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 November 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 Number Description

99.1 <u>Clinical TMS Society Publishes First Coverage Recommendations for the Treatment of Smoking Addiction</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: November 2, 2023

/s/ Hadar Levy Hadar Levy Chief Executive Officer

Clinical TMS Society Publishes First Coverage Recommendations for the Treatment of Smoking Addiction

BrainsWay Deep TMS™ is the Only TMS System FDA-Cleared to Treat Smoking Addiction

BURLINGTON, Mass. and JERUSALEM, Nov. 02, 2023 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) ("BrainsWay" or the "Company"), a global leader in advanced noninvasive neurostimulation treatments for mental health disorders, announced today that the Clinical TMS Society (CTMSS), an influential medical society dedicated to supporting the clinical practice, research, and access to transcranial magnetic stimulation (TMS), has published the first coverage recommendations for smoking addiction treatment using TMS.

BrainsWay Deep TMS™ is the only TMS technology to have received FDA clearance for the treatment of smoking addiction.

The leading specialty society advocating for the clinical benefits of noninvasive brain stimulation, CTMSS has been instrumental in helping expand TMS insurance coverage globally across multiple indications. The group's previously-issued policy guidance helped shape the current TMS treatment reimbursement landscape in the U.S., which is now characterized by near-universal coverage for depression and increasingly expanding coverage for obsessive-compulsive disorder. With this new coverage guidance for insurers, CTMSS now recommends TMS coverage for individuals with a confirmed diagnosis of Tobacco Use Disorder (TUD) who failed two alternative treatment methods, cannot tolerate drugs, or have other comorbid medical conditions (secondary to TUD) such as COPD, artery disease and lung cancer.

"We are encouraged by the ongoing efforts of the Clinical TMS Society to drive favorable coverage for TMS around the world," said Aron Tendler, MD, Chief Medical Officer of BrainsWay. "Nicotine use continues to be the leading cause of preventable death across the globe, and based our data, Deep TMS can be a beneficial solution for those looking to quit without prior success."

Results from BrainsWay's pivotal randomized controlled trial published in 2021 demonstrated that over one in four highly addicted cigarette smokers receiving Deep TMS treatment quit during the course of the study, two in three quitters maintained their abstinence during the follow up period, and the average number of cigarettes smoked per week among the overall active patient group was significantly reduced by 75%.

About Smoking Addiction

Smoking continues to be the leading cause of preventable illness worldwide despite continued cessation efforts. In the United States, 14% of all adults smoke cigarettes (34.1 million) with an economic burden of nearly \$400 billion annually: \$225 billion for direct medical care and over \$156 billion in lost productivity. 480,000 deaths are attributed to cigarette smoking in the US each year. Worldwide, more than 1.3 billion people use tobacco products, and more than 8 million people die annually from direct and indirect exposure. The global economic burden of smoking is estimated to be \$1.852 trillion every year: nearly 2% of the World GDP.

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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