BrainsWay Reports National Institutes of Health Grant to Leading U.S. Research Team Investigating Accelerated Deep TMS for Treatment of Alcohol Use Disorder

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New NIH grant awards $2.5 million over 5 years for mechanistic study

BURLINGTON, Mass. and JERUSALEM, Nov. 04, 2025 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) (“BrainsWay” or the “Company”), a global leader in advanced noninvasive neurostimulation treatments for mental health disorders, today announced that the U.S. National Institutes of Health (NIH) has awarded a new grant – totaling approximately $2.5 million over five years – to a research team led by Principal Investigator Dr. Claudia Padula and Co-Investigator Dr. Michelle Madore of Stanford University and the Palo Alto Veterans Institute for Research. The funding will support a clinical study evaluating the mechanism of action and potential efficacy of an accelerated Deep Transcranial Magnetic Stimulation (Deep TMS™) protocol using BrainsWay’s device to treat Alcohol Use Disorder (AUD).

"This accelerated treatment protocol represents a substantial leap forward in our research on AUD,” said Dr. Colleen Hanlon, Vice President of Medical Affairs BrainsWay. “If we can confirm that this rapid, high-intensity Deep TMS protocol effectively and durably engages the targeted brain circuits and reduces relapse risk, it has the potential to facilitate the development of new, much-needed neuromodulation-based treatment strategies for AUD.”

The study, titled, "*Assessing the Impact of dTMS on Neural Targets Associated with Alcohol Use Disorder*," will utilize BrainsWay’s H7 Coil to target brain regions which are associated with core neural mechanisms underlying addiction and relapse risk.

Accelerated, High-Intensity Treatment Protocol

The study features an accelerated dosing schedule, designed to rapidly engage neural targets and improve patient access:

- **Protocol:** Participants will receive three Deep TMS treatments per day for 10 consecutive business days, totaling 30 treatment sessions.
- **Design:** The study will enroll 100 adults with AUD in a randomized, double-blind, sham-controlled trial.
- **Mechanistic Focus:** Researchers will use neuroimaging assessments to investigate the “target engagement” – i.e. neural activation in the targeted brain regions such as the dorsal Anterior Cingulate Cortex (dACC) – in the active group relative to sham. This seeks to link various clinical outcomes being measured in the study (including percentage of days abstinent and heavy drinking days) to any observed brain changes.

This marks the second major NIH grant awarded to this team of researchers in two years, reinforcing their leadership in neuromodulation for addiction. Last year, the same team received a multimillion-dollar NIH grant – with a $1.49M first-year budget – to study a similar accelerated Deep TMS protocol using the H4 Coil for Stimulant Use Disorder (Methamphetamine Use Disorder (MUD)), primarily focusing on veterans.

“We are excited to see clinical studies evaluating the use of accelerated Deep TMS being conducted by such highly distinguished researchers,” stated Hadar Levy, Chief Executive Officer of BrainsWay. “If successful, the findings from the MUD and AUD studies may lead to significantly expanded adoption of advanced, noninvasive neuromodulation techniques to treat substance use disorders.”

This new research follows other recent Company developments relating to the use of accelerated protocols with its products. BrainsWay recently announced that it received FDA clearance for its H1 Coil for the accelerated treatment of patients suffering from major depressive disorder (MDD), including those with comorbid anxiety symptoms.

About BrainsWay
BrainsWay is a global leader in advanced noninvasive neurostimulation treatments for mental health disorders. The Company is boldly advancing neuroscience with its proprietary Deep Transcranial Magnetic Stimulation (Deep TMS™) platform technology to improve health and transform lives. BrainsWay is the first and only TMS company to obtain three FDA-cleared indications backed by pivotal clinical studies demonstrating clinically proven efficacy. Current indications include major depressive disorder (including reduction of anxiety symptoms, commonly referred to as anxious depression), obsessive-compulsive disorder, and smoking addiction. The Company is dedicated to leading through superior science and building on its unparalleled body of clinical evidence. Additional clinical trials of Deep TMS in various psychiatric, neurological, and addiction disorders are underway. Founded in 2003, with operations in the United States and Israel, BrainsWay is committed to increasing global awareness of and broad access to Deep TMS. For the latest news and information about BrainsWay, please visit www.brainsway.com.

Forward-Looking Statement
This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may be preceded by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “targets,” “believes,” “hopes,” “potential” or similar words, and also includes any financial guidance and projections contained herein. These forward-looking statements and their implications are based on the current expectations of the management of the Company only and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. In addition, historical results or

conclusions from scientific research and clinical studies – especially preliminary data which remains subject to peer-review – do not guarantee that future results would suggest similar conclusions or that historical results referred to herein would be interpreted similarly in light of additional research or otherwise. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: the failure to realize anticipated synergies and other benefits of the proposed transaction; the failure of our investments in management services organizations and/or other clinic-related entities to produce profitable returns; inadequacy of financial resources to meet future capital requirements; changes in technology and market requirements; delays or obstacles in launching and/or successfully completing planned studies and clinical trials; failure to obtain approvals by regulatory agencies on the Company's anticipated timeframe, or at all; inability to retain or attract key employees whose knowledge is essential to the development of Deep TMS products; unforeseen difficulties with Deep TMS products and processes, and/or inability to develop necessary enhancements; unexpected costs related to Deep TMS products; failure to obtain and maintain adequate protection of the Company's intellectual property, including intellectual property licensed to the Company; the potential for product liability; changes in legislation and applicable rules and regulations; unfavorable market perception and acceptance of Deep TMS technology; inadequate or delays in reimbursement from third-party payers, including insurance companies and Medicare; inability to commercialize Deep TMS, including internationally, by the Company or through third-party distributors; product development by competitors; inability to timely develop and introduce new technologies, products and applications, which could cause the actual results or performance of the Company to differ materially from those contemplated in such forward-looking statements.

Any forward-looking statement in this press release speaks only as of the date of this press release. The Company undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws. More detailed information about the risks and uncertainties affecting the Company is contained under the heading "Risk Factors" in the Company's filings with the U.S. Securities and Exchange Commission.

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