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 October 2023

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 [X] 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

Exhibit
NumberDescription99.1BrainsWay Announces Publication of Study Data on Accelerated Deep Transcranial Magnetic Stimulation (Deep TMS™) for Depression

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: October 16, 2023

/s/ Hadar Levy Hadar Levy Chief Executive Officer

BrainsWay Announces Publication of Study Data on Accelerated Deep Transcranial Magnetic Stimulation (Deep TMSTM) for Depression

Peer-reviewed Results Suggest Accelerated Deep TMS Outcomes Comparable to Standard Treatment Protocols

BURLINGTON, Mass. and JERUSALEM, Oct. 16, 2023 (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 the publication of new real-world post-marketing data demonstrating the efficacy of accelerated Deep Transcranial Magnetic Stimulation (Deep TMSTM) for the treatment of major depressive disorder (MDD). The compelling results were published in the peer-reviewed journal, *Psychiatry Research*, in an article titled, "Real-World Efficacy and Safety of Various Accelerated Deep TMS Protocols for Major Depression."

Deep TMS utilizes specially designed H–Coils to stimulate deep and broad cortical regions associated with depression. The standard FDA-cleared Deep TMS protocol involves one treatment session per day, five days a week for 4 weeks, followed by a maintenance period. However, there has been recent interest in "accelerated" dosing schedules which involve multiple sessions each day to allow for quicker overall treatment time. Data collected using this approach to treat depression was compiled from clinical sites and analyzed in this study. Key findings from this post-marketing study included:

- Accelerated Deep TMS led to an 80% response rate and a 51% remission rate across all dosing schedules, using the most rated scale (HDRS, MADRS, PHQ-9, BDI-II).
- There was no statistical difference in outcomes seen between the various accelerated dosing schedules, which varied between 2, 3, 5 or 10 Deep TMS sessions per day.
- Subjects undergoing protocols involving more than 2 sessions per day responded and/or remitted typically within 3-5 days, and the durability of treatment was substantial.

"We are firmly dedicated to identifying innovative solutions for various mental health disorders with the goal of transforming lives," said Colleen Hanlon, Ph.D., Vice President of Medical and Clinical Affairs of BrainsWay. "An accelerated protocol could potentially work better with some patients' schedules. While additional research is necessary to fully understand the benefits of accelerated protocols, these initial results are certainly promising as they suggest outcomes can be achieved which are comparable to those resulting from longer, traditional protocols."

BrainsWay Deep TMS is not currently FDA-cleared for accelerated depression treatments. However, these preliminary results could be leveraged to support efforts to expand current labeling for Deep TMS.

"This publication underscores our commitment to scientific excellence and our determination to enhance the quality of life for individuals battling depression," said Aron Tendler, MD, Chief Medical Officer of BrainsWay. "While TMS has been around for nearly 40 years, we continue to look for ways to optimize the delivery of our Deep TMS therapy and restore hope for the many patients who have not responded to first-line treatments. We intend to further investigate the potential efficacy of accelerated Deep TMS in the treatment of MDD, and look forward to sharing those results."

About Major Depressive Disorder and Anxious Depression

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 TMSTM) 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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