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): July 13, 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:

□ 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 \boxtimes

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 2.02. Results of Operations and Financial Condition.

On July 13, 2020, Axonics Modulation Technologies, Inc. (the "Company") issued a press release announcing its preliminary unaudited revenue for the second quarter ended June 30, 2020 and unaudited cash, cash equivalents and short term investments as of June 30, 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 July 13, 2020
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: July 13, 2020

By:

/s/ Raymond W. Cohen

Raymond W. Cohen Chief Executive Officer

Axonics® Reports Preliminary Second Quarter 2020 Revenue

IRVINE, CA – July 13, 2020 – 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 second quarter 2020 revenue and provided an operational update.

Recent Business and Financial Highlights

- Preliminary unaudited net revenue is expected to be \$15.2 million for the second quarter 2020, as compared to net revenue of \$1.5 million in the prior year period.
- Sales to customers in the United States accounted for approximately 96 percent of total revenue.
 - New order flow in April was de minimis due to COVID-19 related restrictions on elective procedures.
 - New order flow began a gradual recovery in early May as restrictions on elective procedures performed in ambulatory surgery centers and hospital outpatient surgery departments were lifted in certain states.
 - In June, new order flow continued to improve as more states reopened. Average weekly new order flow in June was approximately \$2 million, or 70 percent of the weekly average achieved in the first quarter of 2020 prior to the COVID-19 related postponement of elective procedures in mid-March.
 - Over 485 unique accounts (hospitals and ambulatory surgery centers) in the United States have implanted patients with the Axonics r-SNM System[®] since the product launched in November 2019, including more than 110 new accounts that were added in the second quarter of 2020.
 - European hospital customers in England, the Netherlands, Germany, and Switzerland did not, for the most part, conduct elective procedures in the second quarter of 2020 due to COVID-19 and accordingly, the contribution to revenue from these markets was modest.
- Since April, Axonics has received a number of FDA approvals, including a next generation implantable neurostimulator that extends the interval between recharging to just once per month, a new wireless patient remote control with SmartMRI[™] technology, and approval for 3T full-body MRI scans.
- As of June 30, 2020, unaudited cash and cash equivalents were \$288 million.

Raymond W. Cohen, CEO of Axonics, commented, "Axonics has stayed focused on supporting physicians and their patients during the COVID-19 pandemic, along with building finished goods inventory, signing agreements with national, regional and local hospital systems, and advancing regulatory filings with the FDA. In the second quarter, we continued to make meaningful progress on new customer acquisition, with over 45% of the top 1,000 centers in the United States now having implanted patients with the Axonics r-SNM System. While gross margins will be impacted by lower overhead absorption and other related factors, we are highly encouraged by the trajectory of new order flow in June. Given these factors, we are confident that Axonics is well positioned for growth in the second half of 2020, while recognizing that a sustained recovery in elective procedures is contingent on factors that are outside of our control."

Mr. Cohen continued, "We continue to invest in innovation and enhancing the patient experience, having announced several recent FDA approvals that will accrue to SNM becoming the preferred therapy for overactive bladder and bowel dysfunction. The overwhelmingly positive feedback from clinicians and patients on their experience with our product in tandem with our commitment to increase patient awareness supports our conviction that the SNM market is poised for significant expansion in the years ahead."

Axonics will report complete second quarter 2020 financial results and provide a further operational update after the market closes on August 6, 2020. The preliminary results set forth above are unaudited and remain subject to ongoing review and adjustment.

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. The 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 the Company's website at <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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