



Axonics Receives CE Mark Approval for Fourth-Generation Rechargeable Sacral Neuromodulation System

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IRVINE, Calif.--(BUSINESS WIRE)--Mar. 14, 2024-- Axonics, Inc. (Nasdaq: AXNX), a global medical technology company that is developing and commercializing novel products for the treatment of bladder and bowel dysfunction, today announced that the Axonics R20™ rechargeable sacral neuromodulation (SNM) system has received CE Mark approval.

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 sized 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.

“Delivering a superior patient experience has been at the forefront of our SNM development efforts,” said Raymond W. Cohen, chief executive officer. “Patients with overactive bladder tell us that first and foremost, they value efficacy and a long-lived solution to address their chronic condition. The R20 represents another significant breakthrough for rechargeable neuromodulation devices and underscores Axonics’ commitment to continuous innovation. We are confident that our keen focus on the incontinence patient population has the potential to drive significant market expansion in both the U.S. and international markets in the years ahead.”

Axonics expects to commence sales of the R20 to European customers in mid-April. The R20 received approval from the U.S. FDA in January 2023 and from Health Canada in December 2022.

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. In the U.S., moderate to severe urinary incontinence affects an estimated 28 million women and fecal incontinence affects an estimated 19 million adults. 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.

Additional Information and Where to Find It

In connection with the contemplated Merger, Axonics filed on February 22, 2024 with the SEC a definitive proxy statement relating to a special meeting of Axonics' stockholders to be held for the purpose of obtaining stockholder approval of the Merger Agreement and other related matters (the "Proxy Statement"). The Proxy Statement was mailed to Axonics' stockholders on or about February 22, 2024. Axonics may also file other documents with the SEC regarding the contemplated Merger. This document is not a substitute for the Proxy Statement or any other document that Axonics has filed or may file with the SEC in connection with the contemplated Merger. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND SECURITY HOLDERS OF AXONICS ARE URGED TO READ THE PROXY STATEMENT, ANY AMENDMENTS OR SUPPLEMENTS THERETO, ANY OTHER SOLICITING MATERIALS AND ANY OTHER DOCUMENTS THAT ARE FILED OR WILL BE FILED WITH THE SEC IN CONNECTION WITH THE CONTEMPLATED MERGER OR INCORPORATED BY REFERENCE IN THE PROXY STATEMENT BECAUSE THEY CONTAIN OR WILL CONTAIN, AS APPLICABLE, IMPORTANT INFORMATION ABOUT AXONICS, BOSTON SCIENTIFIC AND THE CONTEMPLATED MERGER. Investors and security holders may obtain free copies of the Proxy Statement and other filings containing important information about Axonics on the SEC's website at www.sec.gov, on Axonics' website at www.axonics.com or by contacting Axonics' Investor Relations department via email at IR@axonics.com.

Participants in the Solicitation

Axonics and its directors and executive officers may, under SEC rules, be deemed participants in the solicitation of proxies from the stockholders of Axonics in connection with the contemplated Merger. Information regarding the identity of potential participants in the solicitation of proxies in connection with the proposed Merger, and their direct or indirect interests, by security holdings or otherwise, is included in the Proxy Statement. Additional information regarding Axonics' directors and executive officers is contained in the Proxy Statement, Axonics' [Definitive Proxy Statement on Schedule 14A](#) for Axonics' 2023 Annual Meeting of Stockholders, which was filed with the SEC on May 1, 2023 (and specifically, the following sections: "Security Ownership of Certain Beneficial Owners, Executive Officers and Directors", "Certain Relationships and Related-Party Transactions", "Executive Officers", "Proposal 1—Election of Directors", "Director Compensation", and "Executive Compensation") and in Axonics' [Current Report on Form 8-K](#), which was filed with the SEC on October 4, 2023. To the extent holdings of the Company's securities by the directors or executive officers have changed since the amounts set forth in the Proxy Statement, such changes have been or will be reflected on Initial Statement of Beneficial Ownership of Securities on Form 3, Statement of Changes in Beneficial Ownership on Form 4, or Annual Statement of Changes in Beneficial Ownership on Form 5 filed with the SEC, which are available at EDGAR Search Results (sec.gov). These documents (when available) are available free of charge as described in the preceding section.

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