NeuroMetrix Provides Quell® Technology Commercial Strategy and Pipeline Update

March 11, 2020

WOBURN, Mass., March 11, 2020 (GLOBE NEWSWIRE) -- NeuroMetrix, Inc. (Nasdaq: NURO) today provided an update on its Quell technology commercial strategy and pipeline.

An estimated 100 million US adults have chronic pain. People with chronic pain may also have low quality sleep, anxiety, depression, and poor overall health. The annual economic cost is $600 billion in the US. There is a critical need for non-pharmacological pain relief options. Transcutaneous electrical nerve stimulation (TENS) is non-invasive stimulation of sensory nerves that results in pain relief. TENS has been used for decades in the treatment of chronic pain.

Quell technology is an advanced TENS platform designed for the symptomatic relief and management of chronic pain. It is enabled by a proprietary neurostimulation microchip that provides precise, high-power nerve stimulation in a small wearable device. Quell technology includes sensors and algorithms to automatically regulate nerve stimulation and track objective health metrics such as sleep and gait. It supports Bluetooth low energy (BLE) to communicate with mobile applications that enhance functionality and connect to the Quell Health Cloud®. To our knowledge, this cloud database is the world's largest chronic pain and TENS-outcomes repository.

The Company plans to offer consumer and prescription versions of Quell technology.

Consumer Health Business

Americans spend $20B annually on over-the-counter (OTC) analgesics and alternative pain treatments. Quell technology is marketed OTC as Quell 2.0, which has FDA clearance and is indicated for symptomatic relief and management of chronic pain. Over the past year, the Company has succeeded in making its consumer health business profitable. This necessitated changes in advertising and distribution, as well as headcount reductions. Quell 2.0 is now only available on QuellRelief.com and Amazon.com. Promotional spending has been reduced to achieve an attractive customer acquisition cost. The objective going forward is to grow this business while maintaining profitability. Starting in Q2 2020, Quell marketing will focus on lower extremity chronic pain, a common issue for our customers. The Company will continue to innovate, with new Quell 2.0 features planned for H1 2021.

The Company is collaborating with GSK Consumer Healthcare through a strategic agreement that began in 2018. It is supporting GSK in their launch of Quell technology outside the US. It is also partnering with GSK on clinical research that resulted in several scientific reports at pain medicine conferences in 2019, with additional presentations expected in 2020. GSK is partially funding Quell R&D.

Prescription Business

NeuroMetrix believes that the advanced technological features of the Quell platform are ideally suited to support physician-directed management of chronic pain. In contrast to the advancements with Quell, there has been limited innovation in the prescription TENS area. The Company currently has two investigational clinical targets in its prescription Quell pipeline: fibromyalgia and chemotherapy-induced peripheral neuropathy (CIPN). These are both billion-dollar markets with few effective treatments and significant unmet needs. Fibromyalgia is estimated to affect about 10M people in the US. CIPN affects about two-thirds of the approximately 650,000 patients that receive chemotherapy annually.

- A double-blind, sham-controlled randomized controlled trial (RCT) of Quell efficacy in patients with primary fibromyalgia pain is currently ongoing and should read-out in H2 2020 (NCT03714425). If the trial is positive, based on its results and the results of other studies, the Company plans to submit a 510(k) for a prescription Quell indicated for treatment of fibromyalgia pain in H2 2020, with a goal of a commercial launch in Q4 2021.

- A RCT of Quell efficacy in patients with CIPN is expected to start this year, which will build on encouraging pilot data published last year (see Gewandter et al. 2019). If the trial is positive, we anticipate submitting a 510(k) in H1 2022 with the goal of a commercial launch in late 2022.

The commercialization strategy for the prescription products is expected to include direct sales and distributors. The Company also plans to explore strategic partnerships. These products will likely launch as self-pay, but with the goal of obtaining third-party reimbursement with additional clinical and real-world outcomes data.

Note: The use of Quell for fibromyalgia and CIPN is investigational only, and safety and effectiveness for these purposes has not been reviewed by the United States Food and Drug Administration.

"Quell technology has helped thousands of people with chronic pain, and we believe there is great potential to help others with this advanced, market-leading platform," said Shai N. Gozani, M.D., Ph.D., President and CEO of NeuroMetrix. "There is a critical need for non-pharmacological pain relief options given the large number of people suffering from chronic pain and the challenges created by the opioid crisis. We look forward to leading this effort by seeking to offer both innovative consumer products and sophisticated physician-prescribed solutions."

About NeuroMetrix

NeuroMetrix is a leading developer and manufacturer of diagnostic and therapeutic neurostimulation-based medical devices that are used throughout the world. The Company has three FDA cleared commercial products. DPNCheck® is a point-of-care test that is used to evaluate peripheral neuropathies. ADVANCE ™ is a point-of-care device that provides nerve conduction studies as an aid in diagnosing and evaluating patients suspected

of having focal or systemic neuropathies. Quell® 2.0 is a wearable, mobile app enabled, neurostimulation device indicated for symptomatic relief and management of chronic pain and is available OTC. The Company maintains an active, industry-leading R&D program. For more information, visit NeuroMetrix.com.

NeuroMetrix, Inc.
Thomas T. Higgins, 781-314-2761
SVP and Chief Financial Officer
neurometrix.ir@neurometrix.com

Source: NeuroMetrix, Inc.

Source: NeuroMetrix, Inc.