

COMPANY BACKGROUND

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

The company is developing a rapid-acting brain stimulation technology delivered via an advanced neuromodulation platform. Its first application will be treatment of major depressive disorder (MDD) in adults who have not improved sufficiently from prior antidepressant medication or other treatments. This form of MDD, in which standard medications prove ineffective, is known as treatment-resistant depression and affects approximately 30% of individuals with MDD.

MDD is an episodic disorder that can last months or years and is the leading cause of disability worldwide.^{1 2} Approximately 17.3 million American adults will suffer a major depressive episode in any given year,³ and an estimated 5 million American adults have treatment-resistant depression.⁴

A New Approach to Personalized Mental Health Treatment

The Magnus System is a novel innovation with the potential to have a significant positive impact on the treatment of severe depression.

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

Based on SAINT technology, the Magnus System uses structural and functional magnetic resonance imaging (MRI) information to inform a proprietary algorithm that identifies the optimal anatomic target for focused neurostimulation in people with MDD. SAINT was

¹ World Health Organization. Depression and Other Common Mental Disorders. 2017;1–24. Available from: <http://apps.who.int/iris/bitstream/10665/254610/1/WHO-MSD-MER-2017.2-eng.pdf?ua=1>

² Friedrich MJ. Depression Is the Leading Cause of Disability Around the World. JAMA [Internet] 2017;317(15):1517–1517. Available from: <http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2017.3826>

³ National Institute of Mental Health “Major Depression”, 2017

⁴ Thomas L, Kessler D, Campbell J, et al. Prevalence of treatment-resistant depression in primary care: cross-sectional data. The British journal of general practice : the journal of the Royal College of General Practitioners 2013;63(617):e852-8.

developed at Stanford and licensed to Magnus Medical for commercialization in October 2021.

Specifically, the Magnus 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.⁵

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 the Magnus System is designed to be 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 intractable depression take weeks to months to begin working, and provide remission from depression for only a fraction of people.

Clinical Results

The SAINT technology has demonstrated profound, rapid results in intractable depression in an investigational setting.

In the [American Journal of Psychiatry](#), results from a double-blinded randomized controlled trial (RCT) evaluating SAINT suggest that the novel approach has the promise to be a reproducible, rapid, and highly effective treatment for severe, refractory depression in an investigational setting. Fourteen people received active treatment, and another 15 people received sham (placebo) treatment. The results show that 79% of people in the active treatment arm entered remission—that is, the elimination of depression symptoms based on the Montgomery-Åsberg Depression Rating Scale (MADRS)—compared to people in the sham treatment arm, where 13% of the people entered remission.

In an earlier pilot [trial](#) evaluating SAINT, 19 of 21 people (90%) entered remission. The restoration of healthy neural activity for many people was life-changing, and within five days, symptoms (including thoughts of suicide) improved dramatically.

⁵ Liston et al. 2015; Weigand et al. 2017.

Clinical trial data from the five-day treatment protocol in treatment-resistant depression indicate that SAINT was safe and well-tolerated in this investigational setting.

Funding, Investors, and the Executive Team Founders

Magnus Medical Inc. has raised \$25M in Series A financing co-led by Jazz Venture Partners and Red Tree Venture Capital. The company's seasoned co-founders possess both professional experience and broad industry knowledge, and together they have assembled an impressive internal team.

Dr. Wingeier has 20 years of neuromodulation industry experience. He co-founded Halo Neuroscience and is an alumnus of NeuroPace and Autonomic Technologies, where he was a principal engineer and clinical scientist, holding more than 60 U.S. patents. Dr. Bentzley is a board-certified psychiatrist and neuroscientist with a track record of NASA & NIH-funded research in basic and clinical domains. Before co-founding Magnus Medical, he was director of innovation of the Stanford Brain Stimulation Lab. Scott Ashworth, who joined the company as CCO, brings over 30 years of leadership experience in the medical device and health care data industries with Fortune 500 and startup organizations. Most recently, he was CCO for DocSpera, a pre-and post-operative care coordination platform addressing care continuum challenges facing procedural specialists and OR professionals.

About Depression

Depression is caused by specific and identifiable changes in an individual's brain network. It is a common and serious medical illness that is the leading cause of disability worldwide.⁶ One in five American adults will experience mental illness each year.⁷ Despite the pervasiveness of depression, misunderstandings, misinformation, and stigma associated with depression can be a severe impediment to treatment options.

According to Nolan Williams, M.D., assistant professor of Psychiatry and Behavioral Sciences at Stanford University Medical Center, psychiatry is the only field in medicine where biological treatment options on average diminish in the hospital setting.

"If you have a heart attack or a stroke, for example, you can go to the hospital and receive sophisticated treatments that are only available at the hospital," explains Dr. Williams. "The options increase as the acuity of the illness increases. Yet, if a person is experiencing a mental health emergency and goes to the hospital, the same options aren't there, and the ability to receive more effective treatment in the hospital is drastically reduced or non-existent."

⁶ https://www.who.int/health-topics/depression#tab=tab_1

⁷ <https://www.nimh.nih.gov/health/statistics/mental-illness>

More than 550,000⁸ American adults are hospitalized annually for suicidal depression. The highest peak in suicide attempt⁹ and completion is immediately after discharge from the hospital.

Depression has a significant impact on America's healthcare and economic system. The financial burden is more than \$210 billion annually in the U.S. alone.¹⁰

About Neuromodulation

Nerve cells in the brain can be stimulated with electrical or magnetic fields, using a variety of methods and devices. This technology is called *neuromodulation*, and can be used to modify network activity, restore healthy function, and treat many diseases.

The SAINT treatment is a form of individually targeted, accelerated neuromodulation that uses electromagnetic pulses to relieve symptoms of depression. It is most closely related to transcranial magnetic stimulation (TMS), which is a type of neuromodulation commonly used for treatment-resistant depression.

The Magnus System, currently an investigational device, is expected to require 510(k) clearance from the U.S. FDA and is not yet commercially available.

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⁸ <https://www.hcup-us.ahrq.gov/db/nation/nis/nisdbdocumentation.jsp>

⁹ <https://pubmed.ncbi.nlm.nih.gov/28564699/>

¹⁰ <https://www.ajmc.com/view/economic-burden-mdd>