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 9, 2020

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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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:

<u>Title of class</u>

Common stock, par value \$0.0001 per share

Trading symbol
AXNX

Name of exchange on which registered
Nasdaq Global Select Market

Item 2.02. Results of Operations and Financial Condition.

On January 9, 2020, Axonics Modulation Technologies, Inc. (the "Company") issued a press release announcing its preliminary unaudited revenue for the fourth quarter and full year ended December 31, 2019 and unaudited cash, cash equivalents and short term investments as of December 31, 2019, 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.Description99.1Press release of Axonics Modulation Technologies, Inc., dated January 9, 2020

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 9, 2020 By: /s/ Raymond W. Cohen

Raymond W. Cohen Chief Executive Officer

Axonics® Announces Preliminary Fourth Quarter and Full Year 2019 Revenue

IRVINE, Calif. – January 9, 2020 – Axonics Modulation Technologies, Inc. (NASDAQ: AXNX), a medical technology company that has developed and is commercializing novel implantable rechargeable Sacral Neuromodulation ("SNM") devices for the treatment of urinary and bowel dysfunction, today reported preliminary unaudited revenue of approximately \$10 million for the fourth quarter of 2019 as compared to \$0.5 million in the prior year period. For the full year ended December 31, 2019, unaudited revenue was approximately \$14 million as compared to \$0.7 million for all of 2018.

In the United States, revenue for the fourth quarter of 2019 was approximately \$8.4 million following the launch of commercial sales of the Axonics r-SNM® System on October 29, 2019, and subsequent FDA approval of urinary clinical indications on November 13, 2019.

Revenue from international markets totaled approximately \$1.6 million in the fourth quarter of 2019 as compared to \$0.5 million in revenue in the prior year period. Sales in the fourth quarter of 2019 were derived primarily from r-SNM implants performed in England, the Netherlands, Germany and Switzerland. For all of 2019, international sales from Europe and Canada totaled approximately \$5.4 million as compared to sales of \$0.7 million in 2018.

Raymond W. Cohen, CEO of Axonics, commented, "The results of our first sixty days in the U.S. market clearly illustrate the level of enthusiasm for the Axonics r-SNM product and provide evidence that urologists and urogynecologists place a high value on clinical results and innovations that improve patient satisfaction with SNM therapy. We are also satisfied with the results over our first six quarters in select European markets where our customer base and procedure volume continue to grow. Moreover, we believe the market opportunity for sacral neuromodulation consists of millions of patients with overactive bladder and bowel dysfunction that are currently untreated or undertreated. Accordingly, we believe the implant rates and corresponding revenue generated in this category should increase significantly in the years ahead."

As of December 31, 2019, subsequent to the follow-on offering completed on November 22, 2019, unaudited cash, cash equivalents and short-term investments were \$183.7 million.

Complete financial results for Q4 2019 and the full year are anticipated to be announced on or about March 4, 2020.

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. SNM therapy has been employed to reduce symptoms and restore pelvic floor function for the past two decades. Reimbursement coverage is well established in the U.S. and Europe. The Axonics System is the first rechargeable SNM system approved for sale in the world, and the first to gain full-body MRI conditional labeling. For more information, visit the Company's website at 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.

Contacts:

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