
**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 July 2019

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):

The following document, which is attached as an exhibit hereto, is incorporated by reference herein:

Exhibit Title

[99.1](#) [Groundbreaking Study Demonstrates Advantages of BrainsWay Deep TMS in Treating Major Depressive Disorder](#)

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: July 18, 2019

/s/ Hadar Levy
Hadar Levy
Chief Financial Officer

Groundbreaking Study Demonstrates Advantages of BrainsWay Deep TMS in Treating Major Depressive Disorder

- First head-to-head, randomized controlled trial of its kind comparing Deep TMS, TMS and medication in depression patients published in July issue of the **Journal of Psychiatric Research** -

JERUSALEM, Israel and HACKENSACK, N.J., , July 18, 2019 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ: BWAY, TASE: BWAY), a global leader in the advanced non-invasive treatment of brain disorders, today announced the publication of a third-party study which demonstrated that Deep Transcranial Magnetic Stimulation (dTMS) plus standard medication was significantly more effective at reducing depression levels among Major Depressive Disorder (MDD) patients compared with standard medication alone.

“This is an important study, because it provides the first head-to-head comparison of two different technologies that use transcranial magnetic stimulation (TMS) to treat depression,” said Markus Heilig, MD, PhD, a Professor of Psychiatry at Linköping University. “Subjects in the study demonstrated clearly higher response rates with Deep TMS, which stimulates more deeply and broadly into the brain, than with figure-8 TMS.”

Researchers at the Psychiatric Hospital “Sveti Ivan” in Croatia conducted this 228-patient randomized controlled study (NCT02917499) independent of industry support. The results appear in the July 2019 issue of the *Journal of Psychiatric Research*.

In this study, a total of 228 patients (the intent to treat population, or ITT) were randomized to either four weeks of dTMS (n = 72) or standard TMS (n = 75) in conjunction with standard pharmacotherapy, or to a control group treated with pharmacotherapy alone (n = 81). The primary endpoint of the study was the proportion of patients achieving remission, defined as a Hamilton Depression rating scale (HAM-D17) score of ≤ 7 after four weeks of therapy (20 treatments).

The remission rate for both the dTMS (H1-coil) group (59.7%) and the standard rTMS (figure 8-coil) group (42.7%) was significantly higher than with the control group (11.1%) in the ITT population ($p < .001$ and $p = .001$, respectively).

Other key findings from the study include:

- 1 The response rate (defined as $\geq 50\%$ decrease in HAM-D17) was significantly greater with dTMS plus pharmacotherapy (66.7%) than with standard rTMS plus pharmacotherapy (44.0%) ($p = .04$).
- 1 There was a trend toward improved remission rate with dTMS (59.7%) compared with standard rTMS (42.7%). Although this trend did not achieve statistical significance in the ITT population, it did achieve statistical significance in the subset of ITT patients who entered the study with moderate-to-severe MDD (HAM-D17 ≥ 17).
- 1 The HAM-D17 was lowered by 59% in the dTMS group, 41% in the standard rTMS group ($P = 0.048$), and 17% in the control group ($P < 0.001$ vs dTMS; $P = 0.003$ vs standard rTMS).
- 1 No difference was seen in safety or tolerability between dTMS and standard rTMS.

“We applaud the authors for completing this landmark study confirming the value of adding Deep TMS therapy as a standard treatment option for patients suffering from moderate to severe depression,” said Yaacov Michlin, CEO of BrainsWay.

About BrainsWay

BrainsWay is a commercial stage medical device company focused on the development and sale of non-invasive neuromodulation products using the Company’s proprietary Deep Transcranial Magnetic Stimulation (Deep TMS) technology for the treatment of major depressive disorder (MDD) and obsessive-compulsive disorder (OCD), for which BrainsWay received marketing authorization from the U.S. Food and Drug Administration (FDA) in 2013 (for MDD) and in August 2018 (for OCD). BrainsWay is currently conducting clinical trials of Deep TMS in other disorders, including smoking cessation and post-traumatic stress disorder, and is planning trials for opioid addiction, fatigue in multiple sclerosis (MS) and post-stroke rehabilitation.

Forward-Looking Statement

This press release contains forward-looking statements about the Company's expectations, beliefs and intentions, including with respect to the favorability and timing of the final results of the clinical study for inducing smoking cessation. 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. Moreover, the data in this press release results from a study conducted outside the US, was not reviewed by the US Food and Drug Administration and could be subject to different statistical analyses which could impact the results as expressed herein. 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 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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A photo accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/376424b6-2dba-421b-9055-800445d72bcd>