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Innovative Neurological Devices LLC is bringing to market their recently FDA-cleared Cranial Electrotherapy Stimulator device the Cervella for treating Patients with Anxiety, Depression, and Insomnia

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CEOCFO: ***Mr. Waclawik, what is the focus at Innovative Neurological Devices, LLC today?***
Mr. Waclawik: Our focus is to design, develop and manufacture affordable medical devices, especially in the field of neurology.

CEOCFO: ***Why? What led you to look at this arena?***
Mr. Waclawik: Personal experience with a family member that was suffering from a general anxiety disorder, for who the drug based therapies were not effective. That really was the genesis for me starting this business.

CEOCFO: ***Would you tell us about Cervella?***
Mr. Waclawik: Cervella is a medical device that was recently approved by the FDA, or cleared as it is called by the FDA, for treatment of anxiety, depression, and insomnia. Cervella is called a cranial electrotherapy stimulator; that is the technical term for this type of medical device. It works by sending micro currents of electricity through the patient's brain. It does it using electrodes that are placed on both sides of the patient's head. This micro current stimulation of the brain has been clinically validated to reduce the anxiety feeling and insomnia that is often accompanies when a patient suffers from anxiety. Long term use of this device has also been clinically validated to reduce patients' depressive mood.

CEOCFO: ***Why does Cervella work? What comes to mind is electric shock therapy.***
Mr. Waclawik: When people think of stimulating the brain with electricity that is what comes to mind and it makes sense, because that is pretty much the main thing that clinicians have been using for many years. Of course, now we look at electrical stimulation and we are also looking at magnetic stimulation. There have been some medical devices that have been approved to interact with the brain also and use magnetic fields.
How Cranial Electrotherapy Stimulation works is still a subject of continued research, but what has been found thus far in using MRI imaging is that when these micro currents of electricity flow through a patient's brain, the brain's DMN or Default Mode Network is being disrupted. The Default Mode Network, very briefly, is an interaction between various structures within the brain. People often think of a brain as a kind of a unified thinking or processing system, but in fact it is a network of various substructures within the brain. Those substructures communicate with one another not unlike a computer communicates with its internal subsystems such as memory, display, peripherals, storage etc. That electrical stimulation disrupts that internal brain communication and gets the patient out of that type of depressive or anxious state that the patient is in. That is kind of the electrical interaction.

The other method of how it works or how it functions is by increasing certain levels of neurotransmitters. Some of the neurotransmitters that you might be familiar with such as serotonin have also been clinically validated to improve the patient's well being. Therefore, it works, at least in those two different methods that have been documented. As far as your question about Electro Convulsive Therapy, ECT, which is still being used in some very acute situations; cranial electrotherapy stimulation is several orders of magnitude lower than what patients would experience during ECT. The best way to describe it, is patient feels a slight tingling sensation during the treatment. In no way, shape or form does this type of stimulation induce anything that is remotely close to what ECT does since the current levels are not high enough to trigger a seizure.

CEOCFO: ***Would this be bought by an individual? Would it be something through a doctor? How will it get to the patient or consumer?***
Mr. Waclawik: This is a by prescription only device. Therefore, the patient would have to obtain a prescription from a licensed healthcare professional, such as a primary care physician, psychologist, therapist or a nurse practitioner. We have to receive a prescription for the patient before we can sell the patient the device. In addition, we of course also want to make sure that the patient is under medical care. As far as how the patient would obtain the device, there are a couple of different methods. One is that they can buy it directly from us and simply upload the prescription when they buy it. Soon we will have the distributors and practitioners who specialize in treatment of these disorders and they will stock our product and patients will hopefully be able to purchase it directly from their provider.

"Cervella is a medical device that was recently approved by the FDA, or cleared as it is called by the FDA, for treatment of anxiety and depression and insomnia. Cervella is important because, according to our research and publically available information, anxiety, depression and insomnia is one of the most prevalent disorders facing this society, especially in the adolescent and the young population."- Bart Waclawik

CEOCFO: ***You had a recent FDA clearance. What are the next steps? What is the time table and how will you be gaining the attention and getting the word out to the medical community?***
Mr. Waclawik: From the standpoint of getting out the awareness, we were very positively surprised by having gotten so many inquiries post our press release that we have received the clearance. We have not started manufacturing the device yet. Obviously, we could not until we had gotten the FDA approval. However, the timetable is that before the end of July we will have our inventory ready to start shipping to the patients. In the meantime, we will be evaluating and potentially selecting the distributors for the device, so that, as I mentioned, patients will be able to obtain it from those providers. What also happened during this time, between the FDA clearance and now, is that we have won a rather prestigious award called the Innovation of the Year MIRA Award, from TechPoint, which is a top award given to Indiana companies.

Winning that award has provided us quite a lot of exposure. We were featured on TV and there was some good press and that generated additional publicity. However, we are now one hundred percent focused on manufacturing, because it is one thing to design and invent something, and it is another thing to deliver a very complex medical device into the hands of the patients. Therefore, right now our focus is one hundred percent on getting the product on time and with the right quality and everything, so the patients can actually start using it.

