UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 7, 2022

Axonics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38721**	**45-4744083**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

26 Technology Drive
Irvine, California 92618
(Address of principal executive offices) (Zip Code)

(949) 396-6322
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of class	**Trading symbol**	**Name of exchange on which registered**
Common stock, par value $0.0001 per share	AXNX	Nasdaq Global Select Market

Item 8.01. Other Events.

On March 7, 2022, Axonics, Inc. (the Company) issued a press release announcing its receipt of approval from the U.S. Food and Drug Administration for its recharge-free sacral neuromodulation system. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of Axonics, Inc., dated March 7, 2022
104	Cover Page Interactive Date File - the cover page XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AXONICS, INC.

Date: March 7, 2022

By: /s/ Raymond W. Cohen
Raymond W. Cohen
Chief Executive Officer

Exhibit 99.1

Axonics® Receives FDA Approval for Recharge-Free Sacral Neuromodulation System

Axonics sets recharge-free neuromodulation benchmark with FDA labeling for 15+ years of functional life at typical stimulation parameters and 20+ years at lower energy settings

IRVINE, Calif – March 7, 2022 – 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 U.S. Food and Drug Administration (FDA) has approved its newly developed, long-lived, recharge-free sacral neuromodulation (SNM) implantable neurostimulator (INS).

The Axonics F15™ recharge-free SNM system has the following key attributes:

- **INS type:** primary cell battery
- **INS longevity:** functional life has been validated for over 15 years at typical stimulation parameters and over 20 years at lower energy settings
- **INS volume:** 10 cubic centimeters (20% smaller than the market's other non-rechargeable SNM device)
- **Stimulation:** constant current automatically adjusts stimulation output
- **MRI compatibility:** full body with 1.5T and 3.0T whole-body scanners
- **Patient remote control:** intuitive, recharge-free key fob featuring *SmartMRI*™ technology
- **Programming:** proprietary algorithm recommends optimal stimulation parameters based on intraoperative responses

"Axonics is keenly focused on developing innovative, best-in-class, patient-centric SNM solutions as well as expanding awareness and access to this life-changing therapy," said Raymond W. Cohen, chief executive officer of Axonics. "Our rechargeable system introduced innovations to the SNM category in late 2019 that clinicians and patients had been requesting for years – longevity in the body, full-body MRI compatibility, a miniaturized implant, fuss-free therapy and a patient remote control that is easy for patients to use. The new Axonics F15 recharge-free SNM system is similarly groundbreaking – a small and thin INS with an expected life in the body of well over a decade that does not require any element of the system to be recharged – and sets a new standard for what is possible in this category. We expect to begin shipping the Axonics F15 system in April."

Cohen continued, "Tens of millions of Americans suffer from one form or another of incontinence and struggle to find long-term symptom relief. SNM was historically utilized as a therapy of last resort as it was only available with a neurostimulator that had an average battery life of four years, requiring patients to undergo multiple replacement surgeries. We aim to change that paradigm and expect the Axonics F15 system to increase adoption of SNM therapy. We will also launch a national television direct-to-consumer advertising campaign in the coming weeks to increase awareness for Axonics therapies, which treat all forms of bladder and bowel incontinence. We remain confident that our commitment to innovation, quality and providing physicians and patients strong support will continue to drive market expansion and advance Axonics on its path to market leadership."

About Axonics

Based in Irvine, Calif., 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. 1 on the 2021 Deloitte Technology Fast 500™, a ranking of the 500 fastest-growing technology, media, telecommunications, life sciences, fintech, and energy tech companies in North America.

The company's sacral neuromodulation (SNM) systems provide patients suffering from overactive bladder and/or fecal incontinence with long-lived, easy to use, safe, clinically effective therapy. In addition, Axonics' best-in-class urethral bulking hydrogel, Bulkamid®, provides safe and durable symptom relief to women with stress urinary incontinence (SUI). Overactive bladder affects an estimated 87 million adults in the U.S. and Europe, with an additional 40 million adults estimated to suffer from fecal incontinence. SUI affects an estimated 29 million women in the U.S. alone. Axonics' clinically proven products are offered at hundreds of medical centers across the U.S. and abroad. Reimbursement coverage is well established in the U.S. and is a covered service in most European countries. For more information, visit www.axonics.com.

Forward-Looking Statements

Statements made in this press release that relate to future plans, events, prospects or performance are forward-looking statements as defined under the Private Securities Litigation Reform Act of 1995. Words such as "planned," "expects," "believes," "anticipates," "designed," and similar words are intended to identify forward-looking statements. While these forward-looking statements are based on the current expectations and beliefs of management, such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results to differ materially from the expectations expressed in this press release, including the risks and uncertainties disclosed in Axonics filings with the Securities and Exchange Commission, all of which are available online at www.sec.gov. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, Axonics undertakes no obligation to update or revise any forward-looking statements to reflect new information, changed circumstances or unanticipated events.

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