NeurAxis Receives New FDA 510(K) Clearance for IB-Stim, Expanding its Addressable Market

Clearance expands indication for use from 11-18 year olds to 8-21 year olds; and from 3 devices, not to exceed 4 weeks, to 1 device per week for 4 weeks

CARMEL, Ind., Nov. 04, 2024 — NeurAxis, Inc. (“NeurAxis,” or the “Company”) (NYSE American: NRXS), a medical technology company commercializing neuromodulation therapies addressing chronic and debilitating conditions in children and adults, today announced that it received a new 510(k) clearance for IB-Stim™ Nonimplanted Nerve Stimulator for functional abdominal pain relief. The new indication expands IB-Stim’s addressable market and overall devices per patient. NeurAxis leveraged its robust published data to receive this new indication.

“We are excited to receive this new 510(k) clearance for IB-Stim, which expands the IB-Stim addressable market by roughly 75%,” said Brian Carrico, President and Chief Executive Officer of NeurAxis. “Furthermore, we expect devices per patient to increase, as this new FDA clearance states on label use of four devices per patient. All of this has been achieved due to the strong body of published research, which has resulted in the increased acceptance of our PENFS technology. This includes ongoing expansion of payer coverage, as well as the recent establishment of a new CPT Category I code by the American Medical Association, effective January 2026. Our recent achievements in our commercialization strategy have set the stage for increased revenue and margin growth in the upcoming quarters.” Mr. Carrico concluded.

NeurAxis’ PENFS technology, IB-Stim, is FDA-cleared for functional abdominal pain associated with irritable bowel syndrome (IBS) in adolescents 8-21 years old. IB-Stim is a non-surgical device that sends gentle electrical impulses into cranial nerve bundles in the ear. There are currently no FDA-approved drug therapies for children with abdominal pain-related disorders of the gut-brain interaction. Pharmacologic treatments that use drugs off-label can often have serious side effects, and most lack scientific evidence of efficacy.

About NeurAxis, Inc.

NeurAxis, Inc., is a medical technology company focused on neuromodulation therapies to address chronic and debilitating conditions in children and adults. NeurAxis is dedicated to advancing science and leveraging evidence-based medicine to drive the adoption of its IB-Stim™ therapy, which is its proprietary Percutaneous Electrical Nerve Field Stimulation (PENFS) technology, by the medical, scientific, and patient communities. IB-Stim™ is FDA-cleared for functional abdominal pain associated with irritable bowel syndrome (IBS) in adolescents 8-21 years old. Additional clinical trials of PENFS in multiple pediatric and adult conditions with large unmet healthcare needs are underway. For more information, please visit http://neuraxis.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are forward-looking statements. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. There are a number of important factors that could cause actual results, developments, business decisions or other events to differ materially from those contemplated by the forward-looking statements in this press release. These factors include, among other things, the conditions in the U.S. and global economy, the trading price and volatility of the Company's stock, public health issues or other events, the Company's compliance with applicable laws, the results of the Company's clinical trials and perceptions thereof, the results of submissions to the FDA, and factors described in the Risk Factors section of NeurAxis's public filings with the Securities and Exchange Commission (SEC). Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements speak only as of the date of this press release and, except to the extent required by applicable law, the Company undertakes no obligation to update or revise these statements, whether as a result of any new information, future events and developments or otherwise.

For contraindications, precaution, warnings, and IFU, please see:

https://ibstim.com/important-information/.

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