - specialty clinic networks
- Workers' Comp 4% of all mild to moderate TBIs, or 84,800 patients (based on 5.3M total chronic TBI patients) and 17,920 new patients/year (based on 2.8M total new patients/year)<sup>2</sup>
- In FY 2011, CMS approved \$1.1 billion of workers compensation (WC) MSAs<sup>3</sup>
- Contract directly with WC/TPA for 14 Week Treatment unit – in Process
  - Market opportunity of \$2.0-\$3.2B based on price of \$25-\$40K for treatment unit (device, therapy and related costs)
  - Medical Device Margin - 90-95%
  - Treatment Unit Margin – 60-65%
- WC Contract enables treatment at rehab clinics without prior authorization or insurance verification

<sup>1,2,3</sup> see appendix

# Using Established Specialty Clinic Network

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- WC/TPA already partner with neuro-rehab clinics where we are negotiating contractual relationships
- Clinics not presently treating significant percentage of TBI patients
  - No approved treatments or coordination of care
- Novel PoNS<sup>®</sup> Treatment draws new patients into clinics with reimbursement coverage
  - Raises profile and prestige of the clinic – PoNS<sup>®</sup> Certification Designation
  - PT plus ancillary services provided (\$5,000-\$10,000 per patient) generates new clinic revenue
  - Bandwidth within clinics to allocate PT's to PoNS<sup>®</sup> Treatment
- Exclusivity for geographic areas requested by clinics

# Investigational Device Clinical Experience Program (CEP)

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- **Build commercial infrastructure prior to clearance of PoNS<sup>®</sup> to establish clinical and economic benefit**
  - Company contracts with Clinics to flow into commercial agreement post-clearance
  - WC/TPAs in close consultation to ensure data generation relevant to their economic models
  - Targeted launch to control quality of treatment delivery
- Collect data to feed:
  - WC actuarial forecasts to build health economic model
  - Commercial and Medicaid/Medicare payers reimbursement
  - Additional clinic interest/penetration

**Goal is to have minimum 4 CEPs to drive 8 commercial clinic contracts at launch - targeted for Q4/18**

***No new business model to create – operating within existing healthcare delivery networks***

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# Significant Barrier to Competitor Entry – Extensive IP Portfolio

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## Exclusively licensed from inventors (4% royalty):

- 7 US Medical Method Patents Issued

## Patents owned by Helius (no royalty):

- 25 US Patents
- 24 International Patents Issued

## Helius Patents Transferred to China Medical System Holdings (CMS):

- 3 Chinese Design Patents

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

Helius owns the intellectual property for any stimulation plus physical or cognitive therapy – anyone wishing to enter the space must come through Helius...

# Other Science

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# Scientific Basis that Trigeminal Nerve Stimulation Positively Impacts Brain Physiology

