NEWS RELEASE

# Axonics Receives Regulatory Approval for Fourth-Generation Rechargeable SNM System in Australia

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IRVINE, Calif.--(BUSINESS WIRE)-- Axonics, Inc. (Nasdaq: AXNX) today announced that it has received regulatory approval from the Therapeutic Goods Administration (TGA) for marketing the Axonics R20 ® rechargeable sacral neuromodulation (SNM) system in Australia to treat adults with overactive bladder and fecal incontinence.

The R20 neurostimulator is labeled for a functional life in the body of at least 20 years and reduces how frequently a patient needs to recharge their implanted device to once every 6 to 10 months for only one hour. The implant utilizes the same small 5cc form factor as the previous generation (Axonics R15 ® ) and is paired with the same tined lead and intuitive, easy to use patient remote control. The R20 also provides physicians and their patients with enhanced programming capabilities and expanded MRI labeling.

“Approval of the Axonics R20 is welcome news for Australians with bladder and bowel dysfunction,” said Dr. Janelle Brennan, a urologist at St. John of God Bendigo Hospital. “I am excited to offer my patients a therapy that provides durable symptom relief with a small rechargeable neurostimulator that can last over 20 years in the body.”

Axonics commenced SNM commercial activities in Australia in March 2023. In May 2024, Axonics received regulatory approval from the TGA to market its F15 ® recharge-free SNM system. In Australia, Axonics also markets Bulkamid ® , the company’s unique hydrogel indicated for female stress urinary incontinence.

“We are delighted to receive regulatory approval for our latest rechargeable SNM system in Australia,” said Raymond W. Cohen, chief executive officer. “Our mission-driven team remains committed to innovating, supporting our dedicated physician customers and their patients, and raising awareness of our best-in-class incontinence therapies.”

Axonics expects to commence sales of the R20 to Australian customers in November.

## About Axonics

Axonics is a global medical technology company that is developing and commercializing novel products for adults with bladder and bowel dysfunction. Axonics recently ranked No. 2 on the **2023** Financial Times ranking of the fastest growing companies in the Americas after being ranked No. 1 in **2022** .

Axonics ® sacral neuromodulation systems provide adults with overactive bladder and/or fecal incontinence with long-lived, easy to use, safe, clinically effective therapy. In addition, the company's best-in-class urethral bulking hydrogel, Bulkamid, provides safe and durable symptom relief to women with stress urinary incontinence. Moderate to severe incontinence affects tens of millions of adults globally. For more information, visit **www.axonics.com** .

## Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words like "may," "will," "likely," "should," "expect," "anticipate," "future," "plan," "believe," "intend," "goal," "seek," "endeavor," "estimate," "project," "continue," and variations of such words and similar expressions. These forward-looking statements are not guarantees of future performance and involve risks, assumptions, and uncertainties, including, but not limited to, risks related to: Axonics' ability to consummate the transactions contemplated by the Agreement and Plan of Merger, dated January 8, 2024 (the "Merger Agreement"), by and among Axonics, Boston Scientific Corporation ("Boston Scientific"), and Sadie Merger Sub, Inc., a wholly owned subsidiary of Boston Scientific ("Merger Sub"), providing for the merger of Merger Sub with and into Axonics with Axonics continuing as the surviving company and a wholly owned subsidiary of Boston Scientific (the "Merger"), in a timely manner or at all; the risk that the Merger Agreement may be terminated in circumstances requiring the payment by Axonics of a termination fee; the satisfaction (or waiver) of the conditions to the closing of the Merger; potential delays in consummating the Merger; the occurrence of any event, change or other circumstance or condition that could give rise to termination of the Merger Agreement; Axonics' ability to timely and successfully realize the anticipated benefits of the Merger; the ability to successfully integrate the businesses of Axonics and Boston Scientific; the effect of the announcement or pendency of the Merger on Axonics' current plans, business relationships, operating results and business generally; the effect of limitations placed on Axonics' business under the Merger Agreement; significant transaction costs and unknown liabilities; litigation or regulatory actions related to the Merger Agreement or Merger; FDA or other U.S. or foreign regulatory or legal actions or changes affecting Axonics or Axonics' industry; the results of any ongoing or future legal proceedings, including the litigation with Medtronic, Inc.,

Medtronic Puerto Rico Operations Co., Medtronic Logistics LLC and Medtronic USA, Inc. (the "Medtronic Litigation"); any termination or loss of intellectual property rights, including as a result of the Medtronic Litigation; introductions and announcements of new technologies by Axonics, any commercialization partners or Axonics' competitors, and the timing of these introductions and announcements; changes in macroeconomic and market conditions and volatility, including the risk of recession, inflation, supply chain constraints or disruptions and rising interest rates; and economic and market conditions in general and in the medical technology industry specifically, including the size and growth, if any, of Axonics' markets, and risks related to other factors described under "Risk Factors" in other reports and statements filed with the U.S. Securities and Exchange Commission ("SEC"), including Axonics' most recent Annual Report on Form 10-K, which is available on the investor relations section of Axonics' website at **www.axonics.com** and on the SEC's website at **www.sec.gov** . Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those indicated or anticipated by these forward-looking statements. Therefore, you should not rely on any of these forward-looking statements.

The forward-looking statements included in this press release are made only as of the date of this press release, and except as otherwise required by federal securities law, Axonics does not assume any obligation nor does it intend to publicly update or revise any forward-looking statements to reflect new information, changed circumstances or unanticipated events.

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Source: Axonics, Inc.