

In Clinical Testing with their Repetitive Transcranial Magnetic Stimulation (rTMS) Approach to Non-Invasive Deep Brain Neuromodulation, CerveL Neurotech, Inc. is Offering hope to Patients Suffering from Depression, Pain and Addiction

**Healthcare
Novel Therapies**

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**Eric Meier
CEO**

BIO:

Eric Meier joined CerveL Neurotech in 2010 and brings over 20 years of medical device industry experience to the company's leadership.

Prior to joining CerveL, he was President, Chief Executive Officer and Founder of Calypso Medical (acquired by Varian Medical Systems) and Executive Director of Ethicon Endosurgery (Johnson & Johnson). During his 10-year tenure at Calypso Medical, he developed and led a 200-person or-

ganization to successfully develop and commercialize a novel, real-time tumor tracking technology for use during delivery of radiation therapy. While at Ethicon Endosurgery, Eric directed worldwide market and business development and US marketing for oncology products. His therapeutic area experience includes oncology, cardiovascular health, women's health, and neurologic and psychiatric disorders. Eric serves on the executive boards for Split Rock Scientific, Inc., Ziba Design, Doernbecher Children's Hospital, Medical Device Manufacturers Association (MDMA) and the Young President's Organization (YPO). He is also a successful restaurateur and co-owns several establishments in downtown Seattle, Washington.

Eric holds a Bachelor of Science in Biomedical Engineering from Duke University and a Master in Business Administration from Stanford University.

About CerveL Neurotech, Inc.

CerveL Neurotech, Inc., located in Foster City, CA is a privately held medical device company that is pioneering an innovative, proprietary approach to non-invasive deep brain neuromodulation. CerveL's technology is a form of repetitive transcranial magnetic stimulation (rTMS), which uses electro-magnetic fields placed on the scalp to modulate the function and activity of specific brain regions. The company was founded in 2008 by M. Bret Schneider, MD, David J. Mischevich, MD, PhD, and entrepreneur Michael J. Patsch, using technology licensed from Stanford University.

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

CEOCFO: Mr. Meier, would you tell us the vision behind CerveL Neurotech?

Mr. Meier: The vision of CerveL is to offer a unique non invasive solution for patients suffering from a variety of psychiatric and neurological disorders such as depression, pain, and addiction. The challenge today with a variety of treatment approaches for these conditions is typically twofold. One is their effectiveness, or efficacy. The second is the patients' ability to tolerate these therapies. If you look at the market segment of depression, for example, we estimate that there are approximately 4.5 million Americans suffering from depression who are either intolerant of medications or the medications just do not work very well. This is the group that we believe our platform can effectively address. Beyond the depression market, we believe that our platform has a meaningful role in the markets of pain management and addiction. These market segments are traditionally treated with medication or pharmacological solutions. We believe that we are at the dawn of an era where electricity used as a drug to induce changes in the body, will be a viable and effective means to treat disorders such as these.

CEOCFO: Would you explain the technology?

Mr. Meier: The general area is referred to as neuro-modulation. Neuro-modulation is defined as the use of electricity in a targeted way to regulate the metabolic activity in regions

in the body such as the brain. If you consider a condition like depression, what typically occurs is that the normal metabolic activity in specific regions of the brain is not optimal. There may either be a decrease or increase in metabolic activity. Our treatment approach provides targeted, very low-voltage, electrical current in a non-invasive way to selective regions of the brain that will allow these areas to return to their optimal level of metabolic activity.

The use of magnetic fields to change the blood flow and the metabolism in particular areas of the brain has been in existence for years. With the advent of technologies like Cervel's, it is now practical, safe, and effective.

CEO CFO: Would you explain how this electric shock therapy is different from people's negative opinions?

Mr. Meier: Our therapy is very different from electroconvulsive or electroshock therapy in the way it is administered and when it is administered. Although electroconvulsive therapy is deemed to be a very effective treatment for patients battling conditions such as depression, it is typically reserved for patients with very severe depression and where pharmacological therapy just has not worked. It is a treatment that is performed under general anesthesia and is administered in a series of 12-15 treatments. The treatment does not target specific brain regions but rather serves as almost like a reboot of brain structures. Side effects can include memory loss.