Journal of Neurology and Stroke, Shiflett J.M. et al 2015<sup>1</sup>

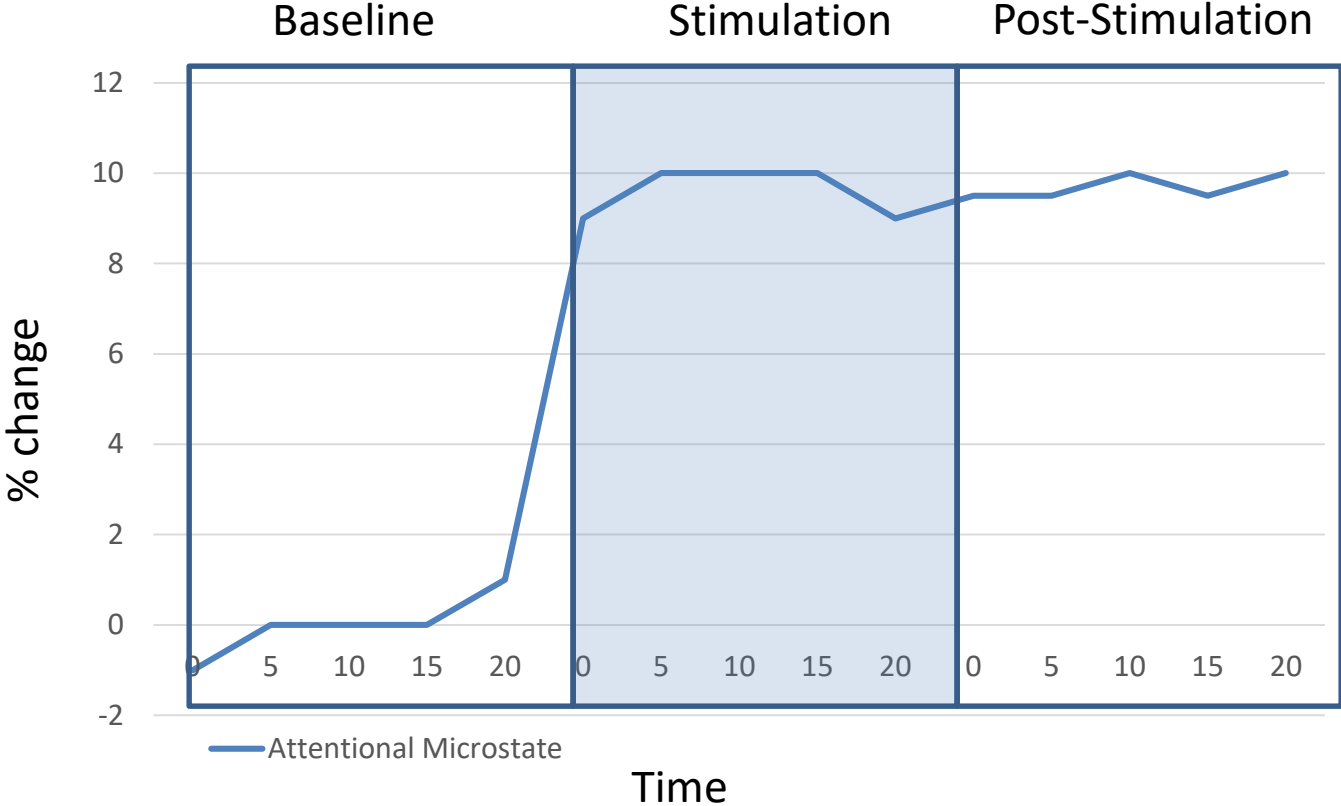
- Standard rat model of middle cerebral artery occlusion
- Indirect TNS led to 31% reduction in stroke
- Direct TNS led to 65% reduction in stroke
- Mediated by diving reflex
- Implications for stroke recovery, acute treatment or prevention?

*Nature Scientific Reports, Chiluwal A., Narayan R., Chung W. et al. 2017<sup>2</sup>*

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

<sup>1,2</sup> see appendix

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



Data on file, Helius Medical 2017

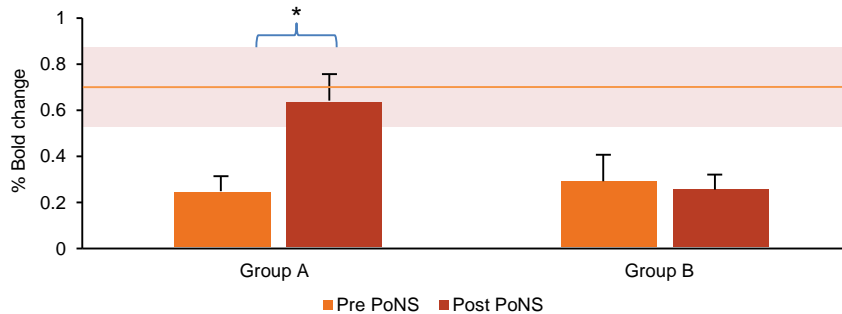
n= 20 neurologically intact volunteers

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

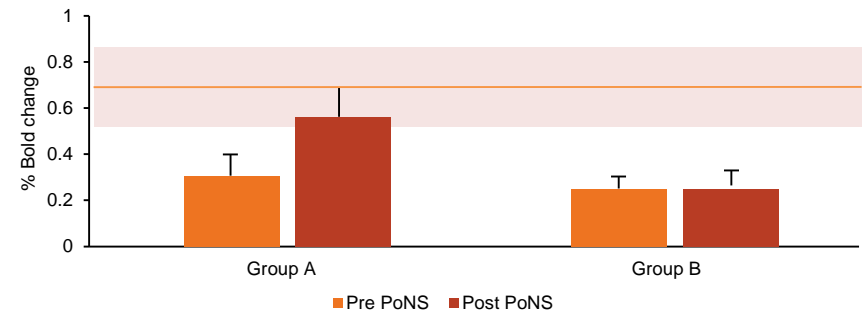
- 14 subject (7/7) study: All received physiotherapy with Group A receiving HFP PoNS<sup>®</sup> stimulation and Group B non-perceivable stimulation PoNS<sup>®</sup>

