

Having received their CE Mark for their previously FDA Cleared NeuroStar TMS Therapy[®] System, Neuronetics, Inc. is First to Market with this Non-Invasive form of Neuromodulation used to Treat Patients with Major Depression

**Healthcare
Medical Devices**

**Neuronetics, Inc.
3222 Phoenixville Pike
Malvern, PA 19355
877-600-7555
www.neuronetics.com**



**Bruce J. Shook
President & CEO**

BIO:

Mr. Shook has 30 years of experience in the medical device industry. Most recently, Mr. Shook was President & CEO and a Director at Neuron Therapeutics, a venture-backed company developing a drug/device product for treatment of CNS disorders. Prior to Neuron Therapeutics, Mr. Shook was President of Abiomed Cardiovascular where he successfully obtained PMA approval for the first FDA-approved ventricular assist device, and built a

direct sales and marketing team to market the product. Prior to Abiomed, Mr. Shook was employed at Cordis Corporation where he was involved with the development of cardiac pacing and anti-arrhythmia products. Mr. Shook serves as a Director for SurgiQuest, a privately held medical technology company, for the Penn State Research Foundation, and for AchieveAbility, a non-profit organization helping homeless families in Philadelphia.

About Neuronetics, Inc.:

Neuronetics, Inc. is a privately held medical device company focused on commercializing non-invasive therapies for psychiatric and neurological disorders using MRI-strength magnetic field pulses. Based in Malvern, PA., Neuronetics is the leader in the development of TMS Therapy[®] (transcranial magnetic stimulation), a non-invasive form of neuromodulation. In October 2008, Neuronetics received FDA clearance to market its NeuroStar TMS Therapy[®] system for patients suffering from major depression and who have failed to benefit from initial antidepressant medication. The Company is currently marketing the NeuroStar[®] system in the U.S. via a direct sales force. In June 2012, Neuronetics received the CE Mark for the NeuroStar TMS system. The Company markets its products internationally through distributors.

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

CEOCFO: Mr. Shook, would you tell us the vision at Neuronetics?

Mr. Shook: We started this company to solve a very important problem. There are millions of people in the US and around the world who suffer from major depressive disorder, despite the fact that they receive aggressive treatment, primarily through drug therapy. These so-called treatment resistant patients have very few alternatives, and the alternatives that they do have come with significant side effects. We set out to create a completely different treatment paradigm to help these patients with treatment resistant depression. We use a technology that does so by non-invasively stimulating the brain in a very targeted way, thus greatly reducing side effects.

CEOCFO: Could you explain the technology?

Mr. Shook: The product is called the NeuroStar TMS Therapy System-TMS is shorthand for Transcranial Magnetic Stimulation. The NeuroStar system produces very powerful MRI strength magnetic pulses. The doctor aims these pulses at the part of the brain that is not working properly in a patient with depression, and the pulses fire the brain cells that are beneath the magnetic coil. The act of firing them or activating them many thousands of times over typically four to six weeks of treatment, turns that part of the brain back on. It releases neurotransmitters in the brain, which help regulate mood, it increases blood flow and metabolism in that part of the brain, and it basically reactivates it.

CEOCFO: Where are you in the process? Is your product commercially available today?

Mr. Shook: Yes, we started Neuronetics in 2003, developed the technology and brought it through a series of clinical trials to prove that it was safe and effective for these patients, and it was cleared by the FDA for the treatment of depression in the very end of 2008. We started marketing the product in 2009, and it is now available in approximately 500 different locations throughout the United States. We have treated approximately 13,000 patients at this point.

CEO CFO: What is the success rate and is it done in conjunction with other therapies?

Mr. Shook: The treatment can be performed on its own or in conjunction with drug therapy, and that is the doctor's decision. The success rate in a very recent large trial was about 60%. 60% of patients were responders, and a little more than a third of patients were remitters. The difference here is that people who respond have what the doctor regards as a clinically meaningful improvement, and the remitters are symptom free. That is an excellent outcome in patients who have already failed to benefit from drug therapy.

CEO CFO: Is there wide acceptance or are you moving toward wide acceptance in the industry?

