
**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 May 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
(+972-2) 582-4030**

(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
<u>99.1</u>	<u>BrainsWay Announces its Multicenter Smoking Cessation Study has reached target enrollment</u>

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).

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: May 22, 2019

/s/ Hadar Levy
Hadar Levy
Chief Financial Officer

BrainsWay Announces its Multicenter Smoking Cessation Study Has Reached Target Enrollment

More than 260 participants have been enrolled to the study

JERUSALEM, Israel and HACKENSACK, N.J., May 22, 2019 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) ("BrainsWay") today announced it reached target recruitment for its multicenter study assessing the safety and efficacy of its deep transcranial magnetic stimulation system (Deep TMS) intended for use as an aid in smoking cessation in patients suffering from chronic smoking addiction.

Yaacov Michlin, President and Chief Executive Officer of BrainsWay, said, "We believe there is a considerable unmet need for a safe and efficient solution for cigarette addiction. We look forward to receiving the results of the study, which, if successful, could lead to a novel, non-invasive, safe and effective approach for people willing to quit smoking."

BrainsWay's Deep TMS device is designed to effectively stimulate deep and broad areas of the brain. The BrainsWay H4-Coil used in this study is designed to non-invasively stimulate specific brain regions known to be associated with addiction, including the bilateral insula and prefrontal cortex, using brief magnetic fields at an amplitude similar to that used in magnetic resonance imaging (MRI) systems. The H4-coil is situated in a helmet, but is different than the Company's already FDA-cleared coils : H1 for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder (MDD) who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode and H7 as an adjunct therapy for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

About the Clinical Study:

Our smoking cessation clinical study is a randomized, double blind, multicenter study. The aim of the study is to evaluate the safety and efficacy of Deep TMS in reducing cigarette use in individuals suffering from chronic smoking addiction. The primary endpoint of the study is a comparison of the four-week continuous quit rate, as a measure of urinary-confirmed complete abstinence from smoking during a consecutive four week period, between active and sham treatment groups. One of the secondary endpoints is the number of cigarettes smoked per day. Participants receive three weeks of daily treatment using either Deep TMS using the H4 coil or a sham treatment, in each case followed by one session per week for three more weeks (a total of 18 treatments over six weeks). Prior to treatment stimulation onset, a smoking related provocation is presented to the subject in order to activate the pathological circuitry that is affected by the Deep TMS pulses. Participants are also required to participate in a four-month follow up status meeting, if they quit smoking at six weeks. BrainsWay has enrolled more than 260 individuals at 14 sites (including 12 in the U.S. and 2 in Israel), and expects to receive final results (including from the four-month follow-up) in the fourth quarter of 2019.

A preliminary study indicated that Deep TMS reduced cigarette consumption and nicotine dependence, especially when applied following the presentation of smoking cues. These results were published in the peer reviewed journal *Biological Psychiatry*. Dinur-Klein L., et al. *Biol. Psychiatry*. 2014 Nov 1;76(9):742-9.

To learn more about the study, please visit ClinicalTrials.gov.

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 psychiatric, neurological and addiction 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 Statements

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. 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.

Company Contact:

Hadar Levy
Chief Financial Officer
hadarl@Brainsway.com

Investor Contact:

Bob Yedid
LifeSci Advisors
646-597-6989
Bob@LifeSciAdvisors.com

Media Contact:

Sara Zelkovic
LifeSci Public Relations
646-876-4933
Sara@lifescipublicrelations.com