
**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 September 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 ☒ 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

<u>Exhibit</u>	<u>Title</u>
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<u>99.1</u>	<u>BrainsWay Announces Significant Private Insurance Coverage from Cigna Corporation for the Treatment of OCD Utilizing Deep TMS™</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: September 14, 2022

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

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



BrainsWay Announces Significant Private Insurance Coverage from Cigna Corporation for the Treatment of OCD Utilizing Deep TMS™

Cigna® Issues Favorable Policy for Deep TMS to Address Medication-Resistant Obsessive-Compulsive Disorder

BURLINGTON, MA and JERUSALEM, Israel, September 14, 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 Cigna Corporation has announced positive coverage applicable to Deep Transcranial Magnetic Stimulation (TMS) for the treatment of obsessive-compulsive disorder (OCD). Cigna, one of the largest major medical insurance company in the United States, provides commercial health coverage to about 17 million members in 13 states, has Medicare Advantage plans in 16 states, and participates in the Health Insurance Marketplace® online exchange. With this new policy, Cigna joins the ranks of Centene, Highmark, Health Care Services Corporation, Blue Cross Blue Shield, Tricare, and Palmetto GBA Medicare, resulting in over 86 million adults now having access to BrainsWay’s pioneering Deep TMS™ OCD treatment.

“The establishment of this positive coverage for OCD further facilitates BrainsWay’s ability to capitalize on its leadership role in advancing treatment of this debilitating condition,” said Christopher von Jako, PhD, President and Chief Executive Officer of BrainsWay. “More importantly, the continued reimbursement momentum for Deep TMS is resulting in increased access of our unique therapy that is critical to our mission of improving the health and transforming the lives of those suffering from disorders with limited treatment options.”

Cigna will be issuing an updated revision to its TMS medical coverage policy effective September 15, 2022 extending coverage to patients aged 18 and older diagnosed with OCD. Under the revised policy, an initial 30-36 TMS treatment session regimen will be classified as medically necessary after a failure of two or more medication trials and a trial of evidence-based psychotherapy without significant improvement in symptoms. Patients with 30% or greater improvement in their Yale-Brown Obsessive Compulsive Scale (Y-BOCS) maintained for at least two months would also be candidates for an additional regimen of 30-36 sessions.

“This achievement is a further acknowledgement of the substantial efforts contributed by the principal investigators in the pilot and pivotal trials of Deep TMS, the clinicians in the field today treating OCD patients, and BrainsWay’s partners dedicated to expanding access and awareness to this life-changing treatment,” said Aron Tendler, MD, Chief Medical Officer of BrainsWay. “OCD is a difficult to treat disease, and almost half of the patients with OCD are treatment-resistant. BrainsWay continues to be a trailblazer in the field, and remains the only TMS company to have demonstrated clinical efficacy in treating OCD through randomized, placebo-controlled data.”

BrainsWay’s patented H7 Coil is designed to penetrate deeper and broader 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 June 30, 2022, 368 OCD coils had been shipped as add-on helmets to accompany BrainsWay platform systems. Approximately 45% of all BrainsWay systems in the field have an H7 Coil.

“The economic burden on the U.S. healthcare system for OCD treatments is over \$10.6 billion per year, and we are excited that Cigna’s medical and behavioral health leadership has recognized the value we can offer these patients,” said Scott Blackman, Director of Market Access at BrainsWay. “This positive coverage decision supplements the growing body of compelling clinical evidence supporting the treatment of OCD with our Deep TMS H7 Coil.”

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 \$10.6 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 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 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. 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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