The Cervel approach with our transcranial magnetic therapy is to selectively deliver very low-voltage electricity that is induced by magnetic fields, to very targeted regions of the brain. There is no anesthesia required. Patients come in for a series of daily treatments for a few weeks. Because the treatment is very well tolerated and effective, patients can go back to work or resume other activities immediately following the treatment. Given its non-invasive nature and given how safe the technology is, it tends to be administered

fairly early on in the episode of depression.

CEO CFO: What is the position in the medical community overall?

Mr. Meier: The position of transcranial magnetic therapy among the community is quite positive. With any new type of medical technology, one typically assesses its acceptance across three areas.

Number 1: Do the thought leaders and the people who influence the market embrace an approach such as transcranial magnetic stimulation (TMS)? The answer is yes. The psychiatry community has embraced this type of therapy as evident by the general position of the American Psychiatry Association, the number of TMS systems in place and the number of clinical publications. .

Number 2: How does the FDA assess technology like transcranial magnetic stimulation? The FDA has provided

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guidance to companies like Cervel on what is required to achieve product approval. This information allows us to streamline our clinical and regulatory activities.

Number 3: The third area is reimbursement. Typically with new technologies, new reimbursement codes are required. Medicare has already created a series of reimbursement codes to warrant use of the technology for patients suffering from depression. The benefit of reimbursement is that it enables more patients to have access to this important treatment.

In summary, we are not yet FDA approved, but as a second generation TMS platform, we are able to leverage what both the FDA and Medicare have provided. The psychiatry community continues to be a strong supporter of this type of technology where the side-effect profile is very modest and therapeutic benefits have been proven. It is very encouraging for patients who have been suffering from a disorder such as depression.

CEO CFO: How does your approach differ from others that are addressing the same issues?

Mr. Meier: The technology was originally licensed from the Stanford University Psychiatry department. The goal back then is the same as the company's goal now: How do we create and offer a selective non-invasive approach to stimulate different regions of the brain for patients suffering from depression? We are well on our way in delivering on this promise to selectively stimulate a variety of structures in the brain including surface and deeper brain structures. The basic tenet is that if you can selectively stimulate deep structures in the brain, a more durable therapeutic effect should be produced, which is a good thing for patients suffering from chronic disorders such as depression. As a next generation TMS platform, we have developed a very unique approach to selectively stimulate deep brain structures non-invasively.

CEO CFO: Where are you in the process of development?

Mr. Meier: We are in the midst of clinical testing. We are venture capital backed and just completed a very nice financing. This money is going to be used to clinically advance our technology through the form of a multi-site, pilot clinical study.

CEO CFO: What challenges do you anticipate?

Mr. Meier: We believe that our company is at a pivotal point where most of our challenges are 'execution based' as opposed to technology validation or proving that this type of approach is going to be clinically effective. We are also focusing our efforts on how we can successfully build a business where our customers can provide compelling solutions to their patients. If we can accomplish these two objectives, we are confident that we will be successful in rapidly growing the market.

CEO CFO: What else is down the road for you?

Mr. Meier: We believe, given our unique ability to selectively neuro-modulate or stimulate not only surface but deeper structures in the brain, that this technology holds promise in the treatment of other disorders, such as pain and addiction. Those are multibillion-dollar opportunities as well.

CEOCFO: Why does Cervel Neurotech stand out to investors and the business community?

Mr. Meier: With any type of investment, you need to look at the risk vs. reward. This is a very large medical device opportunity and with any new type of business you need to evaluate the size of the opportunity to warrant

the investment. Given how scarce capital is today for companies like ours, it is important to make sure that you can have a financial return for your investors. The way we have accomplished this is by pursuing a market that is well understood by the FDA and by the reimbursement community. This means that the ability to provide an economic return for our investors is more probable than one entering with greater uncertainty from either the FDA or Medicare. The other component is that if you look at the existing solutions for disorders such as depression, it is largely pharmaceutical based and many of those products have somewhat limited appeal either due to their effectiveness

or side effects. When you look at it from the standpoint of an investor, we think opportunity resides not only for us to build a stand alone business but to also serve as a complementary business for pharmaceutical based companies and medical device businesses looking to enter this market. We are having fun. Building a business is extremely hard and I am honored to be working with a world-class team of employees, medical investigators, and investors. One of the benefits with working in health care is you have a chance to make a significant impact on many people. That is Cervel and that is the plan.



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