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Portable Neuromodulation Stimulator that Delivers Electrical Stimulation to the Brain from the Surface of the Tongue along with Physical Therapy is offering hope in treating Traumatic Brain Injury and Multiple Sclerosis

Philippe Deschamps
President, Chief Executive Officer and Chairman of the Board of Directors

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For more information visit: www.heliusmedical.com

CEOCFO: ***Mr. Deschamps, it has been about a year since we last spoke. What is the focus today at Helius Medical Technologies?***
Mr. Deschamps: It is nice to talk with you again Miss Fosse. Helius Medical Technologies is developing a device called the Portable Neuromodulation Stimulator or a PoNS device. It is an investigational device being developed and is going through the FDA trials as we speak. We expect the device to make it through the clinical trial process and depending on the study being positive, we expect that the device will be reviewed by the FDA sometime late this year.

CEOCFO: ***What is the PoNS device?***
Mr. Deschamps: The PoNS device essentially works as an amplifier for the signals to your brain. It does this through delivering electrical stimulation to the surface of the tongue. It is thought that the tongue then translates those electrical stimulations into motor neural impulses that go straight to the brain by way of the trigeminal and facial nerves. Why the tongue and why does this seem to help? The tongue is your first sensory organ. When a baby comes out of the womb, anything that is within arms distance goes straight into their mouth where it hits the tongue first and

foremost, and informs about their environment. Therefore, the tongue is very elegantly and naturally tied to the brain's learning centers and that is what the scientists that developed this technology were hypothesizing and we now know that is the case. What happens is when you combine the stimulation that comes from the PoNS device with physical therapy that is designed to overcome a neurological symptom that is caused by either disease or trauma, the combination of the two seems to help people recover from those symptoms, so that is what we are trying to prove in our clinical trials.

CEOCFO: ***Does it matter what the cause is, or is it strictly the symptom?***
Mr. Deschamps: We do not know the distinct answer to that question. We hypothesize that it does not matter, but that is why we are pursuing two separate indications. One is for balance disorder in patients with mild to moderate traumatic brain injury. That is not a disease state, as it is an injury, so there is no disease process going on. We are also investigating the same indication for balance disorder in patients with Multiple Sclerosis. Therefore, we will know the answer to that once we make it through the clinical trials. Our hypothesis is that it does not matter, but that has yet to be proven out.

CEOCFO: ***Does the medical community understand the value of the tongue related to the brain?***
Mr. Deschamps: I do not think that the tongue's full relationship to the brain is widely known, although when we speak to the medical community, it is certainly not something that surprises them. They generally agree that it makes sense. We just completed our pilot study in multiple sclerosis at the Montreal Neurological Institute, and along with that study, we were looking at the brains of people through Functional MRI, and were able to demonstrate that the tongue is in fact a conduit to the brain with regard to sending signals. It does essentially reach the parts of the brain in this case, that helps people to think and walk. That was very exciting data that was released at the end of November 2015. What we know now is that we are able to generate neuroplasticity, which means to get the brain to change itself through the stimulation. We do not yet know if the study was large enough or powered to be able to see if that translates to improvement in balance or gait yet, but it was very exciting to see the differences in the FMRI for the treated patients.
CEOCFO: ***How do you know the right amount of stimulation?***
Mr. Deschamps: The scientists who developed this technology over the last 7 or 8 years have worked with many subjects under the guidance of an IRB (Institutional Review Board). This was a technology that was tested in several subjects to determine this. We know it more through these anecdotal results to date where we have been able to show, anecdotally, that subjects improve with the current amount of stimulation. And, now we have embarked on a major registrational clinical trial to demonstrate it scientifically. Therefore, it was trial and error over the years of developing the device and now that trial and error has yielded a device that we believe is going to be generally effective at being able to help people with balance disorder, tied to traumatic brain injury or neurological disease. We are looking forward to the clinical trials to see what the ultimate results will be.

CEOCFO: ***What do the recent patents cover?***
Mr. Deschamps: Our patent attorneys from Proskauer Rose in Boston have been incredible in supporting the development of our IP portfolio.