## VOIs bold signal vs. Healthy controls

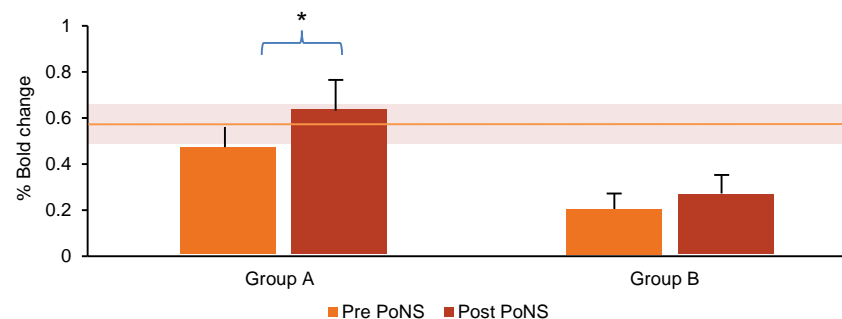
### Left DLPFC\*\*



### Right DLPFC



### rACC\*\*\*



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

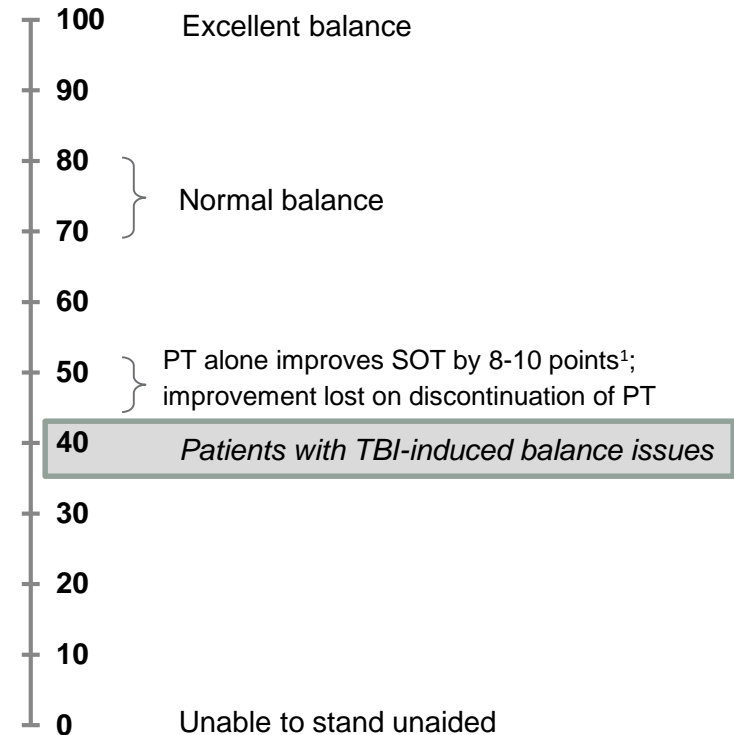
# Sensory Organization Test (SOT) – Standard Clinical Endpoint for Balance

## Sensory Organization Test



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

## Scale: Degree of sway



Change of 10 points represents clinically significant change in SOT in TBI<sup>1</sup>

<sup>1</sup> see appendix

# PoNS<sup>®</sup> Registrational Trial in TBI

<b>Clinical Study</b>	<p>A double-blind, randomized, controlled* study of the safety and effectiveness of the PoNS<sup>®</sup> device for translingual noninvasive neuromodulation stimulation (“TLNS”) training in subjects with a chronic balance deficit due to mild to moderate (mTBI)</p>
<b>Indication</b>	<p>Chronic balance deficit due to non-severe TBI</p>
<b>Study Population and Endpoints</b>	<ul style="list-style-type: none"> <li>• 120 patient double-blind, controlled study HFP vs LFP</li> <li>• Primary endpoint is improvement comparison HFP vs LFP of responders at 5 weeks. Responder = increase in SOT <math>\geq</math> 15</li> <li>• Secondary Endpoints are improvement in SOT scores from baseline at week 2 and week 5</li> <li>• Safety Endpoints             <ul style="list-style-type: none"> <li>• Primary: No increase in frequency of falls</li> <li>• Secondary: No increase in headache disability index</li> </ul> </li> </ul>

