
**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 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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<u>99.1</u>	<u>BrainsWay Announces First Draft Proposal for OCD Coverage by a Regional Medicare Administrative Contractor</u>
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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: June 1, 2021

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

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

BrainsWay Announces First Draft Proposal for OCD Coverage by a Regional Medicare Administrative Contractor

Palmetto GBA, Administrator of Medicare in Seven States, Publishes Draft Local Coverage Determination

CRESSKILL, N.J. and JERUSALEM, Israel, June 01, 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 first draft Local Coverage Determination (LCD) has been published proposing coverage applicable to the BrainsWay Deep TMS™ system for the treatment of obsessive-compulsive disorder (OCD).

The proposed draft LCD, which was issued by the Medicare Administrative Contractor (MAC) Palmetto GBA, is currently available on the Medicare Coverage Database site for public review. Palmetto’s jurisdiction covers Medicare patients in Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia, representing over 9 million covered lives. Palmetto will host a formal meeting open to the public for comment on the draft policy later this month. This will be followed by a review period, with a final policy expected later this year.

“This is a very positive advancement for the Medicare population, with the potential to streamline their access to Deep TMS,” said Hadar Levy, Senior Vice President and General Manager of North America of BrainsWay. “The BrainsWay team has worked closely with the MACs, and specifically Palmetto, to provide the appropriate published clinical literature for Deep TMS in support of this proposed draft LCD. We look forward to the formal policy from Palmetto, and anticipate that other MACs, over time, will also issue their draft policies for Deep TMS coverage of OCD.”

“Following the recent published positive coverage policy for our Deep TMS system in OCD by Centene, the initial draft LCD by one of the seven MACs in the U.S. represents another significant reimbursement milestone for BrainsWay,” said Christopher von Jako, Ph.D., President and Chief Executive Officer of BrainsWay. “We are pleased that, based on the large body of compelling clinical evidence supporting the treatment of OCD with our innovative technology, our Deep TMS system continues to be recognized for the meaningful benefits it can provide to OCD patients, many of whom are unresponsive to current first-line medication and psychotherapy standard of care treatments alone. We remain committed to working to secure further coverage policy decisions from additional payors in the coming months.”

The patient selection criteria identified in Palmetto’s draft 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™) 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. 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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