
**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 June 2024

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 ☐

This Form 6-K is incorporated by reference into the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on April 22, 2019 (Registration No. 333-230979) and the Company's Registration Statement on Form F-3 filed with the Securities and Exchange Commission on September 17, 2021 (Registration No. 333-259610).

EXHIBIT INDEX

<u>Exhibit</u>	<u>Title</u>
<u>99.1</u>	<u>BrainsWay Receives Expanded FDA Labeling to Treat Late Life Depression</u>

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: June 3, 2024

/s/ Hadar Levy
Hadar Levy
Chief Executive Officer

BrainsWay Receives Expanded FDA Labeling to Treat Late Life Depression

Deep TMS™ Becomes the First and Only TMS Device Indicated for Depression Treatment in Patients Between the Ages of 68 and 86

BURLINGTON, Mass. and JERUSALEM, June 03, 2024 (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 US Food and Drug Administration (FDA) has granted an expanded indication for the Company's Deep Transcranial Magnetic Stimulation system (Deep TMS™) allowing for the treatment of patients with major depressive disorder (MDD) ages 22 to 86, changing the previous upper age limit of 68.

This represents the Company's 10th FDA clearance and makes BrainsWay Deep TMS the first and only form of TMS indicated for the treatment of patients over the age of 68 suffering from MDD, including those with comorbid anxiety symptoms.

"Depression does not disappear at age 68, but as we get older, brain atrophy increases the distance from the scalp to the brain which can make it more challenging to reach and treat specific brain targets associated with depression," stated Colleen A. Hanlon, Ph.D., BrainsWay's Vice President Medical Affairs. "We believe that the deeper and broader stimulation of Deep TMS plays a meaningful role in overcoming these age-related, anatomical changes, and were able to present compelling clinical data to the FDA demonstrating the efficacy of Deep TMS on these older patients," concluded Dr. Hanlon.

BrainsWay's application to the FDA included study data showing, for example, that MDD patients over 68 years of age who were treated with the Company's H1 Coil demonstrated 69% and 62% response and remission rates, respectively, using the Hamilton Depression Rating Scale-21 (HDRS-21), and 65% and 35% response and remission rates, respectively, using the self-administered Patient Health Questionnaire-9 (PHQ-9).

"This significant development presents an exciting business opportunity for BrainsWay," said Hadar Levy, Chief Executive Officer of BrainsWay. "As life expectancies continue to rise, we believe there is strong, untapped interest on the part of caregivers, assisted living facilities, and families of those suffering from depression to find new, effective therapeutic solutions that can alleviate the debilitating burden imposed by this condition on our growing elderly population," concluded Mr. Levy.

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 21 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 changes in appetite. 60-90% of depression patients also exhibit comorbid moderate to severe anxiety, a condition commonly referred to as anxious depression. These anxiety symptoms include nervousness, feelings of panic, increased heart rate, rapid breathing, sweating, insomnia, trembling, and difficulty focusing or thinking clearly. The economic burden in the United States for major depressive disorder totaled \$326 billion prior to the recent COVID pandemic.

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 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. 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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