# PoNS<sup>®</sup> Registrational Trial in TBI (con't)

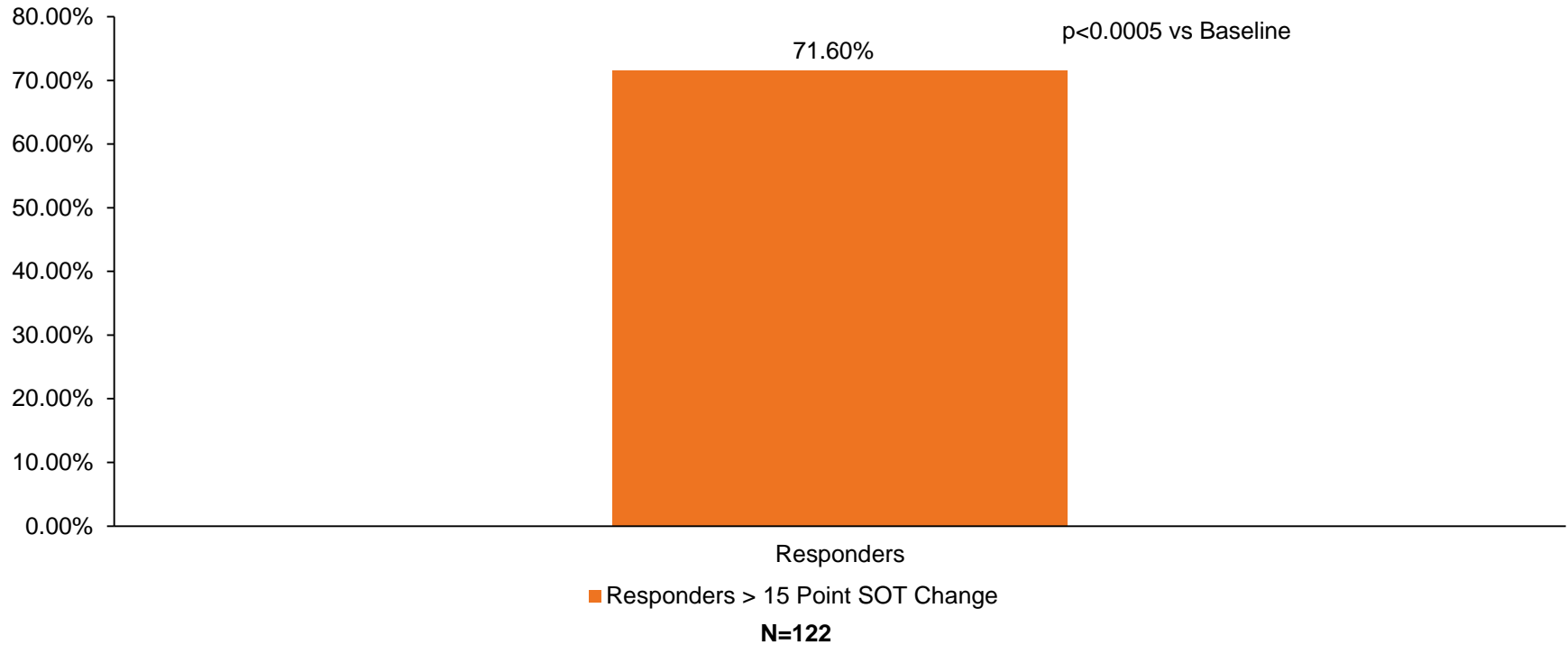
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## Important Criteria For the Study

