BrainsWay Targets Expansion of its Total Addressable Market through a Strategic Investment in Neuromodulation Systems Developer, Neurolief Ltd.

August 21, 2025

This investment marks BrainsWay's entrance into the market for mental health therapies that can be administered outside of a clinic, including at home

Neurolief's breakthrough Proliv ™Rx device is pending Premarket Approval from the U.S. FDA, and if granted, will become the first FDA-cleared medical device for MDD treatment that can be delivered outside of the clinic

BURLINGTON, Mass. and JERUSALEM, Aug. 21, 2025 (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 it has closed an initial strategic investment by means of a $5 million convertible loan to, along with an option to acquire, Neurolief Ltd. ("Neurolief"), developer of the world's first wearable, non-invasive, multi-channel brain neuromodulation platform that is designed for use at home. Neurolief's technology has demonstrated positive clinical outcomes and includes a proprietary therapy for treatment-resistant major depressive disorder (MDD) and migraine. The Agreement also includes additional possible milestone-based funding.

"We are very excited with this strategic investment in Neurolief. Upon an FDA approval, we believe this technology will significantly expand our addressable market, enabling care for patients who cannot easily access clinics and empowering medical professionals to extend treatment beyond traditional settings. This aligns with our strategic goal of accelerating access to and awareness of innovative mental health treatments, especially offerings that we believe are complementary to mental health professionals using our Deep TMS therapy," said Hadar Levy, BrainsWay's Chief Executive Officer. "The BrainsWay team has rapidly expanded sales of the Deep TMS™ system, supported by scaling of our commercial platform and customer network. We are excited by the opportunity to leverage our platform and explore potential synergies between our two companies, as Neurolief brings its at-home neuromodulation systems to the market through mental health professionals."

Neurolief is a pioneering neuromodulation company dedicated to developing innovative solutions for mental health and neurological disorders. Neurolief's Relivion®MG therapy is currently approved in the U.S., Europe and Japan for the treatment of migraine, and it is awaiting Premarket Approval from the U.S. FDA for its Proliv™Rx therapy addressing Major Depressive Disorder (MDD) in treatment resistant patients. If approved, Neurolief will be the first medical device company to offer an FDA-cleared MDD treatment that can be delivered outside of the clinic.

MDD is a leading cause of disability globally, with millions of people affected. The situation is especially dire for those patients who fail to respond to traditional treatments, facing prolonged suffering, higher healthcare costs, and a heightened risk of comorbid conditions such as substance abuse and suicide. Despite the global impact of MDD, there is a critical gap in accessible, effective therapies, particularly for these patients. Proliv™Rx is designed to bridge this gap by offering a revolutionary, non-invasive brain neuromodulation therapy that can be administered at a mental health clinic or a patient's home.

"This strategic investment by BrainsWay is a strong validation of our science, our team, and our vision," stated Scott Drees, Neurolief's Chief Executive Officer. "This partnership enhances our ability to reach the patients who need our therapy most. BrainsWay's market presence, deep expertise, and established commercial platform can complement our innovation and momentum. Together, we aim to reshape the treatment landscape for depression and expand access to evidence-based, effective care."

Beyond the initial $5 million convertible loan, the agreement provides for potential additional milestone-based funding to Neurolief, including a second tranche of up to a $6 million convertible loan upon FDA approval of Neurolief's Proliv Rx system for MDD treatment, and a third tranche consisting of up to a $5 million equity investment upon Neurolief achieving an agreed-upon revenue milestone. BrainsWay has also been granted a "call option" to acquire all outstanding equity interests in Neurolief during clearly defined exercise windows, at a price based on the greater of a specified enterprise value or a revenue multiple, with the values varying depending on timing of exercise.

Through this multi-phased transaction, BrainsWay aims to expand its long-term total addressable market.

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.

About Neurolief
Neurolief is a pioneering neuromodulation company committed to developing breakthrough therapies for mental health and neurological disorders. The company has developed the world's first wearable, non-invasive, multi-channel brain neuromodulation system, that is designed for use at home, engineered to simultaneously stimulate key neural pathways in the head in order to modulate brain regions involved in regulation of mood and pain. Neurolief's technology is currently FDA-cleared and CE-marked for the treatment of migraine, and the company is actively seeking regulatory approvals for Proliv™Rx, its flagship product for the treatment of Major Depressive Disorder. If granted, Neurolief will be the first medical device

company to offer an FDA-approved MDD treatment that can be delivered outside of the clinic. Learn more at: www.neurolief.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.

Contacts:

BrainsWay:
Ido Marom
Chief Financial Officer
Ido.Marom@BrainsWay.com

Investors:
Brian Ritchie
LifeSci Advisors
britchie@lifesciadvisors.com