# 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 January 2022

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 [ ]

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):

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 Title

99.1 BrainsWay Announces Final Local Coverage Determination Issued by Regional Medicare Administrative Contractor Palmetto GBA Providing Coverage of Deep TMS<sup>TM</sup> for the Treatment of OCD

# **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: January 31, 2022

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

# BrainsWay Announces Final Local Coverage Determination Issued by Regional Medicare Administrative Contractor Palmetto GBA Providing Coverage of Deep TMS<sup>™</sup> for the Treatment of OCD

### **Palmetto GBA Covers Medicare Patients in Seven States**

BURLINGTON, Mass. and JERUSALEM, Jan. 31, 2022 (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 a final Local Coverage Determination (LCD) has been published providing coverage applicable to the BrainsWay Deep TMS<sup>TM</sup> system for the treatment of obsessive-compulsive disorder (OCD).

The final LCD was issued by the Medicare Administrative Contractor (MAC) Palmetto GBA, which covers Medicare patients in Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia, representing over 9 million covered lives. The final LCD was published following a formal meeting hosted by Palmetto last year and a subsequent review period. The formal LCD will be effective on March 13, 2022.

"This formal policy issued by Palmetto, one of seven MACs in the U.S., brings the total number of covered lives eligible for Deep TMS OCD coverage to approximately 60 million, an important reimbursement achievement for our company," said Christopher von Jako, Ph.D., President and Chief Executive Officer of BrainsWay. "This final LCD is supported by the large body of compelling clinical evidence demonstrating the meaningful benefits derived by OCD patients from treatment with our innovative Deep TMS technology. We continue to work diligently to secure further coverage policy decisions from additional payors, and believe that, over time, other MACs will issue draft policies for Deep TMS coverage of OCD."

The patient selection criteria included in Palmetto's final LCD is closely aligned with the Clinical TMS Society's recommended OCD coverage policy. The U.S. Food and Drug Administration (FDA) granted BrainsWay De Novo clearance in August 2018 for Deep TMS as an adjunct form of therapy for patients suffering from OCD.

### **About Obsessive-Compulsive Disorder**

Obsessive-compulsive disorder (OCD) is a chronic and debilitating condition with a lifetime prevalence in the United States of 2.3%. Characterized by uncontrollable, reoccurring thoughts (obsessions) and behaviors (compulsions) that the sufferer feels compelled to repeat over and over, OCD is considered by the World Health Organization (WHO) to be one of the top 10 debilitating medical conditions associated with a decreased quality of life and loss of income. Due to the complexity and heterogeneity of the condition, coupled with the high percentage of patients that are drug-resistant, many patients suffering from OCD do not respond well to first line treatment options. The economic burden on the U.S. healthcare system for OCD treatments is estimated to be over \$7 billion per year.

### 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<sup>TM</sup>) 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 (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 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. 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; continuation and/or exacerbation of the global supply chain crisis and its impact on the Company's ability to source components, meet customer demand, fill orders, maintain pricing levels and support the Company's service needs; 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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