

## Magnus receives FDA clearance for neuromodulation system for patients with major depressive disorder

By David Godkin, Staff Writer

Magnus Medical Inc. received FDA clearance for a neuromodulation platform to treat major depressive disorder (MDD) in adults for whom antidepressant medication has been ineffective. In 2021, the Saint neuromodulation system underwent a double-blinded, randomized controlled trial, which Magnus said produced benefits that were “dramatic, rapid and frequently sustained through the study follow-up period.”

“For the more than half a million Americans hospitalized with major depression and who are suicidal this is just about the toughest journey any of us could imagine,” Burlingame, Calif.-based Magnus co-founder and CEO Brett Wingeier told *BioWorld*. “What’s been the inspiration for the folks who have developed our system is a really effective, fast acting and definitive way of addressing treatment-resistant depression.”

### Getting over the hump

The main tools at the disposal of psychiatrists for treating depression are drugs and talk therapy – and these are often successful. Get into the more serious realm of treatment-resistant depression and all bets are off, said Wingeier; even apparent short-term benefits from a change of medication for this group can be misleading.

“Many days later or even a few weeks later, you’re feeling a little better with no reported signs of being suicidal and you are allowed to return home.” The catch, said Wingeier: “suicidality triples the moment people come home from the hospital.”

During early doctoral work in biomedical engineering, Wingeier focused on EEG and then helped develop implantable stimulators for epilepsy at Mountain View, Calif.-based Neuropace Inc. Neuromodulation to treat MDD has been slow to develop “because in so many ways we haven’t understood enough about the brain to have a large effect,” said Wingeier.

As in epilepsy, successful neurostimulation for Parkinson’s disease also proved to be very effective, underscoring for Magnus the potential for its use treating severe depression, this despite a high bar for commercial application treating MDD.



*Using the Saint neuromodulation system, precise patterns of stimulation can restore the health of important brain circuits and yield a significant decrease in depressive symptoms.*

“The key to getting over that hump is understanding more about the underlying networks because then you know where to stimulate and how to stimulate,” said Wingeier. “That’s what unlocks a larger effect size.”

Neuromodulation, as the name suggests, modulates nerve activity at specific neurological sites through electrical or chemical stimulation to restore normal nervous tissue function and treat disease. The Saint neuromodulation system identifies the optimal target to affect poorly functioning brain circuits using new algorithms and neuroimaging for personalized targeting of depression.

Precise patterns of stimulation can restore these brain circuits and yield significant decrease in depressive symptoms. In a double-blind [randomized controlled trial](#) of Stanford Neuromodulation Therapy (SNT) – which builds on a 2020 study

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of the Saint neuromodulation treatment – 32 participants with treatment-resistant depression were enrolled, and 29 participants who continued to meet inclusion criteria received either active or sham SNT.

Scored on the Montgomery-Åsberg Depression Rating Scale, the mean percent reduction from baseline four weeks after treatment was 52.5% in the active treatment group and 11.1% in the sham treatment group. SNT, the Stanford study concluded “was more effective than sham stimulation for treatment-resistant depression,” though further trials would determine its durability in comparison with other treatments.

Core to the technology, said Wingeier, “is that it’s relevant to anything that has an underlying network imbalance, a network pathology across a broad spectrum of psychiatric and neuropsychiatric disease.”

### **Finding the sweet spot**

The technology that comes closest to what the Saint neuromodulation system can achieve is conventional transcranial magnetic stimulation (TMS), which uses magnetic fields to stimulate nerve cells in the brain to improve symptoms of depression. FDA-cleared since 2008 and [promoted by the Mayo Clinic](#), TMS has been effective for treating depression and

helped set the stage for the use of magnetic impulses in the Saint neuromodulation system.

The key “is knowing exactly where to treat and pulling that information from the functional connectivity data inherent in functional MRI,” said Wingeier. In other words, figuring out “where the sweet spot” is in the left dorsolateral prefrontal cortex, i.e., a discrete area of the brain beneath the left forehead and temple.

“These are much more strongly connected to the deeper networks,” said Wingeier. In addition to the algorithm developed by Magnus to help reach those deeper networks “is a different pattern of dosing and spacing between sessions that leverage the underlying neuroscience a lot more powerfully.”

“That’s what combines to make this not just incremental but breakthrough technology,” said Wingeier. Being able during the 2020 Magnus study to achieve a marked reduction of suicidality very rapidly with the treatment “is enormously promising and really a pleasant surprise for our team,” Wingeier added. “It’s a tremendously exciting preliminary result.”

Based on this and the exclusive license granted by Stanford University and its intellectual property, Magnus raised \$25 million in December 2020. A limited commercial launch of the Saint system is planned for some time in 2023.