We have received three patents, called Medical Method Patents that describe the use of the product, and we have received 9 patents now that relate to the design and utility of the product. We have 35 more patents pending that deal with other ways of delivering energy through the tongue to the brain. We already have and are on our way to an even more robust patent portfolio to protect our intellectual property for years to come.

CEOCFO: ***Do you have the funding needed for the next steps?***
Mr. Deschamps: We essentially have the funding to make it through to our next milestones and with those milestones usually come the next phase of the development. However, medical device and pharmaceutical companies are generally raising funding at some point, and I am sure that we will be doing that in the future ourselves to prepare for our commercialization.

CEOCFO: ***Do you find the noise around concussion and brain injuries is helpful in gaining interest in your product?***
Mr. Deschamps: The awareness is palpable. There was a movie that came out around Christmas time that helped to put it on the radar screen. The phrase that you hear quite often is, "Sports Concussive Injuries", and it is put into that context. The reality is that is probably a term that was developed by legal people to try and add a euphemism to the marketplace that helps protect parents of athletes who play football, so that they do not have to say that their sons or daughters have had a "traumatic brain injury". Functionally, a sports concussive injury that results in chronic symptoms is no less a traumatic brain injury than one that is received in a car accident or through some other means. Currently there are not many treatment options for these people, but we hope through our clinical development that we are able to prove that this device may be one of the first to help relieve those symptoms.

CEOCFO: ***Are you aware of other research in this specific area?***
Mr. Deschamps: There is an enormous amount of research around the brain, being talked about in the healthcare industry and scientific publications. For the next five to ten years, the brain will be the subject of an enormous amount of research. Specifically, as it relates to the issues that we have been talking about with respect to traumatic brain injury, most of the research goes into trying to find better ways of diagnosing or tracking the disease or injury process. There has not been much research done so far on the actual treatment beyond what we already know, such as in physical rehabilitation works for a certain number of subjects. Two thirds of people who suffer a concussion or a traumatic brain injury, even a closed head one, will unfortunately suffer from chronic symptoms of that injury for the rest of their lives. Therefore, it is very important that we do find new treatments that will help improve the lives of sufferers.

CEOCFO: ***Would this be ongoing treatment?***
Mr. Deschamps: Right now our clinical trials are going to demonstrate over a 5 week period, in patients who have mild to moderate traumatic brain injury, whether we are able to recover their sense of balance and gait. The answer that we will know is what 5 weeks of treatment is going to yield. The subjects will have to be reevaluated every 5 weeks to determine if the device continues to help and improve. Then future, more long-term research will be able to dictate how the brain might recover

and whether the subjects will be able to stop using the device over time. We do not have enough information to definitively describe that today.

CEOCFO: ***Would you tell us about the treatment process?***
Mr. Deschamps: The proposed treatment that we are developing in the clinical trials is 20 minutes of therapy twice a day per symptom. If you have a balance disorder tied to your traumatic brain injury, which you would have to have, in order to qualify for being in this research, then you would do two treatments per day. The PoNS device delivers 27 million impulses every 20 minutes through the tongue. The electricity only penetrates the tongue less than a millimeter, but the nerve ending translate those electrical impulses into impulses that go to the brain. Then essentially the signal that is created by the physical therapy, which typically travels up your spine and goes to the brain is augmented or amplified by the stimulation through the tongue. It is the combination of those two things that get the brain to reorganize itself through different means. It can be realignment of the neural net, or enlisting other parts of the brain to be able to accomplish something that bypasses the damaged area or neuronal sprouting. We do not know exactly the mechanism that is used, but typically, those are the three ways in which the brain adapts and reorganizes itself to improve. Therefore, that is the proposed mechanism and we now know that the tongue is in fact, able to deliver signal to the brain. We have verified that in our MS pilot studies, so now we are looking forward to seeing in our larger trial, whether that is going to translate that into the benefits that we have seen in the anecdotal data that we have assembled in the past.

