

With their PoNS™ Device now cleared in Canada, Helius Medical Technologies, Inc. now looks forward to treating patients in Chronic Balance Deficit with mTBI outside of the Clinical Trial Framework



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CEOCFO: *Mr. Deschamps, 2018 has been an eventful year for Helius Medical Technologies, Inc. First would you tell us what medical conditions you are looking at today?*

Mr. Deschamps: Our company is dedicated to the noninvasive treatment of neurological symptoms of disease or trauma, include traumatic brain injury, Parkinson’s disease, MS (Multiple Sclerosis), stroke and cerebral palsy. These are the areas we hope our technology will eventually be proven to work in. Just to specify, in the US, we are an Investigational Device, not yet cleared by the FDA. However, in Canada we have been cleared and are now able to deploy our device and treatment.

CEOCFO: *What is chronic balance deficit?*

Mr. Deschamps: Chronic balance deficit is the most common neurological symptom when your brain is afflicted by a neurological disease or trauma. Usually, if you have a balance deficit you are unable to walk properly. Many people with this condition avoid public places because walking through crowds or busy places like restaurants or malls becomes very difficult, and they get disoriented. These conditions are not where someone may feel dizzy on a particular day. Chronic balance deficit is a chronic condition that affects you every day and is a condition that you will likely have for the rest of your life. In patients who have had a traumatic brain injury that has resulted in chronic symptoms, about 40% will have a balance deficit as their primary complaint. In the US, according the Centers for Disease Control, there are approximately 2 million people who have a chronic balance deficit due to a mild to moderate traumatic brain injury.

CEOCFO: *It has been a year since we talked. How has Helius advanced through 2018 and now at the start of 2019?*

Mr. Deschamps: 2018 was a fantastic year for us, primarily because it was the year in which we submitted our filings to the regulatory authorities for clearance in many markets. We submitted our regulatory file to the FDA on August 31st and they prescribe a 150 day process before they would inform us of our status, and that would have taken us to February 1st, but then there is the disgrace that we are seeing in Washington today where the government is shutdown. Therefore, we do not currently know what is happening with our file or whether the FDA is actually open or not according to some conflicting reports. We are looking forward to sanity returning to our capital and getting all of our government working again. This would cause us much more anxiety, if it was not for the fact that we are cleared in Canada. Moreover, we have established 2 clinics in Canada, and soon to be a 3rd that are going to be actively treating subjects starting in the 1st Quarter of 2019. We are very excited about that. In addition, on December 7th we submitted for CE Mark in Europe, we will soon be submitting to Australia, and then our friends from China are set to file in the 1st half of the year.

We are a commercial organization now, which is a wonderful phrase to say, after being a development stage company, in our last discussion with CEOCFO. We are very proud to say that, and we are looking forward to treating subjects.

CEOCFO: *How does the PoNS™ (Portable Neuromodulation Stimulator) treatment work?*

Mr. Deschamps: The real answer is that we do not know exactly how it works, but that is the case with pretty much every drug that you put in your body. Over the last year we have learned a great deal more. What happens is when the stimulator is placed on the top of the tongue it generates electrical stimulation which the nerve endings in the tongue translate to motor neural impulses that travel to the back of the brain. The reason that pathway exists is there are 4 major cranial nerves that are tied from the tongue to the brain, and, one in particular, the trigeminal nerve (CN V) is linked directly to what we euphemistically call the CPU of the brain. It is the Pons area of the brain, and yes the pun is intended, as our device is called the Portable Neuromodulation Stimulator or PoNS™ and it does stimulate the Pons area of the brain. The Pons area of the brain projects to other regions of the brain. The thought is that the stimulation drives to the Pons area of the brain and then puts the brain into what is called a “plastic state”. Then through the exercise that is combined with the stimulation at the same time, the brain responds by finding new pathways or reorganizing itself to be able to achieve what have been damaged by disease or trauma. Virtually, every month independent science is giving us deeper insight into the trigeminal nerve and the stimulation of the brain. Therefore, it is a very exciting time for this area of science.

