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**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 May 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):

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## EXHIBIT INDEX

**Exhibit**   **Title**

[99.1](#)   [BrainsWay Announces First of its Kind Positive Coverage Policy by Centene for the Treatment of OCD Utilizing Deep TMS™](#)

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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: May 24, 2021

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

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

## **BrainsWay Announces First of its Kind Positive Coverage Policy by Centene for the Treatment of OCD Utilizing Deep TMS™**

CRESSKILL, N.J. and JERUSALEM, May 24, 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 Centene Corporation has published a positive coverage policy for Deep Transcranial Magnetic Stimulation (TMS) treatment of obsessive-compulsive disorder (OCD) using the BrainsWay Deep TMS™ system. Centene provides coverage to about 25 million members in all 50 states, including Medicaid and Medicare members, as well as to individuals and families served by the Health Insurance Marketplace, the TRICARE program, and commercial insurance.

Centene’s new policy specifies that coverage will be exclusive for the treatment of OCD utilizing Deep TMS, which is a form of therapy solely associated with BrainsWay’s patented H-Coil technology. This decision follows Centene’s review of an extensive body of published, clinical evidence demonstrating the safety and effectiveness of Deep TMS for OCD, including both pilot and pivotal placebo-controlled, multicenter trials, as well as real-world, post-marketing data.

BrainsWay’s H7-Coil is designed to penetrate deeper and more medial to stimulate the structures of the brain associated with OCD. The Company’s Deep TMS system received De Novo clearance from the U.S. Food and Drug Administration (FDA) for the treatment of OCD in late 2018, and was launched for full market release in 2019. As of March 31, 2021, 225 OCD coils had been shipped as add-on helmets to certain of BrainsWay’s systems.

“It is exciting to achieve this critical milestone after having come so far since the first patients were treated during our pilot study,” said Aron Tendler, MD, Chief Medical Officer of BrainsWay. “OCD is a difficult to treat disease with limited options, and many patients with OCD are treatment-resistant. While this product has been commercially available, the access to meaningful reimbursement should vastly expand access to this potentially life-changing technology.”

“The establishment of this positive Deep TMS coverage policy is the first of its kind for OCD in the broader TMS space. The economic burden on the U.S. healthcare system for OCD treatments is over \$7 billion per year. I am pleased that Centene’s medical and behavioral health leadership has recognized the value that Deep TMS can offer these patients, many of whom are unresponsive to current first-line medication and psychotherapy standard of care treatments,” said Scott Blackman, Director of Market Access at BrainsWay.

“We are thrilled to receive this positive coverage decision, which represents a further demonstration of the increased support for behavioral health challenges adopted by Centene,” said Christopher von Jako, PhD, President and Chief Executive Officer of BrainsWay. “We view this as a significant achievement for our overall business, with the potential to facilitate greater patient and physician access to our Deep TMS system for OCD treatment. Importantly, over one-third of our current total installed base of Deep TMS systems have already opted to offer our OCD treatment prior to the availability of reimbursement, indicating our customers’ strong confidence in the patient benefits made possible through our OCD treatment platform. This positive coverage decision reflects the large body of compelling clinical evidence supporting the treatment of OCD with our Deep TMS H7-Coil, further differentiating it from traditional TMS coils.”

### **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.

### **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](http://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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