CEOCFO: ***What does the patient feel while this is going on?***
Mr. Deschamps: Great question. It feels like Champagne bubbles on your tongue or your first sip of Coke out of the can, where you have that tingling feeling on your tongue. The stimulation is adjustable with respect to its intensity to make sure that it is comfortable for the subjects that are using it. We have had very few subjects throughout the use of this product in the clinical trials that have found it to be uncomfortable. A great majority of the subjects essentially find it very tolerable.

CEOCFO: ***Are you looking at other devices as well?***
Mr. Deschamps: Our eyes are always open. We created this company ultimately to develop, license or acquire non-invasive technology that may help people recover from neurological disorders, so that is always on our radar screen. However, right now we are hyper-focused on completing our clinical trials, which will hopefully result in clearance of the device by the FDA. After that, we will double our efforts to see if there other complementary either devices or medicines that might make people with neurological symptoms of diseases or trauma better.

CEOCFO: ***You have entered an agreement for development in Asia. Is that following through on your efforts in the US or will there be separate studies going on there?***
Mr. Deschamps: There certainly will be. The regulatory process in China gives us a couple of paths; one that includes piggybacking on the FDA approval, which is the path that our partners seem to have favored. We will complete our path through the FDA, and assuming that we eventually get clearance for the device; our partners will then apply and gain clearance in China, because the FDA approval will have helped that process along. They could also decide to do their own clinical trials, but

that typically takes a little longer and is a more expensive pathway, so we expect that they will choose the former.

CEOCFO: ***Is there the same level of interest in Asia as there is in the US?***
Mr. Deschamps: There is a deep interest in the device in the ability to retrain the brain. Traumatic brain injury is certainly a big issue in China, as their latest generation has seen an explosion in the amount of new drivers. Unfortunately, along with that comes accidents and resulting trauma for those accidents are a major issue at this stage. They are also, as the western world, subject to an aging population, so they are very interested in looking at neurological applications with respect to cognitive enhancement in Alzheimer's and dementia, which they are contemplating looking into.

CEOCFO: ***What should we look for one year from now?***
Mr. Deschamps: A year from now, I would hope that we will have completed our registrational clinical trials and the FDA will have cleared the device, so that our PoNS device will be commercially available. Then through our development partnership with the Department of Defense here in the US, we look forward to being in the process of deploying the device to people in the US military who are affected by traumatic brain injury that include associated balance disorder. That is what we have to look forward to, and we are working diligently to make it happen.

CEOCFO: ***Is the DoD helping you with funding?***
Mr. Deschamps: Yes! We have signed a collaborative research and development agreement, as well as a single source, cost sharing contract with the Department of Defense, where they are paying for a portion of the registrational clinical trial that we are doing today. That partnership has been in place for a couple of years now and we continue to enjoy a very fruitful partnership with the DoD. For our friends at the DoD, out of the 2 million active duty soldiers, unfortunately roughly 30,000 of them suffer a traumatic brain injury every year. Two thirds of those will resolve without treatment but, for 20% to 30% of them, they will result in chronic symptoms, which is why there is that deep interest and passion at the DoD for our soldiers, and that is what drove the Department of Defense to see if our device could help those people.

CEOCFO:. ***How do you deal with the frustration of knowing that you have something that could make such a difference, yet it is a long process to get it to the market?***
Mr. Deschamps: Every pharmaceutical and medical device executive is driven by the ability to hopefully make a difference in people's lives. The commercial success is something that flows from that. To think that we may be able to help people with traumatic brain injury and balance disorder tied to their traumatic brain injury is very exciting. We strongly believe in the regulatory system that guides the scientific development of devices like the PoNS. This includes doing large clinical trials to determine the safety and efficacy of medical devices like ours. Therefore, if anyone reading this interview knows of anyone who has balance issues resulting from a traumatic brain injury or themselves have been injured, they can be referred to braininjurytrial.com, or 1-877-844-4960, to see if they might qualify for doing a clinical trial.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine