

Neuronetics gets FDA clearance for depression therapy

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STAFF WRITER

MALVERN — Neuronetics Inc. expects to double the size of its work force over the next year, now that it has secured Food and Drug Administration approval for its transcranial magnetic stimulation therapy to treat depression.

"We are going to create our own sales and marketing team; we're in the process of doing that right now," said Bruce Shook,

the Chester County medical device company's president and CEO. "We'll launch in most of the major metropolitan centers (including Philadelphia). We'll be in a limited number of treatment centers in the beginning, but we hope to grow rapidly."

The company, which now has 30 employees, expects to be at 60 this time next year.

Transcranial magnetic stimulation (TMS) is a non-invasive treatment that uses highly focused, MRI-strength mag-

netic pulses to stimulate nerve cells in the brain. The short pulses target the left prefrontal cortex of the brain, the area thought to affect mood.

Since its inception in 2003, Neuronetics has raised \$70 million from private investors to develop the technology licensed from Emory University for its NeuroStar TMS system.

The NeuroStar was cleared by the FDA last week for adult patients with major depressive disorder whose conditions did

not improve with antidepressant medications.

The company's customers will be psychiatrists, who typically practice in one of three settings: a hospital with a psychiatry department, a psychiatric hospital, or a stand-alone practice.

"Our product is usable in any of those three," Shook said.

The National Institute of Mental Health estimates nearly 21 million adults in the United States suffer from depression. Between 20 percent to 40 percent of that group — or 4.2 million to 8.4 million people — do not benefit sufficiently from psychotherapy treatment of prescription drugs.

With the NeuroStar, patients do not require anesthesia or sedation. They remain awake and alert during the 40-minute procedure designed to be performed in a psychiatrist's office. The treatment, in clinical testing, was administered once a day, Monday to Friday for four to six weeks.

In the clinical studies, more than 10,000 TMS treatments using NeuroStar were performed with no serious side effects and no adverse effects on concentration or memory.

Dr. John O'Reardon, an associate professor of psychiatry at the University of Pennsylvania, led clinical testing of the NeuroStar. He said fewer than 5 percent of the patients involved in testing of the device dropped out of the study because of side effects, primarily scalp pain or discomfort.

"It's quite unusual to have a treatment tolerated that well," O'Reardon said.

Neuronetics still faces the challenge of getting health insurers to cover the treatment.

O'Reardon said the recent approval by Congress of a mental health bill, which prohibits health insurers from placing greater limits or restrictions on mental health care as compared to the benefits provided for medical or surgical care, should help Neuronetics gain acceptance for its therapeutic device.

Steve, 60, a Lower Merion resident who asked that his last name not be used, was among those to receive treatments from the NeuroStar during its testing stage.

"I suffered from chronic unremitting depression since 1990," Steve said. "I went through every therapy imaginable, mainly drugs, and psychotherapy."

Steve said he was sleeping 18 hours a day and unable to work or do much of anything when a University of Pennsylvania Health System doctor recommended TMS therapy. He had read about the experimental therapy and was eager to try it.

"Within a week or so there was a noticeable effect," he said. "Within two weeks it was clear the depression was remitting, and within a month it was gone. There have been some ups and downs. I still go in for treatment once a week. ... It has helped me so much. I had given up all hope, then this came along."



O'Reardon