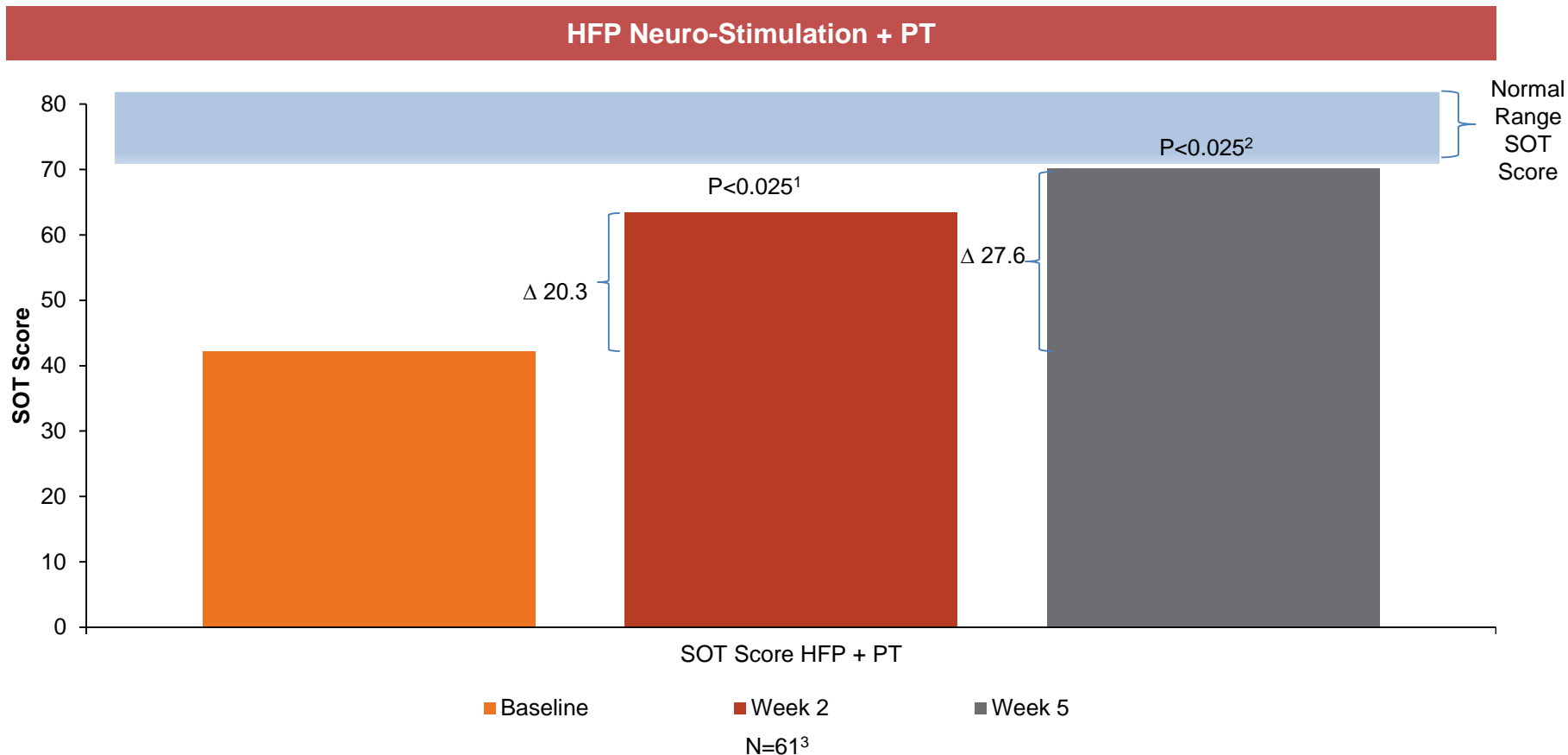
- All subjects were *at least one year post-injury*
  - Further spontaneous recovery unlikely
- All subjects had to:
  - Have participated in a focused physical rehabilitation program and have reached a plateau
  - Still have significant balance issues as they entered the study

# PoNS<sup>®</sup> Responder Analysis

## Percent Responders High Frequency Pulse And Low Frequency Pulse Stimulation Combined



# PoNS<sup>®</sup> Study Efficacy - Time Course Data



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

<sup>1</sup>HFP: Mean increase over baseline at end of Week 2 = 20.9 with 95% lower confidence limit of 16.6,  $p < 0.025$

<sup>2</sup>HFP: Mean Increase over baseline at end of Week 5 = 27.6 with 95% lower confidence limit of 23.1,  $p < 0.025$

