

## COMPANY BACKGROUND

### Overview

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 a developer of brain stimulation technology for the treatment of neuropsychiatric disorders. Its first product is the SAINT™ Neuromodulation System, 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.

MDD is an episodic disorder that can last months or years and is the leading cause of disability worldwide.<sup>1</sup> According to the World Health Organization, over 280 million people suffer from MDD globally, nearly half of whom have treatment-resistant depression, or TRD, and far too many experience suicidal thoughts with no rapidly acting treatment options available to them.<sup>2</sup>

### 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.<sup>3</sup> The SAINT Neuromodulation System is available by prescription 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. SAINT was developed at Stanford and licensed exclusively to Magnus in October 2021 for commercialization.

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<sup>1</sup> 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>

<sup>2</sup> 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>

<sup>3</sup> <https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2021.20101429>

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.<sup>4</sup>

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 SAINT Neuromodulation System 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.

### **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 significant reduction 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.

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.

### **Funding and Investors**

Magnus has raised \$25M in Series A financing co-led by Jazz Venture Partners and Red Tree Venture Capital. The company anticipates raising additional Series B funding to drive platform development and initial commercialization.

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<sup>4</sup> Liston et al. 2015; Weigand et al. 2017.

## 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.<sup>5</sup> One in five American adults will experience mental illness each year.<sup>6</sup> 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."

Therapy for treatment-resistant depression is a critical need in the U.S. and worldwide. More than 550,000<sup>7</sup> adults in the U.S. alone are hospitalized annually for suicidal depression. The highest peak in suicide attempt<sup>8</sup> and completion is immediately after discharge from the hospital.

Depression has a significant impact on America's healthcare and economic system. The financial burden of major depressive disorder among U.S. adults was an estimated \$236 billion in 2018, an increase of more than 35% since 2010.<sup>9</sup>

## 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 Neuromodulation System provides a novel form of rapid-acting, non-invasive, individually targeted neuromodulation that uses electromagnetic pulses to relieve symptoms of treatment-resistant depression.

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<sup>5</sup> [https://www.who.int/health-topics/depression#tab=tab\\_1](https://www.who.int/health-topics/depression#tab=tab_1)

<sup>6</sup> <https://www.nimh.nih.gov/health/statistics/mental-illness>

<sup>7</sup> <https://www.hcup-us.ahrq.gov/db/nation/nis/nisdbdocumentation.jsp>

<sup>8</sup> <https://pubmed.ncbi.nlm.nih.gov/28564699/>

<sup>9</sup> <https://www.psychiatry.org/News-room/APA-Blogs/The-Economic-Cost-of-Depression-is-Increasing>

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