

Q&A with Kate Rumrill, President and CEO of NeoSync Inc developing their Transcranial Magnetic Stimulator (TMS) Medical Device that Synchronizes Brainwaves in Treating Depression and other CNS Disorders



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Interview conducted by:
Lynn Fosse, Senior Editor
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CEOCFO: Ms. Rumrill, would you tell us about NeoSync?

Ms. Rumrill: We are a medical device company, developing a transcranial magnetic stimulator (TMS) that is intended to be used primarily for depression as a start; however we are looking at uses in other CNS disorders, as well. We see our unique value proposition in the way that we treat patients with TMS; specifically we synchronize it to individual patients' brainwaves, measured by electro-encephalograms, so we tailor the actual treatment of the magnetic stimulation to that individual patient.

CEOCFO: What is the range of variation in brainwaves?

Ms. Rumrill: Within an individual's brain there are different bands of frequency that the neurons communicate within the brain. Specifically we are targeting one of those bands called the alpha band which has been shown to play a role in specific mood disorders. If you have changes in the synchrony of your alpha frequency, that could have an effect on mood. We target that alpha band, which is between eight and thirteen Hertz. For example, you may have an individual with an alpha wave of 9.3 or another may be 12.5. It is really nothing different with those other than the frequency being unique for that individual, sort of like a thumbprint.

CEOCFO: How does the device work; what is the science?

Ms. Rumrill: The concept of transcranial magnetic stimulation, regardless of which device you are talking about, is that you are placing a magnetic field upon the brain and by doing that you are resetting the cortical oscillators to bring that brain back to a normal state. It is not something that happens with just a single treatment but needs repetitive treatments to bring the brain back to normal state over time.

CEOCFO: Where are you in the development process?

Ms. Rumrill: We are a clinical stage company, so we are not currently approved for sale in the US or elsewhere. We have approval from the FDA to study this device in a controlled setting under IRB approval, within physician's offices for the sole purpose of collecting information that will be used in our regulatory submissions, seeking clearance to market the product.

CEOCFO: What have you learned so far?

Ms. Rumrill: Probably the most fundamental learning that we had is not necessarily even about our own device but just in general with this field. There are several other transcranial magnetic stimulators that are out there on the market and they have proven that they are safe and effective but they are not getting what you would expect as far as adoption. The reason is because it is cumbersome and difficult for the patients in that they have to first find a center that has this treatment available and they have to go to the physician's office five days a week for four to six weeks for their acute

treatment. It a lot to ask of a patient, especially if they live in a large city or conversely in a rural area where they have to deal with struggles of getting to the center each day. Our goal is having a device that can be used in the home, by prescription, so the patient will still go to the physician's office for their diagnosis and they will receive information about the use of the device and training but then they will take the device home with them and use it in the comfort of their own home. We think this is going to substantially change the way that TMS is delivered allowing greater comfort and access for the patient.

CEOFCO: *What is involved with operating the device?*

Mr. Rumrill: First, the physician collects the patients' EEG at baseline before he/she receives their first treatment. That is what we consider to be the digital prescription and it identifies the frequency at which the treatment is delivered. That is done in the physician's office, then the patient is trained on the use of the treatment device, which is fairly simple to operate where the digital prescription card is inserted into the device; our proprietary algorithm then guides the mechanical components of our device to administer that treatment. The user interface is a simple start and stop button with a screen that prompts the patient what to do next. They place it on their head and secure it firmly and then they are ready to receive the treatment. They press start and it runs for thirty minutes. There is also a safety mechanism by which we have a lock-out period so there has to be a certain number of hours between treatments administered. Therefore, in many ways we are actually safer than a prescription because we do not have the risk of having a patient over treat themselves, they can only receive the duration of treatment that the physician programs on the digital prescription.

"We see our unique value proposition in the way that we treat patients with TMS." - Kate Rumrill

CEOFCO: *Are there certain types of depression or certain types of patients that are more likely to adhere to the regime?*

Ms. Rumrill: If you look at the literature, there are two different categories of patients with depression. The one that you are touching on is how severely depressed they are. We have not necessarily studied our device yet in severely depressed patients. Most of our patients, studied so far are categorized as moderately depressed. The other category of depression is what is called treatment resistance and that has become an even more important question of later years now that many antidepressant medications have been on the market and available for as many decades as they have. What we have seen is that depending on how many treatments a patient has failed to respond to, it does correlate to whether or not they will respond to the next medication or treatment. We do pay attention to the level of treatment resistance of a patient.

CEOFCO: *What have you found from the people in the medical community that have seen what you are doing?*

Ms. Rumrill: It is wonderful to see the level of excitement by those folks in the medical community that we have discussed this with because they understand the limitations today in availability of these novel treatments for patients. Not only availability of these devices, but they are very large pieces of capital equipment; not every physician can afford to purchase them and does not necessarily have the space for them. The concept of our device being portable and less costly and having a component that is useful to patients in the home allows greater expansion of availability and that is what gets the physicians excited when we talk to them.

CEOFCO: *Where are you with funding?*

Ms. Rumrill: We filed a press release a couple of weeks ago announcing that we just closed our Series D Round of funding of \$13 million in total for this round. This is going to fuel the clinical trial that we need to complete in order to file with the FDA for 510K clearance. It will allow us to continue to develop our manufacturing processes and our prototypes in preparation for what we anticipate to be the launch of the product.

CEOFCO: *Do you need a reimbursement code?*

Ms. Rumrill: We do and because of the office and home-use components to this, it is a waterfall effect as far as the way the reimbursement will come. Part of this funding is to start those wheels in motion, so that we can get the codes as soon as we are able to do so.

CEOFCO: *What do you understand about bringing a medical device to market?*

Ms. Rumrill: We are very blessed in that we have a wonderful team of employees and consultants who are seasoned medical device professionals with a variety of backgrounds and expertise in different aspects of bringing product to market whether that be clinical or regulatory or manufacturing or engineering, as well as different experiences in different fields that they bring to the table. I consider myself lucky in the fact that I have a great team that really believes in the

technology and are working together to bring all of that collective expertise to the table. We have a very supportive board of directors as well, all of whom are seasoned investors that have a proven track record in bringing products to market.

CEOCFO: *Why is NeoSync so important and why should people pay attention to what you are doing right now?*

Ms. Rumrill: Earlier in my career, I was with a pharmaceutical company that developed one of the first antidepressant treatments. We found that they do work very well in some patients but they do not work for everyone. They also have untoward side effects for many. If you look at the numbers, fourteen million Americans alone suffer from depression annually. If you look at the effect that has on the patient and their loved ones, the system, including the workplace, there is still a huge need for therapies that will give the patients the relief that they need and bring them back to a place where they can feel joy and enjoy their lives...

The logo for NeoSync features the word "NeoSync" in a blue, serif font. A blue, curved line arches over the letters "Neo" and "Sync". A registered trademark symbol (®) is located to the upper right of the "c" in "Sync".

NeoSync®