



NEWS RELEASE

# Inspire Medical Systems, Inc. Announces FDA Approval of the Inspire V System

8/2/2024

MINNEAPOLIS, Aug. 02, 2024 (GLOBE NEWSWIRE) -- Inspire Medical Systems, Inc. (NYSE: INSP) (Inspire), a medical technology company focused on the development and commercialization of innovative, minimally invasive solutions for patients with obstructive sleep apnea (OSA), today announced the FDA approval of the Inspire V therapy system which includes the next generation neurostimulator and the associated Bluetooth® patient remote and physician programmer.

“We are thrilled to announce the FDA approval of our next generation Inspire neurostimulation system,” said Tim Herbert, Chairman and Chief Executive Officer of Inspire Medical Systems. “The FDA approval marks a key milestone for the future of Inspire therapy and reinforces the many years of hard work by our team members.”

The company’s focus remains on operational readiness, which includes product manufacturing and establishing inventory levels to support a full commercial launch in the United States. The company continues to target a soft launch in late 2024 and a full launch in 2025.

## About Inspire Medical Systems

Inspire is a medical technology company focused on the development and commercialization of innovative, minimally invasive solutions for patients with obstructive sleep apnea. Inspire’s proprietary Inspire therapy is the first and only FDA, EU MDR, and PDMA-approved neurostimulation technology that provides a safe and effective treatment for moderate to severe obstructive sleep apnea.

For additional information about Inspire, please visit [www.inspiresleep.com](http://www.inspiresleep.com).

## Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts are forward-looking statements, including, without limitation, statements regarding our planned timing to launch our Inspire V therapy system. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “future,” “outlook,” “guidance,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential,” “continue,” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

These forward-looking statements are based on management’s current expectations and involve known and unknown risks and uncertainties that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, estimates regarding the annual total addressable market for our Inspire therapy in the U.S. and our market opportunity outside the U.S.; future results of operations, financial position, research and development costs, capital requirements and our needs for additional financing; commercial success and market acceptance of our Inspire therapy; the impact of macroeconomic trends; general and international economic, political, and other risks, including currency, inflation, stock market fluctuations and the uncertain economic environment; our ability to achieve and maintain adequate levels of coverage or reimbursement for our Inspire system or any future products we may seek to commercialize; competitive companies and technologies in our industry; our ability to enhance our Inspire system, expand our indications and develop and commercialize additional products; our business model and strategic plans for our products, technologies and business, including our implementation thereof; our ability to accurately forecast customer demand for our Inspire system and manage our inventory; our dependence on third-party suppliers, contract manufacturers and shipping carriers; consolidation in the healthcare industry; our ability to expand, manage and maintain our direct sales and marketing organization, and to market and sell our Inspire system in markets outside of the U.S.; risks associated with international operations; our ability to manage our growth; our ability to increase the number of active medical centers implanting Inspire therapy; our ability to hire and retain our senior management and other highly qualified personnel; risk of product liability claims; risks related to information technology and cybersecurity; risk of damage to or interruptions at our facilities; our ability to commercialize or obtain regulatory approvals for our Inspire therapy and system, including our next generation Inspire therapy system, or the effect of delays in commercializing or obtaining regulatory approvals; FDA or other U.S. or foreign regulatory actions affecting us or the healthcare industry generally, including healthcare reform measures in the U.S. and international markets; and the timing or likelihood of regulatory filings and approvals. Other important factors that could cause actual results, performance or achievements to differ materially from those contemplated

in this press release can be found under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as updated in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 filed with the SEC, and as such factors may be updated from time to time in our other filings with the SEC, which are accessible on the SEC's website at [www.sec.gov](http://www.sec.gov) and the Investors page of our website at [www.inspiresleep.com](http://www.inspiresleep.com). These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, unless required by applicable law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Thus, one should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. These forward-looking statements should not be relied upon as representing our views as of any date after the date of this press release.

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