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 August 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 Receives New FDA Clearance for Treating Depression and Anxious Depression

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: August 29, 2022

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

EXHIBIT 99.1

BrainsWay Receives New FDA Clearance for Treating Depression and Anxious Depression

Depression Clearance for the Proprietary Deep TMS™ H7 Coil Represents the Company's 9th FDA Clearance

BURLINGTON, Mass. and JERUSALEM, August 29, 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 it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the Company's Deep TMS™ H7 Coil for its use in treating adults suffering from major depressive disorder and depression including those with comorbid anxiety symptoms commonly known as anxious depression.

"This clearance is a significant milestone in BrainsWay's pursuit of refining and optimizing noninvasive options for treatment-resistant mental health conditions," said Christopher von Jako, Ph.D., President and Chief Executive Officer of BrainsWay. "Clinicians are accustomed to having myriad pharmaceutical options to tailor treatment plans for their patients, and expanding depression clearance to the Deep TMS H7 Coil provides them with another powerful non-pharmaceutical tool. Similar to most medical interventions, TMS treatment for depression is not a one-size-fits-all solution with respect to all anatomical targets: The H1 Coil targets one region of the brain and the H7 Coil targets a different region, and we now see that stimulating either of these regions can mitigate depressive symptoms. We believe that this clearance may advance our goal of enabling clinicians to provide more personalized medicine for their patients depending upon what works best for them."

The FDA's grant of clearance was based on its review of successful results from a randomized, double-blind, controlled multicenter trial completed by the Company. The trial was designed to better understand the H7 Coil's efficacy in addressing treatment-resistant depression. The study, which included 144 subjects, found overall efficacy rates for the H7 Coil which were comparable to those achieved with BrainsWay's H1 Coil.

"This study was originally conducted after receiving feedback from Deep TMS practitioners in the field which indicated that certain depressed patients not responding to treatment with the H1 Coil would sometimes see success when switched over to the H7 Coil," said Dr. Aron Tendler, BrainsWay's Chief Medical Officer. "Now we have high-quality randomized study data which validates this observation scientifically."

With this new clearance, there is no need to upgrade or add software to systems currently installed in the field. BrainsWay's Deep TMS H7 Coil, which is housed within a cushioned, cooled helmet, has been cleared to treat obsessive-compulsive disorder since 2018. It can now be put to use against depression. The H7 Coil is designed to allow for stimulation of deeper and broader brain structures than traditional TMS coils.

BrainsWay will be implementing a training program in the coming months to educate customers on using the Deep TMS H7 Coil to treat depression within the new FDA clearance.

"This latest clearance, our ninth from the FDA, is a testament to BrainsWay's unparalleled commitment to take on ambitious research projects that continue to advance the field. This research further cements BrainsWay's leadership position in the field and exemplifies its relentless dedication to the improved health and transformed lives of its growing patient base," said Dr. von Jako.

About Major Depressive Disorder and Anxious Depression

Major depressive disorder (MDD) is a common and debilitating form of depression characterized by physiological, emotional, and cognitive symptoms. According to the World Health Organization (WHO), depression affects approximately 264 million people worldwide, and the U.S. National Institute of Mental Health (NIMH) estimates that 21 million adults in the United States suffer from an MDD episode within a given year. Common symptoms of MDD include loss of interest, depressed mood, reduced energy, disturbed sleep, and changes in appetite. 60-90% of depression patients also exhibit comorbid moderate to severe anxiety, a condition commonly referred to as anxious depression. These anxiety symptoms include nervousness, feelings of panic, increased heart rate, rapid breathing, sweating, insomnia, trembling, and difficulty focusing or thinking clearly. The economic burden in the United States for major depressive disorder totaled $326 billion prior to the recent COVID pandemic.

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 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.

EXHIBIT 99.1

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