

0001171843-24-0064736-K Brainsway Ltd. 2024112020241120080019080019080019 0 0001171843-24-006473 6-K 2 20241120 20241120 20241120 Brainsway Ltd. 0001505065 3841 000000000 L3 6-K 34 001-35165 241478312 19 HARTUM STREET, BYNET BUILDING, 3RD FL Har HaHotzvim Jerusalem L3 91451 972 2 581-3140 19 HARTUM STREET, BYNET BUILDING, 3RD FL Har HaHotzvim Jerusalem L3 91451 6-K 1 f6k_111924.htm FORM 6-K A 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 2024 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 [X] A A A A 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 July 22, 2024 (Registration No. 333-280934). EXHIBIT INDEX Exhibit Title A A 99.1 BrainsWay Reports Promising Feasibility Data Showing Pain Reduction with Deep TMS Therapy 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. A A A A BRAINSWAY LTD. A A A A (Registrant) A A A A Date: November 20, 2024 A A A A /s/ Hadar Levy A A A A Hadar Levy A A Chief Executive Officer A A A A EX-99.1 2 exh_991.htm PRESS RELEASE Edgar Filing EXHIBIT 99.1 BrainsWay Reports Promising Feasibility Data Showing Pain Reduction with Deep TMS Therapy Reductions also seen in comorbid anxiety and depression symptoms BURLINGTON, Mass. and JERUSALEM, Israel, Nov. 20, 2024 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) (the "Company"), a global leader in advanced noninvasive neurostimulation treatments for mental health disorders, today announced the publication of positive feasibility clinical data evaluating the analgesic effects of deep transcranial magnetic stimulation (Deep TMS[®]) in patients with peripheral neuropathic pain. The results were published in the Neuromodulation journal, in a peer-reviewed article entitled, "H-Coil Repetitive Transcranial Magnetic Stimulation Relieves Pain and Symptoms of Anxiety and Depression in Patients with Chronic Peripheral Neuropathic Pain: A Randomized Sham-Controlled Crossover Study." The double-blind, randomized crossover trial included seventeen (17) patients with chronic neuropathic pain. Participants were assigned to either an active Deep TMS or sham treatment arm for a five-day period, followed by a nine-week washout, before crossing over to the other arm. The study's primary outcome measure was a comparison between the patterns of the active and sham groups' self-reported changes in pain levels from baseline. Secondary outcomes included changes in pain ratings at specific time points in the two arms, as well as changes in comorbid symptoms experienced by the patients, including, for example, anxiety and depression. Results showed that Active deep-TMS therapy significantly reduced "usual pain intensity" in patients with chronic peripheral neuropathic pain compared to sham treatment and improved symptoms of anxiety and depression in the same patient population. "We are excited to announce the results from this double-blind crossover study of Deep TMS therapy revealing that five active Deep TMS sessions induced significantly stronger analgesic effects compared with sham stimulation over the course of the treatment, as well as statistically significant reductions in anxiety and depression symptoms," said Hadar Levy, BrainsWay's Chief Executive Officer. "The results of this study, which we hope to further explore with additional research, are the most recent dataset in a growing portfolio of clinical evidence on the potential efficacy of Deep TMS in treating multiple brain-related indications. BrainsWay Deep TMS is not currently cleared by the FDA for the safe or effective treatment of neuropathic pain. Additional outcomes from research conducted on these and other neuropathic pain patients were recently published, lending additional support to the findings of this study on the potential benefits of Deep TMS. 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. Contacts: BrainsWay: Ido Marom Chief Financial Officer Ido.Marom@BrainsWay.com Investors: Brian Ritchie LifeSci Advisors LLC britchie@lifesciadvisors.com