CEOCFO: *How long and how often would a patient receive treatment?*

Mr. Deschamps: The first indication for which we are cleared in Canada is for Chronic Deficit Disorder, tied to mild to moderate traumatic brain injury (mTBI). In our clinical trials, people would do 2 weeks of treatment in a clinic, twice a day for an hour, making it is quite intensive. They would go to the clinic for the first two weeks for 2 hours a day, with one hour in the morning and one hour in the afternoon. Then you are

discharged to do your exercises at home for 12 more weeks. Within 14 weeks what our clinical trial data said was that for people who had Chronic Balance Deficit and have had it for on average 4 years prior to treatment, and likely a prognosis of a lifetime of that disorder, we made 54% of those people go into the normal range of balance measurement. This is extremely exciting! 30% of the patients, on top of that, had a very significant improvement in their balance, while not quite reaching the normal range. That is what our data showed. We look forward to seeing in the clinic system we setup in Canada, how these results translate to people in real life, other than just clinical trial subjects.

CEOFO: *Are the improvements in balance permanent?*

Mr. Deschamps: Seemingly so. This was a very important question FDA asked us very early in our discussions around the design of the trial. The standard of care today for balance deficits is to do physical therapy (PT) alone. The efficacy of PT in treating balance deficit is well known clinically and reported on in the medical literature. When you do physical therapy alone, the results are not very robust. Further, when you stop doing the exercises you tend to drift back over several days or a couple of weeks to your original level of disability. Therefore, FDA had asked us to design a trial to show what happens after you discontinue treatment, assuming people would get better. Our data demonstrated that after discontinuation of treatment, on average people in our clinical trials maintained their benefit. This suggested that there was a permanent change to the brain, so there was no need to continue the treatment after that; at least for 54% of the patients. That was an extraordinarily satisfying finding in that we have a treatment that seems to at least for 3 months be able to maintain the benefit.

CEOFO: *How long did it take to get to the sweet spot of twice a day for two weeks and then time at home? When did you know that was the successful formula?*

Mr. Deschamps: That is a great question. When you develop any kind of technology or medicine you typically do dose ranging work and you try to figure out the best balance of efficacy and safety. In neuromodulation, which is what our therapeutic area is called, there does not seem to be a dose effect. It seems to be an “on-off” effect. Therefore, the scientists who developed this technology saw very early on that the intensity of the exercise portion of the treatment was important, and our experience tells us that twice a day was the right frequency of treatment. In particular, researchers chose to do this testing in people who had already done physical therapy and had already been deemed to have reached a plateau for physical therapy alone. This meant these people were not going to get better by doing more physical therapy. It was in these kinds of PT treatment resistant patients we were able to see 3- or 4-times larger improvement in their balance than when doing physical therapy alone as described in the literature. Unlike many medical devices PoNS was tested clinically very early in its development. We learned it by treating subjects and we have done 5 clinical trials and 1 registry. The PoNS has been studied in well over 300 subjects. For a non-significant risk medical device regulatory filing, this is an unusually large number of patients treated. This enabled us to learn by trying. Now that we are cleared in Canada, we are going to test in the real world, how people respond to our treatment outside of the clinical trial framework.

CEOFO: *How difficult or how easy might it be for people to tolerate something attached to their tongue for an hour?*

Mr. Deschamps: Another great question, and one that we get all of the time. First, the tongue is a pleasure center, which is why we love kissing so much and why eating is so satisfying. The feeling that people report when they use the PoNS very much depends on the generation. When they are older people, such as in my generation (in their 50's), they will say that it feels like "pop-rocks" on your tongue. The younger set often describes it as your first sip of a cola or Champaign bubbles on your tongue. In our clinical trials in over 163 subjects, only 3 discontinued treatment and none discontinued because of discomfort on the tongue. It turns out that it is not only tolerable, but people have reported that it is quite pleasurable.

