
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE
SECURITIES EXCHANGE ACT OF 1934**

For the month of April 2021

Commission File Number: **001-35165**

BRAINSWAY LTD.

(Translation of registrant's name into English)

19 Hartum Street

Bynet Building, 3rd Floor

Har HaHotzvim

Jerusalem, 9777518, Israel

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

EXHIBIT INDEX

<u>Exhibit</u>	<u>Title</u>
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99.1	BrainsWay Receives FDA Clearance for Three-Minute Theta Burst Treatment Protocol for Major Depressive Disorder
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BRAINSWAY LTD.

(Registrant)

Date: April 26, 2021

/s/ Christopher R. von Jako, Ph.D

Christopher R. von Jako, Ph.D
President and Chief Executive Officer

BrainsWay Receives FDA Clearance for Three-Minute Theta Burst Treatment Protocol for Major Depressive Disorder

Shorter Protocol Further Expands Access to Care

CRESSKILL, N.J. and JERUSALEM, April 26, 2021 (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. Food and Drug Administration (FDA) granted 501(k) clearance for the Company's Theta Burst three-minute protocol utilizing its proprietary Deep Transcranial Magnetic Stimulation (Deep TMS) system for the treatment of major depressive disorder (MDD).

"Adding our three-minute treatment protocol to the list of growing solutions available to our provider partners expands the platform nature of this lifechanging technology," said Hadar Levy, Senior Vice President and General Manager of BrainsWay. "Many patients and providers can benefit from significantly shorter treatment sessions, and our Theta Burst protocol can provide these patients with another option to manage their treatment resistant depression."

In support of its successful application to the FDA – the Company's seventh to date – BrainsWay submitted safety and efficacy data from 146 subjects who had received either the standard Deep TMS protocol or the three-minute Deep TMS protocol. Subjects in both groups demonstrated a statistically and clinically meaningful reduction in depression scores, and the results met the equivalence criteria needed for clearance of the shorter treatment.

"The addition of Theta Burst to the available protocols further demonstrates BrainsWay's commitment to expanding the utility of the BrainsWay Deep TMS system," said Moria Ankri, Vice President of Research & Development. "This protocol shows that innovation need not be revolutionary or radical to have a positive effect on peoples' lives. Having a three-minute option for patients has the potential to expand access to care by providing patients with added flexibility in selecting courses of treatment that may fit better with their lifestyle."

The BrainsWay Theta Burst protocol will be immediately available on all BrainsWay systems already installed.

About Major Depressive Disorder

Major depressive disorder (MDD) is a common and debilitating form of depression characterized by physiological, emotional, and cognitive symptoms. According to the World Health Organization (WHO), depression affects approximately 264 million people worldwide, and the U.S. National Institute of Mental Health (NIMH) estimates that 17.3 million adults in the United States suffer from an MDD episode within a given year. Common symptoms of MDD include loss of interest, depressed mood, reduced energy, disturbed sleep and appetite, and comorbid anxiety. The ongoing pandemic continues to exacerbate the incidence of depression globally with more than a three-fold increase in depression symptoms since the onset of COVID-19, and more recent research suggests that more than 50% of patients recovering from COVID-19 suffer from symptoms of MDD.

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 studies demonstrating clinically proven efficacy. Current indications include major depressive disorder, 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 Cresskill, NJ and Jerusalem, Israel, BrainsWay is committed to increasing global awareness 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, and include, but are not limited to, statements about the expected proceeds, use of proceeds and closing of the underwritten offering. 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. 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, and the effect of the global COVID-19 health pandemic on our business and continued uncertainty and market impact relating thereto.

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, including the Company's Annual Report on Form 20-F. Investors and security holders are urged to read these documents free of charge on the SEC’s web site at <http://www.sec.gov>.

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