Mr. Shook: We are certainly moving in the direction of wide acceptance. We have around 500 physicians who are providing this therapy. That is a great start, but there is also a tremendous opportunity to grow that number given that there are 40,000 psychiatrists in the U.S. Psychiatrists do not have a history of doing office-based procedures, and this is the first such procedure they have had. NeuroStar represents a very different treatment paradigm. Whenever you bring a completely new tool to any profession, it does take some time to get in to the majority of practitioners.

CEO CFO: How do you reach the doctors?

Mr. Shook: We do that in a variety of ways. There are the traditional meth-

ods- large psychiatric medical meetings where we exhibit, and we sponsor a wide variety of research studies that end up in psychiatric literature, which is where doctors can read about it. We also do a lot of internet-based medical education so that doctors can access information about the technology and results via the internet. There is an entire host of web portals through which you can do that, one being Web MD.

CEO CFO: Are you aiming for patients as well as doctors?

Mr. Shook: Absolutely, there are millions of people in the US that have this disease and there are well over 14 million adults every year that experience a major depressive disorder episode. Many of these people do not get well through drug therapy, or they

"We are doing something that is akin to what happened when angioplasty was developed and put in the hands of cardiologists. It changed cardiology completely, and that is the way we think about this. Ours is an opportunity to treat a very large and expensive disease in a new way, and we are the first mover. We are creating that market, and from a business perspective I think that is very exciting."

- Bruce J. Shook

struggle with the side effects and stop taking the drugs. Those are the people we are aiming to help, and the most efficient way we reach out to them is through digital means. We do a lot of internet-based patient education through a host of different methods. There has also been a lot of press coverage for our technology, such as hundreds of evening news stories, newspaper, and magazine articles about how the technology has helped other people. Those are the primary ways that we get the word out to patients.

CEO CFO: When you are speaking with a doctor one-on-one, is there a particular moment when they understand how helpful your technology can be?

Mr. Shook: I think so. When doctors start to think about their own patients and they can bring a specific patient to mind who has struggled to get well

and is having difficulty with drug side effects, that is when the light bulb most often goes off.

CEO CFO: When are the guidelines clear that a patient might be an appropriate candidate for your technology? Is the decision up to the doctor or are there standards that are set from your end?

Mr. Shook: The clinical data clearly define when the technology should be used, and the American Psychiatric Association also publishes treatment guidelines for all sorts of different treatments. Our technology is now in those treatment guidelines as well. In simple terms, it should be used when patients have failed to respond to initial medication therapy.

CEO CFO: Neuronetics has a CE Mark- are you working overseas as well right now or is that in your future plans?

Mr. Shook: We are, in fact it international sales and marketing is a relatively new thing for us. We made a decision when we launched the product to concentrate on the US first, and that is what we did for the first several years we were market-

ing. Last year, we began to grow outside of the US and we now have business partners in Japan, Korea, Southeast Asia, in the Middle East, and we are currently looking at European and South American opportunities as well.

CEO CFO: Do you find much difference in acceptance among different areas of the world?

Mr. Shook: I think it is too soon to tell. I would not say we have enough experience yet to answer that question definitively, so we will see. One thing is for certain: every region of the world has 6% to 8% of the adult population suffering from depression.

CEO CFO: Could you tell me about your recent Red Herring Award?

Mr. Shook: We were nominated for the Red Herring award, which is something that covers all forms of

technology companies from somebody doing enterprise software to a medical company like ours- it is a broad universe. I was invited to their annual meeting in Monterey, which happened a few weeks ago, and there were several hundred CEOs there. All of them had twelve minutes to make their case, and we were very fortunate and grateful to be selected as one of the top 100 companies in North America.

CEOCFO: Do you think that is something meaningful when you are approaching prospective customers, or more of a sideline?

Mr. Shook: The first question doctors have is if the new technology works and if it is safe. You have to be able to answer all of those questions in a very compelling way, and if you cannot, something such as the Red Herring Award is not going to make any difference. Once you get past those initial questions and the doctors start to get into secondary questions such as who is this company, and are you going to be around five years from now if I go into business with you? Then, it does help, because it says that an independent group of skilled business people evaluated the organization and held it in very high regard. I think it is helpful at establishing credibility for us at a company, given that we are not a household name.

CEOCFO: How costly is the machine and is it an outright sale? Could you walk us through the product aspect?

