Neuronetics Files Federal Lawsuit Against Brainsway for Misleading Psychiatrists and Patients

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MALVERN, Pa., May 11, 2022 (GLOBE NEWSWIRE) -- Neuronetics, Inc. (NASDAQ: STIM), a commercial stage medical technology company focused on designing, developing, and marketing products that improve the quality of life for patients who suffer from neurohealth disorders, today announced the filing of a federal lawsuit in the District of Delaware against Brainsway Ltd. and Brainsway USA Inc. for unfair competition under the Lanham Act and state law.

In the litigation, the Company asserts that, for commercial gain, Brainsway egregiously misrepresented efficacy data for the treatment of anxious depression with NeuroStar Advanced Therapy for Mental Health. Specifically, the Company argues that Brainsway manipulated NeuroStar's effect size by presenting an endpoint representing an incomplete course of therapy. Brainsway then compared these results to inappropriately aggregated data from three disparate studies using Brainsway devices with effect sizes derived from full courses of therapy. The Company alleges Brainsway's manipulated presentation of these results misled clinicians and patients about NeuroStar's efficacy. In the litigation, Neuronetics is seeking injunctive relief as well as monetary damages.

"Neuronetics views strong, high-quality data as the cornerstone of driving TMS as a mainstream treatment for mental health disorders. We have made a significant investment to develop a robust body of clinical evidence and believe that we have the best data in the industry," said Keith J. Sullivan, President and Chief Executive Officer. He added, "We will vigorously defend against the mischaracterization of the efficacy of NeuroStar TMS, the damage it causes to our business and the confusion it causes medical professionals and their patients. We look forward to pursuing this case through the federal courts and to begin to correct this grievous mischaracterization of our efficacy data beginning later this week during the Clinical TMS Society annual meeting in Chicago."

About Neuronetics
Neuronetics, Inc. believes that mental health is as important as physical health. As a global leader in neuroscience and the largest TMS company in the industry, Neuronetics is redefining patient and physician expectations by designing and developing products that improve the quality of life for people suffering from psychiatric disorders. An FDA-cleared, non-drug, non-invasive treatment for people with depression and obsessive-compulsive disorder, Neuronetics' NeuroStar ® Advanced Therapy system is today's leading transcranial magnetic stimulation (TMS) treatment for major depressive disorder with over 4.3 million treatments delivered. NeuroStar is widely researched and backed by the largest clinical data set of any TMS system for depression, including the world's largest depression Outcomes Registry. Neuronetics is committed to transforming lives by offering an exceptional treatment that produces extraordinary results. For safety information and indications for use, visit NeuroStar.com.

"Safe harbor" statement under the Private Securities Litigation Reform Act of 1995:
Statements in the press release regarding Neuronetics, Inc. (the "Company") that are not historical facts constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may be identified by terms such as "outlook," "potential," "believe," "expect," "plan," "anticipate," "predict," "may," "will," "could," "would" and "should" as well as the negative of these terms and similar expressions. These statements are subject to significant risks and uncertainties and actual results could differ materially from those projected. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this release. These risks and uncertainties include, without limitation, risks and uncertainties related to: the impact of COVID-19 on general political and economic conditions, including as a result of efforts by governmental authorities to mitigate COVID-19, such as travel bans, shelter in place orders and third-party business closures and the related impact on resource allocations, manufacturing and supply chains and patient access to commercial products; the Company's ability to execute its business continuity, operational and budget plans in light of the COVID-19 outbreak; the Company's ability to achieve or sustain profitable operations due to its history of losses; the Company's reliance on the sale and usage of its NeuroStar Advanced Therapy System to generate revenues; the scale and efficacy of the Company's salesforce; availability of coverage and reimbursement from third-party payors for treatments using the Company's products; physician and patient demand for treatments using the Company's products; developments in respect of competing technologies and therapies for the indications that the Company's products treat; product defects; the Company's ability to obtain and maintain intellectual property protection for its technology; developments in clinical trials or regulatory review of NeuroStar Advanced Therapy System for additional indications; and developments in regulation in the United States and other applicable jurisdictions. For a discussion of these and other related risks, please refer to the Company's recent SEC filings which are available on the SEC's website at www.sec.gov. These forward-looking statements are based on the Company's expectations and assumptions as of the date of this press release. Except as required by law, the Company undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information, future events or changes in the Company's expectations.

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