COMPANY BACKGROUND

Overview

Magnus Medical, Inc. is a privately held therapeutic neuromodulation company headquartered in Burlingame, California. The company was co-founded by Brandon Bentzley, M.D., Ph.D., to offer individuals who suffer from neuropsychiatric disorders more personalized, rapid-acting, effective treatment options.

Magnus is a developer of brain stimulation technology for the treatment of neuropsychiatric disorders. Its first commercial product is the SAINT® neuromodulation system, which provides a novel form of rapid-acting, non-invasive, individually targeted neuromodulation therapy. The SAINT therapy uses electromagnetic pulses to relieve symptoms of treatment-resistant depression.

The SAINT neuromodulation system was granted Breakthrough Device Designation and 510(k) clearance by the U.S. Food & Drug Administration (FDA) in September 2022 for the treatment of major depressive disorder (MDD) in adults who have failed to achieve satisfactory improvement from prior antidepressant medications in the current episode.

SAINT therapy was developed at the Stanford Brain Stimulation Lab and licensed exclusively to Magnus in October 2021 for further development and commercialization.

Major Depression

Major Depressive Disorder, or MDD, is an episodic disorder that can last months or years.[1] Treatment-resistant MDD is a condition that impacts over 50% of people with depression who don't respond to medications and psychotherapy.[2]

In the U.S., 20% of adults experience depression at some point in their lives,[3] which amounts to approximately 52 million people out of 260 million adults.[4]

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1 https://apps.who.int/iris/bitstream/handle/10665/254610/WHO-MSD-MER-2017.2-eng.pdf

2 Pigott, H. E., Kim, T., Xu, C., Kirsch, I. & Amsterdam, J. What are the treatment remission, response and extent of improvement rates after up to four trials of antidepressant therapies in real-world depressed patients? A reanalysis of the STAR*D study's patient-level data with fidelity to the original research protocol. BMJ Open 13, e063095 (2023).

3 https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2671413#:~:text=Findings%20In%20this%20national%20survey,associated%20with%20comorbidity%20and%20impairment

4 https://www.google.com/url?q=https://www.census.gov/library/stories/2021/08/united-states-adult-population-grew-faster-than-nations-total-population-from-2010-to-2020.html%23:~:text%3DIn%25202020%252C%2520the%2520U.S.%2520Census,from%2520234.6%2520million%2520in%25202010&sa=D&source=docs&ust=1713912031443932&usg=AOvVaw2I_UfAmNQEge_wWwHnDI1Y

Research shows that 10.4% of adults experience MDD within a 12-month period and 20.6% over their lifetime.[5] Considering the total adult population, this means an estimated 26 million Americans struggle with depression each year.

A New Approach to Personalized Mental Health Treatment

The SAINT neuromodulation system is a novel innovation that is having a very positive impact on the treatment of severe depression. In clinical trials, treatment with SAINT for major depressive disorder has resulted in a significant reduction in depressive symptoms at four weeks post-treatment following the five-day treatment protocol.[6] The SAINT neuromodulation system is commercially available in the U.S.

For the first time, advanced imaging technologies combined with personalized targeting and novel stimulation patterns yield a new form of individualized neurostimulation for people with treatment-resistant depression.

The SAINT neuromodulation system uses structural and functional magnetic resonance imaging (MRI) scans to inform a proprietary algorithm that identifies the optimal anatomic target for focused neurostimulation in people with MDD.

Specifically, the SAINT neuromodulation system uses MRI images of brain activity to identify the most strongly connected portions of the left dorsolateral prefrontal cortex with respect to a deeper subregion, the subgenual cingulate. In people who have MDD, the subgenual cingulate becomes overactive, and the ability to inhibit inwardly directed negative thoughts is impaired. By precisely stimulating part of the dorsolateral prefrontal cortex, activity in the subgenual cingulate is reduced, and mood regulation can be restored.[7]

Stimulation to this precise region is delivered with a specialized, high-dose pattern of repetitive magnetic pulses that induce neurons to fire. This form of stimulation is capable of safely and effectively modifying activity in brain networks related to major depression. Treatment with SAINT is delivered on an accelerated timeline—10 sessions a day, composed of 10-minute treatments with 50-minute breaks for five consecutive days. This patterned stimulation with regular rest periods activates the neuroscience underlying *spaced learning:* short, intensely focused periods of learning with breaks over a period of time.

By comparison, conventional treatments for treatment-resistant depression take weeks to months to begin working.

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5 https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2671413#:~:text=Findings%20In%20this%20national%20survey,associated%20with%20comorbidity%20and%20impairment

6 https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2021.20101429

7 Liston et al. 2015; Weigand et al. 2017.

Clinical Data
Results from a double-blinded randomized controlled trial (RCT) evaluating SAINT were published in the American Journal of Psychiatry and demonstrate that the novel approach has the promise to be a reproducible, rapid, and effective treatment for severe, refractory depression. Fourteen people received active treatment, and another 15 people received sham (placebo) treatment. The results indicate that 79% of people in the active treatment arm entered remission—that is, they experienced a significant reduction of depression symptoms based on the Montgomery-Åsberg Depression Rating Scale (MADRS)—compared to people in the sham treatment arm, whereas 13% of the people entered remission.

The SAINT neuromodulation system has additionally been studied in non-RCT (open-label) studies. Overall, the therapy has been shown to be effective in the treatment of MDD, with approximately 80-90% of patients achieving remission of depression symptoms following the five-day treatment protocol.

Reimbursement for SAINT
Magnus received approval for a New Technology Add-on Payment (NTAP) from the Centers for Medicare & Medicaid Services (CMS) for its SAINT neuromodulation system. This is the first time CMS has approved a NTAP for Interventional Psychiatry. The NTAP is available for Medicare patients treated with SAINT therapy and is eligible for additional reimbursement of up to $12,675 per hospital inpatient treatment.

The American Medical Association (AMA) issued new Category III Current Procedural Terminology (CPT) codes for targeted, accelerated iTBS for depression, encompassing the SAINT neuromodulation system, effective July 1, 2024. The company is actively pursuing robust payment for SAINT therapy through Medicare in the hospital outpatient setting and working directly with private insurance companies. Magnus Medical expects to have selective insurance coverage in both the hospital inpatient and outpatient setting and the physician's office. The company anticipates that coverage will grow over the next several years.

Funding, Investors and Commercialization.
Magnus has raised $25M in Series A financing, co-led by Jazz Venture Partners and Red Tree Venture Capital. The company announced commercialization of the SAINT neuromodulation system on April 30, 2024. Magnus anticipates raising additional Series B funding to further drive commercialization. Magnus Additional information may be found here.

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