
**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): November 4, 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

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

Item 2.02. Results of Operations and Financial Condition.

On November 4, 2020, Axonics Modulation Technologies, Inc. (the Company) issued a press release announcing its financial results for the quarter ended September 30, 2020. 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, 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, 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 November 4, 2020
104	Cover Page Interactive Data 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.

Date: November 4, 2020

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics® Reports Third Quarter 2020 Results

Axonics generated net revenue of \$35.2 million in the third quarter ended September 30, 2020

Over 5,500 patients have been implanted with the Axonics r-SNM System since U.S. commercial launch

IRVINE, CA – November 4, 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 results for the third quarter 2020.

Raymond W. Cohen, CEO of Axonics, said, “In the third quarter, despite headwinds from COVID-19 and the launch of a rechargeable device by our competitor, we continued to add new customers, sign additional hospital system agreements, gain regulatory approvals, and expand our growing body of clinical literature. Our strong revenue results reflect the close working relationships we have developed with implanting physicians, the successful launch of our second-generation implantable neurostimulator, and most importantly, the high satisfaction rates being reported by patients since our U.S. launch a year ago. It is our conviction that the SNM market is poised for significant market expansion and given the quality of our team and product pipeline, we are confident that Axonics is well positioned for continued growth in the years ahead.”

Third Quarter 2020 Financial Results

- Net revenue was \$35.2 million in the third quarter ended September 30, 2020, as compared to net revenue of \$1.3 million for the same period of the prior year.
 - U.S. net revenue accounted for \$34.1 million, with select international markets accounting for \$1.1 million of net revenue.
 - Over 600 unique accounts (hospitals and ambulatory surgery centers) in the United States have implanted patients with the Axonics r-SNM® System since commercial launch in November 2019, including more than 115 new accounts that were added in the third quarter of 2020.
- Net revenue through the first nine months of 2020 was \$76.8 million, as compared to \$3.9 million for the same period of the prior year.
- Gross margin was 61.9% in the third quarter 2020, as compared to 51.7% for the same period of the prior year.
- Operating expenses were \$30.6 million in the third quarter 2020, as compared to \$25.7 million for the same period of the prior year. This increase was primarily due to higher personnel costs for the U.S. commercial team and in other parts of the organization.
- Net loss was \$9.2 million in the third quarter 2020, as compared to a net loss of \$25.0 million for the same period of the prior year.
- As of September 30, 2020, cash and cash equivalents were \$269.3 million.

Clinical and Regulatory Highlights

- On July 1, 2020, the Axonics r-SNM System received FDA approval for 3.0 Tesla full-body MRI scans.

- In August 2020, Axonics began shipping its second-generation implantable neurostimulator (INS) to U.S. customers. The new INS extends the recharge interval for patients to just once a month for one hour.
- On September 8, 2020, Axonics announced NICE’s recommendation of the Axonics r-SNM System.
- On September 10, 2020, Axonics reported 2-year clinical results from its ARTISAN-SNM pivotal study.
- On September 21, 2020, Axonics announced Health Canada’s approval of its second-generation INS.
- On September 24, 2020, Axonics announced that the U.S. Patent Trial and Appeal Board has instituted a review regarding the validity of six Medtronic patents that Axonics is contesting.
- On October 5, 2020, Axonics announced survey results of patients treated with the Axonics r-SNM System that were previously implanted with InterStim™ II.

Webcast and Conference Call

Axonics will host a conference call today, November 4, 2020, at 4:30 p.m. Eastern Time, to discuss financial results and recent business developments. Interested parties may access the live teleconference by dialing 866-687-5771 (U.S.) or 409-217-8725 (International) and using conference ID 8446338.

A live webcast of the conference call may be accessed by visiting the Events & Presentations section of the Axonics investor relations website at ir.axonics.com. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the Axonics website for 90 days.

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 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.

Axonics contact:
Neil Bhalodkar
949-336-5293
IR@axonics.com

Axonics Modulation Technologies, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	September 30, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	\$ 269,280	\$ 171,082
Short-term investments	—	12,592
Accounts receivable, net of allowance for doubtful accounts of \$465 and \$75 at September 30, 2020 and December 31, 2019, respectively	17,650	7,879
Inventory, net	44,308	15,659
Prepaid expenses and other current assets	3,220	4,468
Total current assets	334,458	211,680
Property and equipment, net	5,792	3,047
Intangible asset, net	225	311
Other assets	7,196	4,784
Total assets	\$ 347,671	\$ 219,822
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 9,415	\$ 5,882
Accrued liabilities	5,977	2,174
Accrued compensation and benefits	7,516	3,375
Operating lease liability, current portion	908	602
Debt, current portion	15,000	—
Total current liabilities	38,816	12,033
Operating lease liability, net of current portion	9,027	4,450
Debt, net of unamortized debt issuance costs, net of current portion	5,930	20,336
Total liabilities	53,773	36,819
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, par value \$0.0001, 50,000,000 shares authorized at September 30, 2020 and December 31, 2019; 39,753,638 and 34,110,995 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	4	3
Additional paid-in capital	517,659	363,012
Accumulated deficit	(223,151)	(179,584)
Accumulated other comprehensive loss	(614)	(428)
Total stockholders' equity	293,898	183,003
Total liabilities and stockholders' equity	\$ 347,671	\$ 219,822

Axonics Modulation Technologies, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net revenue	\$ 35,243	\$ 1,309	\$ 76,752	\$ 3,874
Cost of goods sold	13,434	632	31,792	1,952
Gross profit	21,809	677	44,960	1,922
Operating Expenses				
Research and development	7,748	4,855	21,030	13,948
General and administrative	5,773	5,162	18,963	13,539
Sales and marketing	17,057	15,707	47,846	32,371
Total operating expenses	30,578	25,724	87,839	59,858
Loss from operations	(8,769)	(25,047)	(42,879)	(57,936)
Other Income (Expense)				
Interest income	35	627	742	2,500
Interest and other expense	(434)	(586)	(1,429)	(1,747)
Other income (expense), net	(399)	41	(687)	753
Loss before income tax expense	(9,168)	(25,006)	(43,566)	(57,183)
Income tax expense	—	—	1	1
Net loss	(9,168)	(25,006)	(43,567)	(57,184)
Foreign currency translation adjustment	99	(112)	(186)	(165)
Comprehensive loss	\$ (9,069)	\$ (25,118)	\$ (43,753)	\$ (57,349)
Net loss per share, basic and diluted	\$ (0.24)	\$ (0.89)	\$ (1.20)	\$ (2.05)
Weighted-average shares used to compute basic and diluted net loss per share	38,830,924	28,098,564	36,312,984	27,958,376