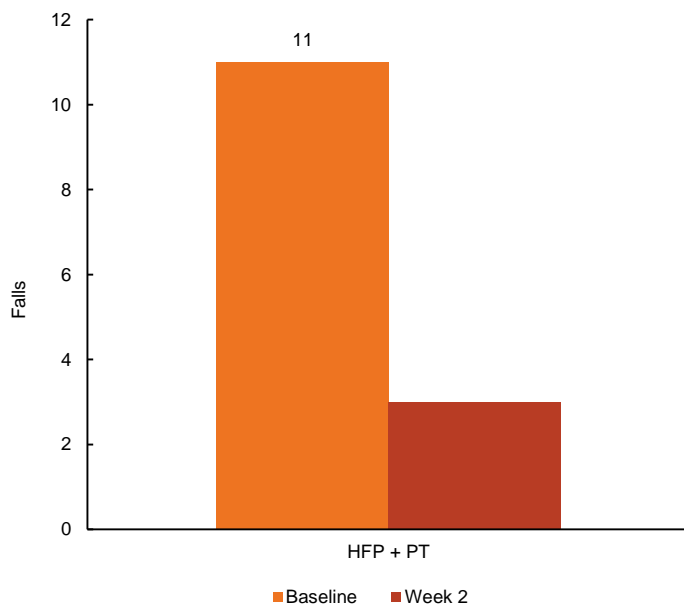
<sup>3</sup> LFP data not shown since it was not statistically different from HFP



# Primary and Secondary Safety Endpoints Met

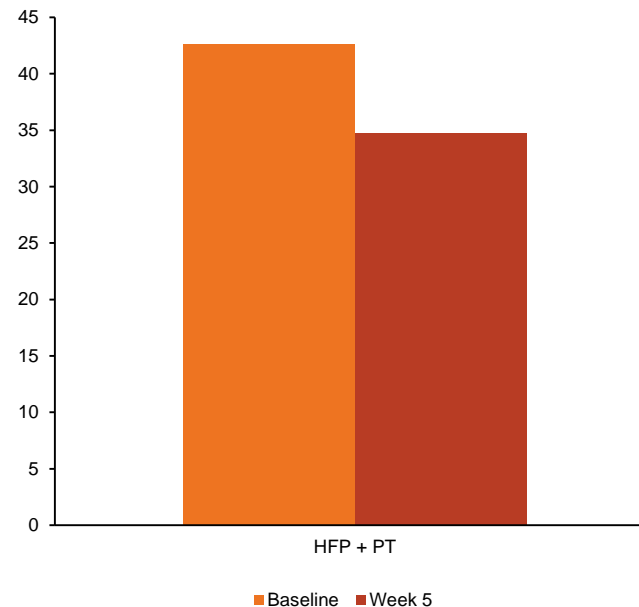
Primary Safety Endpoint Met – Decrease in Number of Falls

