



## **BrainsWay Reports Results of Interim Analysis of H7 Deep Transcranial Magnetic Stimulation Study in Post-Traumatic Stress Disorder**

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### **Company to discontinue funding of study following insufficient demonstration of efficacy**

PATTERSON, N.J., Feb. 06, 2020 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) ("BrainsWay") today announced interim results from a multicenter randomized controlled double-blind clinical trial assessing the safety and efficacy of the Company's H7-coil deep transcranial magnetic stimulation (dTMS) System for the treatment of adults with post-traumatic stress disorder (PTSD). Results showed that the H7 dTMS, which targets the medial prefrontal cortex (mPFC), did not demonstrate sufficient efficacy relative to sham control treatment in PTSD patients. Based on the interim analysis, the Company will not invest additional resources in order to continue this study. BrainsWay is performing additional analysis and will consider future PTSD studies using alternative parameters.

### **About the Study**

The study utilized the Company's H7-coil, one of BrainsWay's proprietary coils, to target the mPFC, which has traditionally been associated with PTSD symptoms. The study was a randomized double-blind multicenter study, designed to evaluate the safety and efficacy of H7 dTMS treatment in reducing symptoms in individuals suffering from PTSD. The trial was conducted at 16 clinical sites, including leading academic institutions, primarily in the United States. Subjects received either H7 dTMS or sham treatment over the course of four weeks (three sessions per week), with two booster sessions at weeks five and nine. For both the active and sham groups, treatments were administered following tailored symptom provocation in the form of a pre-prepared audio recording of a script of the traumatic event. The primary endpoint was a comparison between active and sham treatment groups of the change in CAPS-5 score (the gold standard score used to measure PTSD) from baseline to week five.

The interim analysis was conducted on the first 87 eligible subjects who completed the study protocol, and it revealed a significant reduction of PTSD symptoms in both the active and sham groups. The clinical benefit observed in the sham group may possibly be explained by the brief exposure therapy (administered to both groups) as part of the tailored provocation. However, the results did not demonstrate sufficient clinical benefit induced specifically by the active treatment (relative to sham treatment) to justify continuation of the trial. Overall, the treatment was found to be well-tolerated by participants in the study and no seizures were reported. There were no serious adverse events reported in the study related to the device.

"We are disappointed with the outcome of the interim analysis, and believe discontinuing the trial at this time is the best course of action as we reevaluate our options with this very complex mental health condition," said Christopher R von Jako, Ph.D., President and CEO of BrainsWay. "We remain focused on executing our growth strategy through our current FDA-cleared indications of Major Depressive Disorder and Obsessive Compulsive Disorder, which represents an addressable market of approximately \$9 billion. In addition, we continue to maintain a robust pipeline of additional applications with our proprietary dTMS platform targeted at other large-market psychiatric, neurological, and addiction conditions."

"I would like to thank the patients and investigators for their participation in this important study," said a principal investigator of the study, Dr. Kerry Ressler, *Chief of the Division of Depression & Anxiety Disorders at McLean Hospital and Professor of Psychiatry at Harvard Medical School*. "While the interim results of this trial did not justify its continuation using these stimulation parameters, we did gain valuable insight into PTSD, which is a highly debilitating disease. I am confident that what we learn from this study will be critical for the development of future important PTSD treatments."

### **About BrainsWay**

BrainsWay is engaged in the research, development and sales and marketing of a medical system for non-invasive treatment of common brain disorders. The medical system developed and manufactured by the Company is based on a unique breakthrough technology called dTMS, which can reach significant depth and breadth of the brain and produce broad stimulation and functional modulation of targeted brain areas. In the U.S., the Company's device has been FDA cleared for the treatment of major depressive disorder (MDD) and of Obsessive Compulsive Disorder (OCD). The Company's systems have also received CE clearance and are sold worldwide for the treatment of various brain disorders.

### **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," "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. Moreover, the data presented herein represent the company's description of the preliminary analysis following completion of the study. 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 dTMS products; unforeseen difficulties with dTMS products and processes, and/or inability to develop necessary enhancements; unexpected costs related to dTMS 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 dTMS technology; inadequate or delays in reimbursement from third-party payers, including insurance companies and Medicare; inability to commercialize dTMS, 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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