



Bioventus Receives 510(k) Clearance for StimRouter Pain Management Device

March 1, 2022

Industry Leading Peripheral Nerve Stimulator Upgraded to Improve Patient User Experience with Control of their Unique Chronic Pain Condition, Longer Battery Life

DURHAM, N.C., March 01, 2022 (GLOBE NEWSWIRE) -- [Bioventus Inc.](#) (Nasdaq: BVS) ("Bioventus" or the "Company"), a global leader in innovations for active healing, announced that the US Food and Drug Administration (FDA) has awarded 510(k) clearance to the next generation StimRouter® Neuromodulation System for the treatment of chronic pain of peripheral nerve origin, excluding craniofacial pain. StimRouter is a minimally invasive neuromodulation medical device consisting of a thin, implanted lead with conductive electrode, external electric field conductor (E-EFC), and StimRouter Plus Mobile Application. Electrical signals are transmitted transcutaneously from the E-EFC and conducted to the target nerve by the implanted lead.

Thousands of patients have successfully used the StimRouter Neuromodulation system, and the newly cleared StimRouter system provides the same clinically proven, long-term pain relief while significantly improving the patient's control and user experience. The next generation system includes a smartphone application and a new state of the art external electric field conductor, allowing patients greater freedom to return to active lives.

"The impact of chronic, debilitating pain is more than just managing the impacted anatomy, it is also about helping return the individual back to a life pre-pain," said John Nosenzo, Chief Commercial Officer, Bioventus. "The emotional and psychological damage from living with pain is horrific and we are pleased to support all the physicians who are committed to improving patient lives, in particular with alternatives to opioids when possible. The next generation StimRouter will support patients and physicians to meet their pain treatment goals as the previous generation of peripheral nerve stimulation has done for many years."

Every day, individuals attempt to live their lives while suffering from debilitating pain that prevents each from working, enjoying their personal time and maintaining relationships with family and friends. Respecting the long-term and potentially negative consequences of opioids, patients have successfully undergone the minimally invasive StimRouter implant procedure and are now living a productive and comfortable life. Peripheral nerve stimulation (PNS) is the future of pain management. With over [50 million Americans](#) living with daily chronic pain, PNS technology provides a focal, non-opioid treatment option and adoption is growing rapidly amongst clinicians and patients due to PNS' proven effectiveness at reducing chronic pain.

The upgraded StimRouter technology and associated mobile application will help improve the experiences of patients who find pain relief through this innovative technology.

About Bioventus

Bioventus delivers clinically proven, cost-effective products that help people heal quickly and safely. Its mission is to make a difference by helping patients resume and enjoy active lives. The Innovations for Active Healing from Bioventus include offerings for pain treatment, restorative therapies and surgical solutions. Built on a commitment to high quality standards, evidence-based medicine and strong ethical behavior, Bioventus is a trusted partner for physicians worldwide. For more information, visit www.bioventus.com, and follow the Company on [LinkedIn](#) and [Twitter](#). Bioventus and the Bioventus logo are registered trademarks of Bioventus LLC. Bioventus and the Bioventus logo are registered trademarks of Bioventus LLC. StimRouter, Bioness, are trademarks of Bioness Inc.

Individual results may vary. Patients are advised to consult with a qualified healthcare professional to determine if this product is right for them. Important Safety Information and Risks: For Indications for Use, Warnings, Precautions, and other safety information please refer to www.stimrouter.com/safety-information/.

Forward-Looking Statements

This press release contains 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 contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements concerning Bioventus's future growth, operating margins, market leadership and strategy. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results to differ materially from those contemplated in this press release include, but are not limited to, the adverse impacts on our business as a result of the COVID-19 pandemic; our dependence on a limited number of products; our ability to develop, acquire and commercialize new products, line extensions or expanded indications; the continued and future acceptance of our existing portfolio of products and any new products, line extensions or expanded indications by physicians, patients, third-party payers and others in the medical community; our ability to differentiate the hyaluronic acid ("HA") viscosupplementation therapies we own or distribute from alternative therapies for the treatment of osteoarthritis; the proposed down-classification of non-invasive bone growth stimulators, including our Exogen system, by the U.S. Food and Drug Administration ("FDA"); our ability to achieve and maintain adequate levels of coverage and/or reimbursement for our products, the procedures using our products, or any future products we may seek to commercialize; our ability to recognize the benefits of our investments; our ability to complete acquisitions or successfully integrate new businesses, products or technologies in a cost-effective and non-disruptive manner; competition against other companies; the negative impact on our ability to market our HA products due to the reclassification of HA products from medical devices to drugs in the United States by the FDA; our ability to attract, retain and motivate our senior management and qualified personnel; our ability to continue to research, develop and

manufacture our products if our facilities are damaged or become inoperable; failure to comply with the extensive government regulations related to our products and operations; enforcement actions if we engage in improper claims submission practices or in improper marketing or promotion of our products; the FDA regulatory process and our ability to obtain and maintain required regulatory clearances and approvals; failure to comply with the government regulations that apply to our human cells, tissues and cellular or tissue-based products; the clinical studies of any of our future products that do not produce results necessary to support regulatory clearance or approval in the United States or elsewhere; and the other risks identified in the Risk Factors section of the Company's public filings with the Securities and Exchange Commission ("SEC"), including Bioventus' Annual Report on Form 10-K for the period ended December 31, 2020, as updated by the Company's Quarterly Report on Form 10-Q for the quarter ended October 2, 2021, and as such factors may be further updated from time to time in Bioventus' other filings with the SEC, which are accessible on the SEC's website at www.sec.gov and the Investor Relations page of Bioventus' website at ir.bioventus.com. Except to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection, or forward-looking statement. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in the Company's business.

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