
**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 November 2025

Commission File Number: **001-35165**

BRAINSWAY LTD.

(Translation of registrant's name into English)

16 Hartum Street RAD Tower, 14th Floor

Har HaHotzvim

Jerusalem, 9777516, Israel

(+972-2) 582-4030

(Address and telephone number of Registrant's 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 Statements on Form F-3 filed with the Securities and Exchange Commission on July 22, 2024 (Registration No. 333-280934) and on April 22, 2025 (Registration No. 333-286672).

EXHIBIT INDEX

<u>Exhibit</u>	<u>Title</u>
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99.1	BrainsWay Launches First Clinical Trial of Deep TMS 360™ System for Alcohol Use Disorder
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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: November 17, 2025

/s/ Hadar Levy

Hadar Levy
Chief Executive Officer

BrainsWay Launches First Clinical Trial of Deep TMS 360™ System for Alcohol Use Disorder

Multicenter, randomized, controlled study will evaluate Company's next-generation multichannel TMS technology in reducing heavy drinking and cravings

BURLINGTON, Mass. and JERUSALEM, Nov. 17, 2025 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) ("BrainsWay" or the "Company"), a global leader in advanced noninvasive brain stimulation technologies, today announced the launch of a multicenter clinical trial investigating the use of its novel Deep TMS 360™ system in individuals with Alcohol Use Disorder (AUD). AUD represents a major economic and health burden, affecting about 29 million Americans (10% of those aged 12+) and, despite available treatments, up to 60% of patients relapse within 3-6 months. This study will mark the first multicenter clinical trial utilizing BrainsWay's next-generation multichannel TMS platform, representing a major milestone in advancing the company's innovation pipeline.

The Company's new Deep TMS 360 technology has been designed to provide more comprehensive and uniform stimulation of the neurons in the targeted brain regions. BrainsWay believes that the multichannel architecture of this new system may be better suited for complex clinical populations such as those suffering from chronic AUD, where there may be greater difficulty in achieving desired stimulation levels due to cortical atrophy (i.e. brain shrinkage).

"The launch of this trial represents a pivotal step in expanding our quest to advance into new and highly important therapeutic areas," said Hadar Levy, CEO of BrainsWay. "Alcoholism is one of the most pressing public health challenges worldwide, and we believe our new 360 technology has the potential to make a meaningful difference for patients seeking to reduce or overcome alcohol dependence."

The study will be a randomized, double-blind, sham-controlled clinical trial, and will enroll over 200 patients aged 18–86 with moderate to severe AUD as determined using the DSM-5 criteria. Participants will receive either active or sham Deep TMS 360 treatments for approximately six months, including an intensive treatment phase during the first 3–5 weeks, followed by weekly maintenance sessions until the 6-month follow-up visit. Each visit comprises two sessions per day. The trial's primary endpoint is the proportion of participants who experience no heavy drinking days (NHDD) during the initial four-month treatment period – an endpoint recognized by the FDA as clinically meaningful in AUD research. Subjects will also undergo educational and behavioral sessions focused on coping strategies and alcohol use reduction.

"BrainsWay's new Deep TMS 360 system is an exciting evolution of our platform, designed to deliver more robust stimulation patterns," said Dr. Colleen Hanlon, Vice President of Medical Affairs BrainsWay. "We anticipate this study will advance our understanding of how noninvasive neuromodulation can help reduce alcohol cravings and promote long-term recovery."

The study will be conducted at multiple research sites across the US – including Alabama, California, Florida, Illinois, New York, and West Virginia – as well as several select international sites in Israel and Sweden. The study follows previous studies investigating BrainsWay's current Deep TMS system in AUD which resulted in promising data.

Individuals wishing to learn more about potentially enrolling in this study may visit <https://www.go.brainsway.com/brainsway-aud-trial-participants>.

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 operations in the United States and 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,” “targets,” “believes,” “hopes,” “potential” or similar words, and also includes any financial guidance and projections contained herein. 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 – especially preliminary data which remains subject to peer-review – 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: the failure to realize anticipated synergies and other benefits of the proposed transaction; the failure of our investments in management services organizations and/or other clinic-related entities to produce profitable returns; 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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