
**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 2024

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 ☐

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 Number</u> | <u>Description</u> |
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| <u>99.1</u> | <u>BrainsWay Launches Prospective, Randomized, Controlled, Multicenter Trial Evaluating Accelerated Deep TMS™ for Depression</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 10, 2024

/s/ Hadar Levy
Hadar Levy
Chief Executive Officer

BrainsWay Launches Prospective, Randomized, Controlled, Multicenter Trial Evaluating Accelerated Deep TMS™ for Depression

Shortened Acute Treatment Period Could Enhance Appeal and Market Opportunities of Deep TMS™

BURLINGTON, Mass. and JERUSALEM, June 10, 2024 (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 the initiation of a prospective, randomized, controlled, multicenter clinical trial evaluating an accelerated treatment protocol for the Company's proprietary Deep Transcranial Magnetic Stimulation (Deep TMS™) system to treat major depressive disorder (MDD).

The clinical trial is anticipated to enroll over 100 patients with major depressive disorder (MDD) who will be split into two groups – one receiving a novel accelerated treatment protocol featuring an acute phase over several treatment days, and the other receiving the FDA-cleared standard-of-care protocol which entails an acute phase over several weeks. The design of this non-inferiority trial, which was determined in discussion with the U.S. Food and Drug Administration (FDA), aims to compare the outcomes achieved with the accelerated Deep TMS protocol versus the current standard-of-care Deep TMS protocol.

"We are excited to begin this important clinical trial," said Colleen Hanlon, Ph.D., Vice President of Medical and Clinical Affairs of BrainsWay. "Previously published post-marketing data has shown outcomes achieved with accelerated protocols to be comparable with those from longer, traditional protocols. We seek to explore this hypothesis more conclusively during this multicenter study," concluded Dr. Hanlon.

In the study, the standard-of-care Deep TMS protocol will involve the traditional four week acute treatment phase, with one session per each day of treatment. The accelerated protocol will involve a significantly shorter acute phase taking place over several treatment days, with multiple "theta burst" sessions per each day of treatment. Both protocols will conclude with a maintenance phase.

"An accelerated treatment protocol has the potential to improve convenience and thereby make Deep TMS substantially more appealing to many prospective patients," said Hadar Levy, Chief Executive Officer of BrainsWay. "We look forward to the results of this important trial as we continuously work to enhance the value proposition offered by our life-changing mental health solutions," concluded Mr. Levy.

Recruitment for the study is currently underway at multiple clinical sites throughout the U.S.

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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