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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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

**Date of Report (Date of earliest event reported): February 25, 2021**

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**Axonics Modulation Technologies, Inc.**

(Exact name of registrant as specified in its charter)

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**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)**

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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

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**Item 2.02. Results of Operations and Financial Condition.**

On February 25, 2021, Axonics Modulation Technologies, Inc. (the Company) issued a press release announcing its financial results for the quarter ended December 31, 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 (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.

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release of Axonics Modulation Technologies, Inc., dated February 25, 2021</a>
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

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**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: February 25, 2021

By:

/s/ Raymond W. Cohen

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Raymond W. Cohen

Chief Executive Officer

## **Axonics® Reports Fourth Quarter and Fiscal Year 2020 Results**

**IRVINE, Calif – February 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 results for the fourth quarter and fiscal year ended December 31, 2020.

Raymond W. Cohen, Axonics CEO, said, “In the first year of Axonics’ commercial launch in the United States, we exceeded our ambitious goals despite the pandemic and only having approximately ten months of selling time. We are grateful for the overwhelmingly positive response from physicians and patients to the introduction of our r-SNM System. We look forward to more Americans getting vaccinated and a return to a more normalized elective procedure environment in which we can take full advantage of the strong growth outlook for Axonics and the SNM market.”

### **Fourth Quarter 2020 Financial Results**

- Net revenue was \$34.8 million in the fourth quarter 2020, as compared to net revenue of \$9.9 million for the same period of the prior year. Net revenue was consistent with the preliminary revenue result Axonics previously reported in January.
  - U.S. net revenue accounted for \$33.7 million, with select international markets accounting for \$1.1 million of net revenue.
- 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. These cancellations represented approximately \$5 million of revenue that was not recognized in fourth quarter 2020. Management expects the majority of deferred cases to be rescheduled for the second half of 2021 as more individuals are vaccinated.
- Gross margin was 63.6% in the fourth quarter 2020, as compared to 54.4% for the same period of the prior year.
- Operating expenses were \$33.0 million in the fourth quarter 2020, as compared to \$28.1 million for the same period of the prior year.
- Net loss was \$11.3 million in the fourth quarter 2020, as compared to a net loss of \$22.8 million for the same period of the prior year.
- As of December 31, 2020, cash and cash equivalents were \$241.2 million.

### **Fiscal Year 2020 Financial Results**

- Net revenue was \$111.5 million in fiscal year 2020, as compared to net revenue of \$13.8 million in fiscal year 2019.
  - U.S. net revenue accounted for \$107.5 million, with select international markets accounting for \$4.0 million of net revenue.
- Gross margin was 60.2% in fiscal year 2020, as compared to 53.0% in fiscal year 2019.
- Operating expenses were \$120.9 million in fiscal year 2020, as compared to \$87.9 million in fiscal year 2019.
- Net loss was \$54.9 million in fiscal year 2020, as compared to a net loss of \$79.9 million in fiscal year 2019.

## Clinical and Regulatory Highlights

- On October 5, 2020, Axonics published survey results of patients treated with the Axonics r-SNM System that were previously implanted with InterStim™ II.
- On October 20, 2020, Axonics launched the ARTISTRY study, a post-market clinical registry following patients treated with the Axonics r-SNM System.
- On October 29, 2020, Axonics announced the submission of a premarket approval supplement to the FDA for the purpose of gaining detachable extremity coil MRI conditional labeling for 1.5T and 3.0T MR scanners. The filing is currently under review by FDA.
- On November 10, 2020, Axonics announced the publication of fecal incontinence study results for patients treated with its r-SNM System.
- On January 28, 2021, a manuscript was published online in Neurourology and Urodynamics discussing the two-year outcomes of the ARTISAN-SNM study.
- On February 16, 2021, Axonics announced FDA approval of its third-generation implantable neurostimulator.

## Webcast and Conference Call

Axonics will host a conference call today, February 25, 2021, at 4:30 p.m. Eastern Time, to discuss financial results and recent business developments.

