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Q&A with Philippe Deschamps, President, Chairman and CEO of Helius Medical Technologies, Inc. releasing Registrational Trial Data for their Portable Neuromodulation Stimulator, PoNS™ Device showing ability to help Patients Recover from Balance Disorder caused by Traumatic Brain Injury

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CEOCFO: ***Mr. Deschamps, what is the focus at Helius Medical Technologies, Inc. today?***
Mr. Deschamps: Helius is a company that develops, licenses or acquires technologies that are designed to help people with neurological issues. Our first candidate is a device called the Portable Neuromodulation Stimulator or PoNS™. It is an investigational device being developed to help people recover their balance when they have been subject to a traumatic brain injury. That is the first indication we will be seeking from the FDA.

CEOCFO: ***How does the PoNS device work?***
Mr. Deschamps: The PoNS device works by stimulating a nerve called the trigeminal nerve through the tongue. The tongue is tied to the back of the brain or the brain stem through the trigeminal nerve and it is thought that by stimulating it in that way and combining that stimulation with physical therapy or cognitive therapy, the brain will go through changes. Those changes happen to the brain to try and bypass the areas of the brain that have been affected by either disease or trauma.

CEOCFO: ***Where are you in the process of development, testing and FDA clearance?***
Mr. Deschamps: We are very excited that yesterday we released the data from our registrational trials. It is a 120 person trial; a double blind randomized controlled trial. Yesterday morning at 8:00 am, we released the data from that trial and we also reported on some long-term treatment data in response to questions that the FDA had asked us to report on, which is quite exciting. We are now looking forward to entering our discussions with the FDA and seeking clearance for our technology.

CEOCFO: ***How did the trials work? What were you looking at? What did you find out and what surprised you?***
Mr. Deschamps: There were plenty of surprises. This is the first study of its kind, so we were quite excited, because regardless of what the results would be, we were going to significantly contribute to science. We did a trial of 60 subjects on a high-frequency pulse device, and then 60 patients on a low-frequency pulse device, expecting that the low-frequency pulse device would be inactive. However, no science had ever been done on that, so we had preplanned in a statistical analysis to figure out what happens if the low-frequency pulse was in fact therapeutically active and how we would then treat the data. Therefore, the first surprise was that in fact the low-frequency PoNS was found to be significantly active, so we rather than thinking that we had one product, we may actually have two products that flow out of this, because the results showed a statistically significant response by both the high-frequency pulse and the low-frequency pulse machine.

That was very exciting! Then the results of our long-term trial demonstrated that with the high-pulse PoNS, we were able to help people restore their balance in patients who had mild to moderate traumatic brain injury from a fairly impaired position to perfectly normal balance after a 14 week period, on average. Further, after they discontinued treatment, they maintained that benefit for another 12 weeks, so it is possible that we actually may be helping people restore their vestibular system. However, before our therapy, these people were unfortunately often stuck with the disability in their vestibular system lasting a lifetime. Therefore, we are very excited about our data and we are really looking forward to discussing them with the FDA, which we will be doing over the next several months.

CEOCFO: ***Where would the lower-frequency pulse device be applicable, and where would the higher-frequency pulse device be necessary? In addition, what are the potential side effects of using the higher-frequency pulse?***
Mr. Deschamps: That is an excellent question. What we found in our data is that there were no differences in the safety profile of both the high-frequency pulse and the low-frequency pulse machine. Essentially, it did not matter from a safety standpoint. There were no additional side effects. In the high-frequency response group we found that 74.5% of patients responded to treatment and response was set as an increase of 15 points on the sensory organization test (SOT), and on that scale a difference of 8 points is considered to be clinically significant. Therefore, we saw almost a 40 point change in the subjects with the high-frequency machine, and roughly 10% lower response, but still a significant response from the low-frequency pulse machine. The next step in that data is to now dive much more deeply into the things like the gender of people, the age of people and the distance from injury. That will take several weeks for us to complete.