CEOCFO: ***Have similar products been tried or marketed?***
Mr. Waclawik: Yes, people should understand that as far as the Cranial Electrotherapy Stimulation (CES) is concerned, we did not invent this type of technology. This type of stimulation dates back to the 1950s. It actually originated out of, of all places, the Soviet Union. That was because at that time the Soviets were experimenting with this for treating astronauts, or the aerospace pioneers; the people that were going for the very first time into space and those people were exhibiting severe amounts of anxiety insomnia. They could not sleep and somehow they had to get these astronauts to calm down. Back then, there was no drug treatment, so they were trying to figure out what they could do. They stumbled across this and since then the device had actually been approved in the United States in the late 1970s. Since then more than one hundred clinical trials have been conducted for the technology, so this is not new. It may not be very well known; because of course the first line of treatments for these disorders have been pharmacological approaches.

What we hope to have done is simply make the technology much more user friendly and patients will be able to integrate the device much easier into their lifestyles. How we did that is rather than having the patients wear the electrodes, like the currently available devices or the devices that have been around for a while, conspicuously on the forehead or mastoid area, which is the area behind the ears or on the ear lobes, we integrated the electrodes into a kind of high tech, nice looking, stereo headset. Therefore, patients can now be listening to music or can be working or studying and they can be receiving the treatment, which is one benefit. Secondly and quite importantly too, nobody needs to know that the patient is

suffering from this condition or is actually undergoing the treatment, which is a big point that we considered during the design, based on patients' feedback.

Lastly, we have also noticed that none of the devices on the market were able to gather any of the treatment information. This means when the patient went to the doctor, unless the patient remembered to write down when and how often and with what treatment parameters he or she was using, the doctor really had no clue. Therefore, what we have done is we have made the device app-controlled. The app now automatically, on a smartphone, gathers all of the information; when the patient uses it, for how long, with what intensity, all of the technical parameters. Now, when the patient goes for a consult to their healthcare provider, they will be able to share that information. Now, hopefully the end result will be a better treatment outcome, because people will then really understand how much or how little the patient has used the device. With the combination of this kind of user friendliness and new approach to making a device that has been around for a while, we hope it is going to increase the compliance and also improve the treatment outcomes.

CEOCFO: ***Is it possible to overuse the device?***
Mr. Waclawik: That is the beauty of these cranial electric therapy stimulators. It is not only impossible to over use it or over stimulate yourself, and also the second thing is that unlike the drugs it is not habit forming or addictive. Therefore, we always say that the worse case scenario with using this device is simply that it is not going to work. The efficacy of this type of device is about fifty to sixty percent, depending on the severity of the disorder. However, just like everything else out there, it will not work for everybody. However, unlike the drugs that might exhibit some adverse events with using the drug, there will not be any significant side effects, just simply ineffective treatment worst-case. As far as over using it, it has also been clinically validated that after about thirty minutes of daily usage there is no additional benefits of it, so people who will just use it more than that are just basically not going to get additional benefits.

CEOCFO: ***Are you seeking partnerships, funding or investment as you move forward?***
Mr. Waclawik: What we simply are looking for are people that are in the clinical space, that want to become distributors or our product and/or are in the research field and want to use our device for their research, because we would like to continuously advance the state of the art and the knowledge behind this technology. As far as the financial aspect, we are self-funded. Right now we are not looking for funding and/or partnerships.

CEOCFO: ***Are there other products or upgrades that you are working on now or is Cervella the main focus today?***
Mr. Waclawik: As far as Innovative Neurological Devices, because the product needs to enter manufacturing, as I said, this is our focus. It is a very complex device. It might look simple. To the user it should appear simple, because if it is complicated people will not use it. However, I just want to stress that underneath it is a rather complex device. With that being said, we definitely want to put all of our efforts on the quality, on the production and making sure that people will basically have a flawless experience when they open the box for the first time.

CEOCFO: ***Why is Innovative Neurological Devices LLC important and why is Cervella important?***
Mr. Waclawik: Cervella is important because, according to our research and publically available information, anxiety, depression and insomnia is one of the most prevalent disorders facing this society, especially in the adolescent and the young population. It has been recently named the number one issue facing the younger generation. Therefore, we are trying to provide a solution to a very large problem that is affecting, according to our research and publicly available information, at least twenty percent of the population. Also, it is not just a USA problem. We know that this is a disorder that affects people all over the world. People, especially the clinicians, should know that there are now non-pharmacological approaches to treating these disorders. Not just us! There is also magnetic brain stimulation that has been FDA approved. Given the fact that, at least in our case, the adverse events or contra indications or side effects are minimal or not serious, we hope that more and more clinicians will look at this as a great adjunct to the toolbox that they already have. This device may be used with medication. It may be used without medication. It might be used with other non-drug therapies, like cognitive base therapies. We just hope that we provide something that is going to give patients more solutions for what we think is a very big problem.