



BrainsWay Announces Positive Results in Late-Life Depression Post-Marketing Analysis

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Data Published in Leading Peer-Reviewed Publication, Journal of Clinical Medicine

JERUSALEM and BURLINGTON, Mass., March 28, 2024 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) ("BrainsWay" or the "Company"), a global leader in advanced noninvasive neurostimulation treatments for mental health disorders, announced positive results in a recently published post-marketing study of its Deep Transcranial Magnetic Stimulation (Deep TMS™) for the treatment of late-life depression.

The data were highlighted in an article entitled, "Never Too Late: Safety and Efficacy of Deep TMS for Late-Life Depression," that was published in the *Journal of Clinical Medicine*, an international, [peer-reviewed](#), open access journal. The post-marketing study demonstrated real-world outcomes for older adults (60-91 years of age) suffering from major depressive disorder (MDD). In the study, data was analyzed from 247 depression patients at 16 clinical sites in this age group who had been treated with BrainsWay's proprietary H1 Coil. The results showed a 79.4% response rate (≥50% reduction in symptoms) and a 60.3% remission rate for those patients who had received at least 30 treatment sessions, and were based on the rating scale that was most utilized for each individual patient. The outcomes were comparable to those reported in a post-marketing analysis of over 1,350 patients published in 2023.

"As our population is living longer, late-life depression is fast becoming a critical health care concern that affects a significant number of families and care facilities worldwide. While the use of noninvasive neurostimulation with TMS has shown excellent efficacy for depression patients aged 20-65, there has been some concern that older adults may not receive adequate relief due to typical age-related changes in their brains. Specifically, as we get older, the distance from our scalp to our brain tends to expand due to brain atrophy. This can make it challenging for certain non-invasive technologies to reach the brain areas involved in depression," said Colleen Hanlon, PhD, Vice President of Medical and Clinical Affairs at BrainsWay. "We believe that the deeper and broader stimulation of BrainsWay's Deep TMS can play a meaningful role in overcoming these age-related challenges."

BrainsWay's existing FDA depression labeling does not extend to patients aged over 68, and the results of this study are subject to further review by the FDA.

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 offices in Burlington, MA and Jerusalem, 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 Statements

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," "believes," "hopes," "potential" or similar words. 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 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: 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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