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CEOCFO: ***Is this a brand new way of treating balance disorder in traumatic brain injury? Are there current therapies that are at all useful?***
Mr. Deschamps: Today, there are no approved therapies for the treatment of balance disorder in traumatic brain injury. Essentially, it is treated symptomatically, so if you have had a concussion or sports concussion injury you would be treated symptomatically. If your concussion results in headaches you would take pain relief pills, or if your concussion results in a balance disorder, which happens in about 43% of patients, some of the times you would be sent to do balance rehabilitation. However, according to the literature about doing physical therapy for recovery from balance disorder, it does not usually result in robust change. It would typically be between 8 and 13 points on the scale that I reported earlier. It is clinically significant, so people do feel a little bit better, but that typically takes 6 to 9 months to happen, and we were seeing our results within 2 weeks, and then 5 weeks and 14 weeks. We looked at those three time points, and at 14 weeks a significant number of subjects got better. In fact, they were restored to perfectly normal balance on average at the end of the study.

CEOCFO: ***How many people suffer from the balance disorder due to brain injury problems?***
Mr. Deschamps: At any given time in the US, there are about 5 million people in our community with chronic symptoms as a result of traumatic brain injury or concussion, and as I mentioned, roughly 43% of those, so roughly 2 million people would have a balance disorder tied to a TBI, and unfortunately about 1.7 million new injuries happen every year. About two thirds of those people will recover spontaneously, but that leaves another 600,000 people that unfortunately go on to have chronic symptoms from their injuries. Therefore, it is a significant issue and according to reports it has cost our economy about $76 billion a year in terms of lost productivity.

CEOCFO: ***How has Helius worked with the US Army?***
Mr. Deschamps: The US Army has supported our work through a grant to perform our clinical trials and they have been wonderful partners. The Army is interested in this particular area because there are no approved treatments, and unfortunately, out of the million or so active duty soldiers out there, 30,000 of them suffer a traumatic brain injury every year. Lest you think they happen in combat, unfortunately 85% of those happen in training exercises. They happen every year, whether soldiers are in combat or not. Therefore, the Department of Defense was interested in investing in research that would help find a potential treatment and we are happy to report that we very well may have found one.

CEOCFO: ***What is feeling in the medical community?***
Mr. Deschamps: The medical community is quite unanimous in their description of the treatment of traumatic brain injury today. They commonly report that the treatments are left wanting and there is not much that can be done once chronic

symptoms set in. Most people are prescribed occupational therapy to live with the results of their trauma. Therefore, there is a great need for therapies that may help people recover from some of those chronic symptoms and the first one we chose, which is one of the most common, was balance and gait tied to these traumatic brain injuries. We seem to have been able to do a very good job in helping restore vestibular function in these subjects.

CEOCFO: ***Do you envision the treatments being done by patients at home, in a doctor's office or a physical therapy clinic?***
Mr. Deschamps: The protocol that we did in our clinical trial was to do two weeks in clinic, so they would be in a physical therapy clinic for two weeks. Then subjects in the trial were discharged to home where they did the same exercises for another three weeks at home. In the long-term treatment trials, they did two weeks in the clinic and twelve weeks at home to yield the results that we have and an overwhelming majority of the patients were able to stick to that treatment schedule. Also important was that we had virtually a very small number of dropouts.

CEOCFO: ***Would you tell us about your new corporate facility?***
Mr. Deschamps: We were very pleased in early August to move into our new facility located in Newtown, Pennsylvania, just a little bit north of Philadelphia. It was very nice for our staff to find a place to call home. We were previously in rental offices to be as judicious as we could on the cost, so again we are very pleased to be in our new space.

CEOCFO: ***Are there other applications for your PoNS device, other than brain injury, such as neurological diseases?***
Mr. Deschamps: We have already reported some published work with our technology in MS (Multiple Sclerosis), which showed a statically significant improvement with our technology, verses physical therapy alone. We have also demonstrated some work in stroke, which again showed our device to be statistically significantly better than physical therapy alone. We also did a study in cerebral palsy that showed the same results. These were all pilot level trials in the sense of being 10 to 65 subjects to be treated, but the results were very consistent. Therefore, we are encouraged by that, but right now we are sticking to our knitting to work with the FDA to clear our device for treating balance disorder in subjects with traumatic brain injury, and we are looking forward to that before we go down a path of looking at other disease states.

CEOCFO: ***Put it together for our readers in healthcare, business and investment community. Why pay attention to Helius Medical Technologies?***
Mr. Deschamps: As of yesterday, rather than conjecture, I can now definitively say that our PoNS technology, when used in patients with mild to moderate TBI, who have a significant balance disorder, we seem to be able to completely restore their vestibular system over a 14 week period. In addition, that restoration of their system lasts 12 weeks post treatment. This is certainly data that is quite compelling and we look forward to having a discussion with the FDA on whether they feel our results are as compelling as we feel.