The live teleconference may be accessed by dialing 888-771-4371 (U.S.) or 847-585-4405 (International) and using passcode 50112306.

The live webcast of the conference call may be accessed by visiting the [Events & Presentations](#) section of the Axonics investor relations website. The 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.

Based in Irvine, Calif, Axonics has developed and is commercializing novel implantable SNM devices for patients with urinary and bowel dysfunction, and through its acquisition of Bulkamid, offers solutions for patients with stress urinary incontinence. These conditions significantly impact quality of life. Overactive bladder affects an estimated 87 million adults in the U.S. and Europe, and another estimated 40 million adults are reported to suffer from fecal incontinence/accidental bowel leakage. Stress urinary incontinence affects an estimated 20 million women in the U.S. 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](http://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](http://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:**  
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**Axonics Modulation Technologies, Inc.**  
**Consolidated Balance Sheets**  
(in thousands, except share and per share data)

	December 31,	
	2020	2019
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 241,181	\$ 171,082
Short-term investments	—	12,592
Accounts receivable, net of allowance for doubtful accounts of \$465 and \$75 at December 31, 2020 and 2019, respectively	18,270	7,879
Inventory, net	63,060	15,659
Prepaid expenses and other current assets	5,435	4,468
Total current assets	327,946	211,680
Property and equipment, net	6,328	3,047
Intangible asset, net	196	311
Other assets	7,736	4,784
Total assets	\$ 342,206	\$ 219,822
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 10,660	\$ 5,882
Accrued liabilities	6,684	2,174
Accrued compensation and benefits	5,948	3,375
Operating lease liability, current portion	1,280	602
Debt, net of unamortized debt issuance costs, current portion	21,110	—
Total current liabilities	45,682	12,033
Operating lease liability, net of current portion	9,154	4,450
Debt, net of unamortized debt issuance costs	—	20,336
Total liabilities	54,836	36,819
Stockholders' Equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, par value \$0.0001 per share, 50,000,000 shares authorized at December 31, 2020 and 2019; 39,931,030 and 34,110,995 shares issued and outstanding at December 31, 2020 and 2019, respectively	4	3
Additional paid-in capital	522,296	363,012
Accumulated deficit	(234,499)	(179,584)
Accumulated other comprehensive loss	(431)	(428)
Total stockholders' equity	287,370	183,003
Total liabilities and stockholders' equity	\$ 342,206	\$ 219,822

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

	Three Months Ended December 31,		Years Ended December 31,	
	2020	2019	2020	2019
	(unaudited)	(unaudited)		
Net revenue	\$ 34,783	\$ 9,946	\$ 111,535	\$ 13,820
Cost of goods sold	12,652	4,538	44,444	6,490
Gross profit	22,131	5,408	67,091	7,330
Operating Expenses				
Research and development	8,140	6,233	29,170	20,181
General and administrative	6,588	5,537	25,551	19,076
Sales and marketing	18,284	16,301	66,130	48,672
Total operating expenses	33,012	28,071	120,851	87,929
Loss from operations	(10,881)	(22,663)	(53,760)	(80,599)
Other Income (Expense)				
Interest income	19	474	761	2,974
Loss on disposal of property and equipment	(41)	—	(41)	—
Interest and other expense	(445)	(562)	(1,874)	(2,309)
Other income (expense), net	(467)	(88)	(1,154)	665
Loss before income tax expense	(11,348)	(22,751)	(54,914)	(79,934)
Income tax expense	—	—	1	1
Net loss	(11,348)	(22,751)	(54,915)	(79,935)
Foreign currency translation adjustment	183	153	(3)	(12)
Comprehensive loss	\$ (11,165)	\$ (22,598)	\$ (54,918)	\$ (79,947)
Net loss per share, basic and diluted	\$ (0.29)	\$ (0.75)	\$ (1.48)	\$ (2.80)
Weighted-average shares used to compute basic and diluted net loss per share	38,971,859	30,374,223	36,981,335	28,567,302