CEOCFO: *Would you tell us about the business side now that Helius is commercial?*

Mr. Deschamps: The way that I can describe it is in the size and scale of the market for our first treatment indication, in Chronic Balance Deficit with mTBI. In Canada, there are 200,000 people who have our precise diagnosis and for which today there is no treatment. That represents about a \$2.8 billion market opportunity for us in Canada alone. Then when I translate that to the US, using the old Canada to US rule, which is sort of "ten times" rule, there are about 2 million people in the US with our precise diagnosis, which represents a \$28 billion addressable market. That would be if we treated every single one of those people. Therefore, the market is very, very large. We are going to do this very responsibly. When we start working with the clinics that are going to deploy our technology, which will be large very well-known neuro-rehab centers across the US, we are going to make sure that we can reproduce in real life, the impressive results we got in our clinical trials. We are going to go slow, learn, confirm and deploy. We call it a "Focused Launch" or a "Proof-of-Concept" launch. We will want to make sure that we prime the quality of the outcomes and once we clearly understand how flexible the technology is, then we will much more rapidly, expand the access to the treatment. This is a very large market in our first indication, and that is not even considering potentially getting indications for stroke, cerebral palsy, and Multiple Sclerosis, which we will also be pursuing over time.

CEOCFO: *How will you raise awareness within the healthcare systems and the various communities?*

Mr. Deschamps: We are going to work through very large neuro-rehab centers, because we are delivering a treatment, which is a combination of physical therapy plus neuromodulation at the same time. All of these centers are already working with us today, prior to launch, to generate health economic data so that we may help payors better understand the economic impact of improving balance. These centers will be able to query their database for people that they could have perhaps treated in the past with less robust outcomes and give them a call notifying them of a potential new treatment. Those centers are large healthcare systems who "own" their physicians. We will make sure that in those systems we are going to raise awareness in the referral system that the center is now a certified PoNS Center and can treat people for something that was not able to be treated prior. Finally, we are going to look at local direct to consumer advertising that will raise the awareness for people in the community today. Remember, for those 2 million people, the healthcare system has not been able to help them for the most part, so they have suffered a loss of enjoyment of life and perhaps a loss of ability to work. Therefore, we will advertise to those people and let them know that there

is potentially a new treatment to help them. We feel quite confident that is the means in which we are going to raise awareness for the treatment to be deployed.

CEOCFO: *How have you decided what else to look at and in what order, as there are so many areas that your PoNS device could potentially help?*

Mr. Deschamps: You are correct. We have had many requests for funding in terms of different clinical avenues, so what we are thinking strategically is how we can go closer to what we know and what we have proven in our clinical trials. That could be under the umbrella of what is called an acquired brain injury. Stroke is another form of an acquired brain injury. Multiple Sclerosis, although that is a neurodegenerative disease, could also be described as an acquired brain injury. Cerebral Palsy certainly falls under that category for children that had an acquired brain injury at birth. It is really leveraging what we already know are good clinical models for us to generate data. In our pilot trials we have generated positive data in Multiple Sclerosis with two studies and positive data in stroke. We also have had the opportunity in Russia, where our technology is cleared, to have treated over 100 children with Cerebral Palsy. The data from a subset analysis of those treated patients who underwent MRI scans will be published soon. However, before we talk about expansion of indications, our first indication in Chronic Balance Deficit with mTBI is a very large opportunity for us to help millions of people get better.

CEOCFO: *Would you address the healthcare and investment communities? Why is now the time to look at Helius Medical Technologies?*

Mr. Deschamps: There are investors that like to look at opportunities just pre-clearance by the FDA, with the modifier that there are other countries around the world that have already cleared the device, so there is a de-risking of that path, giving it some regulatory pathway upside. There are also legitimately other people who would rather wait until that milestone is past. However, generally speaking in the neuromodulation area, which is a rapidly expanding area of science and medicine, we certainly have proven through beyond reproach clinical work that we are certainly a viable solution for a very large population of people. We humbly say that we are a good opportunity for the investment community before all of this gets proven out.