Comparison of Falls at Baseline and End of Week 2



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

Headache Disability Index



N=60

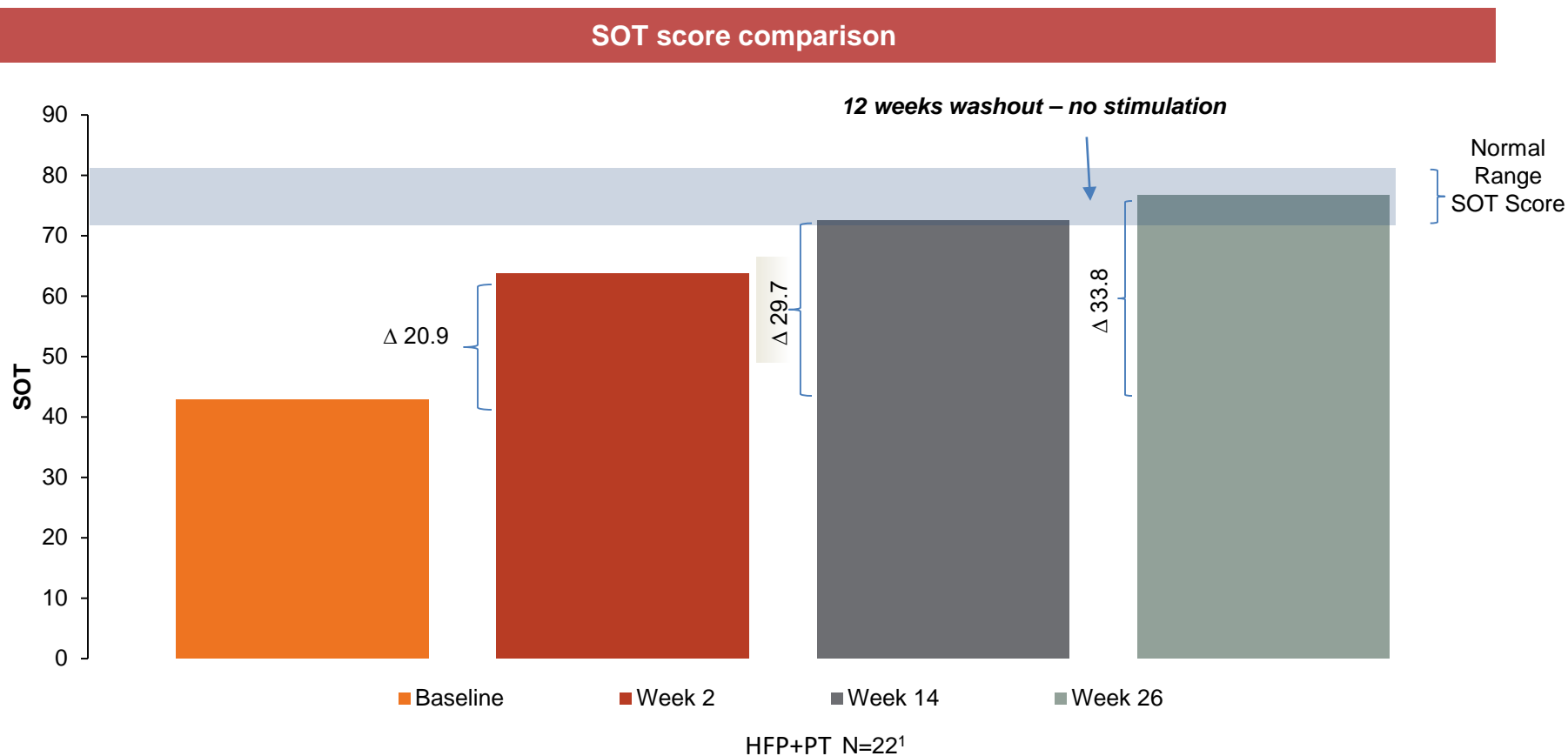
# Long Term Treatment Study in TBI

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## 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 patients with mild to moderate TBI
- 22/21 patients received High Frequency Pulse stimulation and Low Frequency Pulse stimulation
- 14-weeks active treatment followed by a 12-week washout period

# Patients Balance was Significantly 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 and normal score was maintained throughout 12 week washout period for all participants*

<sup>1</sup> LFP data not shown since it was not statistically different from HFP



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# References

## Slide 8: Future Market Opportunities

- TBI - [http://www.cdc.gov/traumaticbraininjury/pdf/TBI\\_Report\\_to\\_Congress\\_Epi\\_and\\_Rehab-a.pdf](http://www.cdc.gov/traumaticbraininjury/pdf/TBI_Report_to_Congress_Epi_and_Rehab-a.pdf)
  - 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(No. SS-9):1–16. DOI: <http://dx.doi.org/10.15585/mmwr.ss6609a1>
- 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](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](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/Statistics>

# References

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## Slide 10 - Traumatic Brain Injury

1. 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/>;
2. <http://dvbic.dcoe.mil/dod-worldwide-numbers-tbi>
3. [http://www.ncsl.org/documents/statefed/health/TBI\\_Vets2013.pdf](http://www.ncsl.org/documents/statefed/health/TBI_Vets2013.pdf)
4. 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.
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.
6. 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.

## Slide 12 – Worker’s Compensation

1. <https://www.ssa.gov/policy/docs/statcomps/supplement/2016/workerscomp.html>
2. L.E.K. research and analysis titled “Helius Commercial Opportunity Assessment,” dated October 3, 2017, as commissioned by the Company
3. US Government Accountability Office (GAO), Medicare Secondary Payer—Additional Steps Are Needed to Improve Program Effectiveness for Non-Group Health Plans, GAO-12-333, March 2012, Table 4, p. 20

# References

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## Slide 17: 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 20 – SOT Scores

1. Wrisley, Diane M., et al. "Learning effects of repetitive administrations of the sensory organization test in healthy young adults." *Archives of physical medicine and rehabilitation* 88.8 (2007):1049-1054; Broglio, Steven P., et al. "Reliable change of the sensory organization test." *Clinical Journal of Sports Medicine* 18.2 (2008):148-154.