



**BrainsWay**

## **BrainsWay Announces Positive Data from Smoking Cessation Multicenter Study Evaluating Use of Deep TMS at Society for Research on Nicotine & Tobacco 2020**

March 14, 2020

**Positive results showed that Deep TMS may help chronic smokers quit – Data collected from first multicenter pivotal study ever conducted on a non-invasive brain stimulation device in the addiction space**

BrainsWay Ltd. (NASDAQ & TASE: BWAY) (“BrainsWay” or the “Company”), a global leader in the advanced non-invasive treatment of brain disorders, today presented positive data from its multicenter study evaluating the Company’s proprietary deep transcranial magnetic stimulation (Deep TMS) system as an aid in smoking cessation in an oral presentation at the Society for Research on Nicotine & Tobacco (SRNT) annual conference, which takes place March 11-14, 2020, in New Orleans, Louisiana.

Dr. Aron Tendler, Chief Medical Officer at BrainsWay, presented the data in an oral presentation entitled, “Smoking Cessation Induced by Deep Magnetic Stimulation: A Double-Blind Sham Controlled Multi-Center Study,” which took place today, Saturday, March 14, 2020, from 10:45-11:00 AM CT.

“Tobacco smoking is one of the primary causes of preventable death and also leads to other serious conditions, such as cancer and heart disease,” said Dr. Tendler. “While there are several treatment options currently available, the development of other therapies is critical to increasing the continuous quit rate among smokers. Findings from our multicenter study indicate that Deep TMS could potentially serve as a treatment option for inducing smoking cessation. BrainsWay is proud to be at the forefront of non-invasive brain stimulation for addiction and we are focused on working to make Deep TMS available to patients attempting to successfully quit smoking as expeditiously as possible.”

The results presented are from a randomized, double-blind, multicenter study designed to evaluate the safety and efficacy of Deep TMS treatment as an aid in reducing cigarette smoking in individuals suffering from chronic smoking addiction. The trial was conducted at 14 sites, primarily in the U.S., and enrolled 262 eligible subjects randomized into two groups: an active treatment group treated with BrainsWay’s proprietary H4-coil targeting addiction-related brain circuits, and a sham (placebo) control group. The primary endpoint of the study was a comparison between the two groups of the four-week continuous quit rate (CQR), representing abstinence during a consecutive four-week period.

Of the 168 participants in the study who actually completed three weeks of active Deep TMS or sham treatment, plus the mandatory additional three weeks of follow-up (reaching the six-week endpoint), the CQR was 28.4% in the treatment group compared to 11.7% in the sham group ( $p=0.0063$ ). The primary endpoint was defined based on the CQR among those subjects who received at least one Deep TMS (or sham) treatment session and had at least one post-baseline assessment, even if not completing the treatment period. Within this cohort (which consisted of 234 participants and included dropouts) the CQR was 19.4% in the treatment group and 8.7% in the sham group ( $p= 0.0174$ ).

### About Smoking Addiction:

Smoking is one of the leading causes of death in developed countries. The addiction to nicotine, similar to the addiction to drugs and alcohol, involves modulation of the brain reward system and causes uncontrollable desire to smoke. Approximately 38 million U.S. adults smoke cigarettes, and 480,000 die from smoking each year. Cigarette smoking has been found to harm nearly every organ system in the body and is the leading cause of preventable death in the U.S. and of disease burden worldwide (Brian L et al., JAMA Intern Med 2014).

### About SRNT

The Society for Research on Nicotine & Tobacco (SRNT) is the only professional association dedicated exclusively to the support of researchers, academics, treatment professionals, government employees, and the many others working across disciplines in the field of nicotine and tobacco research. With members in more than 40 countries, SRNT is global in its reach. As a scientific society, SRNT’s mission is to stimulate the generation and dissemination of new knowledge concerning nicotine in all its manifestations. It accomplishes its mission by presenting an annual scientific conference, where researchers at every career stage present their latest findings, and by providing an outlet for publication of cutting edge research through its scientific journal, *Nicotine & Tobacco Research*, which is published by the Oxford University Press.

### About BrainsWay

BrainsWay is a commercial stage medical device company focused on the development and sale of non-invasive neuromodulation products using the Company’s proprietary Deep Transcranial Magnetic Stimulation (Deep TMS) technology for the treatment of major depressive disorder (MDD) and obsessive compulsive disorder (OCD), for which BrainsWay received marketing authorization from the U.S. Food and Drug Administration (FDA) in 2013 (for MDD) and in August 2018 (for OCD). BrainsWay is currently conducting clinical trials of Deep TMS in various psychiatric, neurological and addiction 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. This data, including patient safety information and adverse event data, remain subject to further analysis and may be subject to further modification. Certain results as expressed herein may be subject to further analysis, modification and/or statistical penalties. 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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