Mr. Shook: We sell the machine for approximately \$77,000 dollars, and the doctor can either buy it or lease it. There is a single-use device that is called the Senstar. Those sell for \$98 dollars, and a patient goes through an average of about 28 treatments, which is spread over 4-6 weeks. The patient usually comes in from Monday to Friday, and it takes about forty minutes to do a treatment.

CEOCFO: Are the treatments reimbursable?

Mr. Shook: That is starting to happen at an accelerating pace. When we launched the product in 2009, there was no reimbursement at all, which is

typical for brand new technologies. We have been working with our customers to educate insurance companies and move them to coverage, and in the last fourteen or fifteen months that has begun to happen in a meaningful way. Sitting here today, we have 66 million lives in the US that are covered. Those 66 million people have insurance with a company that will cover TMS for depression. We are not at full coverage yet, but we have made a lot of progress in recent months and we expect that to accelerate.

CEOCFO: Are patients easily on board; are they skeptical or are they generally willing to try different methods?

Mr. Shook: It is hard to answer that question one way, because patients are not monolithic. I am sure there are patients that fit all of the descriptions you just gave me- there are some that are very enthusiastic, and there are some that are skeptical. People who are highly skeptical we probably never even get to talk to, so it is hard to know how many of them might be out there. In general, the patient group that we focus on helping is a very motivated group of people because they have a very bad disease that is debilitating and it affects their ability to work as well as their relationships with friends as family. It is a very difficult thing to suffer with, and these people have already tried most of the routine drug therapies. Those therapies have not worked for them, and they are looking for a new and different solution. I think that if you or a loved one is actually in that spot, you will be quite motivated to try and get well or get the loved one well.

CEOCFO: How have you discovered that 28 is the right amount of treatments needed? What is happening inside the brain that changes after that amount?

Mr. Shook: I do not want to give you the idea that 28 is some sort of magic number. That is the average number, and there is a distribution around that. Doctors will treat the patient to effect, so they will treat the patient until they appear to be substantially better. That might be 20 and it might be 36, so

there is a distribution. In terms of what is going on in the brain, a patient is coming in Monday through Friday and having these treatment sessions. In each treatment session, they are getting 3,000 pulses, which mean that 3,000 times the brain cells are being reactivated. It is similar to exercising the brain, because as with exercising a muscle, if you do it repetitively and for long enough, the muscle becomes stronger and more functional. In many ways, we are doing something similar in the brain except that in the case of the brain, strength comes in the form of releasing neurotransmitters, improving blood flow in that part of the brain, and there is also evidence that the brain starts to regenerate in a phenomenon called neurogenesis. All of those things taken together restore brain function and improves the patient's mood, which is ultimately what we are after.

CEOCFO: Would you tell us what the financial picture looks like for Neuronetics today?

Mr. Shook: We are addressing an exciting opportunity because it is very large and very poorly served. If you look at what is going on in the pharmaceutical development world, there is nothing in the pipeline that is significantly different from what doctors already have available to them. Those solutions are imperfect, which is why we exist- there was a need for something novel. I think that as we make progress developing the market, educating doctors and patients, and getting more and more insurance coverage, this has the potential to change psychiatry. Some of our customers talk about themselves as interventional psychiatrists, which is a completely new thought for the profession. I think that is very telling and they are starting to change the way they think about what they do. They can do more than write drug prescriptions or do talk therapy- there are other opportunities for them now to provide therapy to their patients.

CEOCFO: Why should people in the business and investment community pay attention to Neuronetics?

Mr. Shook: We are in a completely new, green field opportunity and we

are the first mover in this space. We are the only meaningful medical device company today that is calling on psychiatrists and addressing the large and growing disease of depression. As I pointed out earlier, it is a huge opportunity, which dwarfs most of the other medical markets. Those other

markets usually have many established players in them, cardiovascular disease for example, so new entrants are typically bringing in the tenth version of a product like a stent. We are doing something that is akin to what happened when angioplasty was developed and put in the hands of car-

diologists. It changed cardiology completely, and that is the way we think about this. Ours is an opportunity to treat a very large and expensive disease in a new way, and we are the first mover. We are creating that market, and from a business perspective I think that is very exciting.

NEURONETICS

Neuronetics, Inc.

3222 Phoenixville Pike

Malvern, PA 19355

877-600-7555

www.neuronetics.com