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): January 25, 2021

Axonics Modulation Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-38721 (Commission File Number) 45-4744083 (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 \Box

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:

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

Item 2.02. Results of Operations and Financial Condition.

On January 25, 2021, Axonics Modulation Technologies, Inc. (the Company) issued a press release announcing its preliminary unaudited revenue for the fourth quarter ended December 31, 2020, based on the information and data currently available. 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.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of Axonics Modulation Technologies, Inc., dated January 25, 2021
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 MODULATION TECHNOLOGIES, INC.

Dated: January 25, 2021

By:

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

Axonics® Reports Preliminary Fourth Quarter and Fiscal Year 2020 Revenue

IRVINE, Calif – January 25, 2021 – Axonics Modulation Technologies, Inc. (NASDAQ: AXNX), a medical technology company that has developed and is commercializing novel implantable sacral neuromodulation (SNM) devices for the treatment of urinary and bowel dysfunction, today reported preliminary unaudited net revenue for the three months and fiscal year ended December 31, 2020.

- Preliminary unaudited net revenue is expected to be in the range of \$34.7 to \$34.9 million in the fourth quarter 2020, as compared to net revenue of \$9.9 million in the prior year period.
- Sales to customers in the United States accounted for approximately 97% of total revenue in the quarter.
- Management estimates that in the fourth quarter 2020, approximately 320 *confirmed and scheduled* permanent implants were canceled due to COVID-19 based upon a detailed territory by territory analysis.
- The cancellations represented approximately \$5 million of revenue that was neither shipped nor invoiced in the fourth quarter.
- Preliminary unaudited net revenue for fiscal year 2020 is expected to be approximately \$111.5 million, as compared to net revenue of \$13.8 million for fiscal year 2019.

Raymond W. Cohen, Axonics CEO, said, "We are proud of this quarter's revenue result considering the sharp acceleration of COVID-19 cases and hospitalizations in November and December, and the lower number of patients that met their insurance deductibles in 2020. While the recent surge in COVID-19 activity has slowed uptake of elective procedures in the United States and Europe, we expect the majority of canceled cases to be rescheduled and completed in the second half of 2021 as more individuals are vaccinated and the impact of the pandemic recedes."

Mr. Cohen continued, "In the first year of Axonics' commercial launch in the United States, we exceeded our ambitious goals despite the pandemic and only having ten months of selling time. The results are a testament to our mission-driven culture, the strong support our team provided clinicians and patients, and the trust physicians have placed in Axonics. We are grateful for the overwhelmingly positive response from the SNM implanting community and patients to the introduction of our r-SNM System. Despite the COVID headwinds, it is clear that based on increasing awareness, exceptional clinical outcomes for patients and less fuss for physicians and their staff, sacral neuromodulation's time has arrived. We remain bullish on the growth outlook for Axonics and the SNM market in 2021 and beyond."

The preliminary results set forth above are unaudited and remain subject to ongoing review and adjustment. Axonics will report complete fourth quarter 2020 financial results and hold a corresponding conference call in the second half of February.

About Axonics Modulation Technologies, Inc.

Axonics, based in Irvine, Calif., has developed and is commercializing novel implantable SNM devices for patients with urinary and bowel dysfunction. These conditions are caused by a miscommunication between the bladder and the brain and significantly impacts quality of life. Overactive bladder affects an estimated 87 million adults in the U.S. and Europe. Another estimated 40 million adults are reported to suffer from fecal incontinence/accidental bowel leakage. Axonics SNM therapy, which has been clinically proven to reduce symptoms and restore pelvic floor function, is now being offered at hundreds of medical centers across the U.S. and in dozens of select hospitals in Western Europe. Reimbursement coverage is well established in the U.S. and is a covered service in most European countries. The Axonics System is the first long-lived rechargeable SNM system approved for sale in the world, and the first to gain full-body MRI conditional labeling. For more information, visit <u>www.axonics.com</u>.

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 <u>www.sec.gov</u>. 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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