NeurAxis Announces New Submission to the FDA for the Expansion of its IB-Stim Label; Provides Compliance with NYSE Guidelines on Audit Disclosure

CARMEL, Ind., June 07, 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 a submission to the FDA for expansion of its IB-Stim label. The new submission is significant as it would allow access to a larger patient population beyond 11-18 years of age and allow for marketing of 4 devices per prescription.

A systematic literature review demonstrated that at least 9 published studies that used the IB-Stim technology in children with chronic abdominal pain used a total of four devices over 4 consecutive weeks. The systematic literature review also demonstrated that many patients as young as 8 years and up to 21 years, which is outside of the current indication age range, have been successfully treated with IB-Stim. No study reported serious adverse events. These data were submitted to the FDA through a 510k application to expand the current label.

“We are excited about our new submission to the FDA to expand the label for IB-Stim which would include ages 8-21, and 4 devices over 4 weeks. IB-Stim is currently indicated for ages 11-18 years of age, using 3 devices not to exceed 4. This potential label expansion could impact many children who would otherwise fall into an “off-label” category and allow for them to receive the proper care that is supported by the scientific literature. We are cautiously optimistic that the FDA will grant the request for a label expansion,” said Brian Carrico, President and Chief Executive Officer of NeurAxis. “We continue to make progress on our robust pipeline of indications, as we have positioned NeurAxis to become a leader in the treatment of disorders of the gut-brain interactions,” Mr. Carrico concluded.

Compliance with NYSE Guidelines on Audit Opinion

As previously disclosed in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, which was filed on April 16, 2024 with the Securities and Exchange Commission, the audited financial statements contained an unqualified audit opinion from the Company’s independent registered public accounting firm that included an explanatory paragraph related to the Company’s ability to continue as a going concern. This announcement is being made solely to comply with Section 610(b) of the NYSE American LLC Company Guide, which requires public announcement of the receipt of an audit opinion containing a going concern paragraph. This announcement does not represent any change or amendment to the Company’s audited financial statements or to its Annual Report on Form 10-K for the year ended December 31, 2023.

Management continues to improve the Company's financial position to achieve its objectives. In addition to securing $3.0 million in committed convertible note financing from affiliates of Inspire Health Alliance on November 8, 2023, the Company also closed an additional $3.1 million in committed financing from various investors, including affiliates of Inspire Health Alliance, with identical terms in the first quarter of 2024, with the financing scheduled to be paid in monthly amounts through the first quarter of 2025. The Company further strengthened its balance sheet and liquidity position on May 21, 2024 as it closed on an additional $3.0 million in convertible notes with a healthcare focused fund managed by institutional accredited investors.

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 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 11-18 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.

For Important Information about IB-Stim, please visit. http://ibstim.com/important-information/

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, the results of the shareholder vote to enable the issuance of the Preferred Stock, 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.

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