
**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): March 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 March 4, 2020, Axonics Modulation Technologies, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended December 31, 2019. 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	<u>Press release of Axonics Modulation Technologies, Inc., dated March 4, 2020</u>

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: March 4, 2020

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics® Announces Fourth Quarter and Fiscal 2019 Financial Results

IRVINE, CA – March 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, reported today financial results for the fourth quarter and year ended December 31, 2019 and provided an update on operational initiatives.

Recent Business & Financial Highlights

- In the fourth quarter of 2019, net revenue of the Axonics r-SNM® System totaled \$9.9 million. Net revenue was consistent with the Company’s pre-announcement from early January. Demand for the Axonics product in the United States was brisk during the initial launch period following U.S. Food & Drug Administration (“FDA”) approval on November 13, 2019 resulting in net revenue from the United States of \$8.4 million, with net revenue from select European markets accounting for \$1.5 million.
- Approximately 200 hospitals and ambulatory surgery centers implanted the Axonics r-SNM System into patients in the months of November and December. A total of 35 hospitals in England, the Netherlands, Switzerland, Germany and Canada implanted the Axonics r-SNM System in 2019.
- In November 2019, Axonics raised approximately \$118 million of gross proceeds in an underwritten public follow-on offering.
- In December 2019, Axonics gained Health Canada approval for the use of 1.5T and 3T full body MRI scanners for patients implanted with the Axonics r-SNM System.
- In January 2020, the FDA approved an enhanced, second-generation Programmer for the Axonics r-SNM System under a premarket approval application supplement. The new Programmer is used to program the Axonics external trial neurostimulator as well as the implantable neurostimulator in both the procedure and post-operative environments.
- In February 2020, the German Institute for the Hospital Remuneration System granted reimbursement approval to the Axonics r-SNM System under a New Examination and Treatment Method (“NUB”) allowing hospitals to apply to the German government for additional funding.
- In February 2020, Axonics executed its first post-FDA commercial exhibition at a major medical congress, participating in the Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) meeting in Scottsdale, AZ, attended by approximately 650 physicians. At the conference, the one-year results from the Company’s ARTISAN-SNM pivotal study were presented, demonstrating 89% efficacy and significant improvements in patient quality of life.

Raymond W. Cohen, CEO of Axonics commented, “The initial results of our U.S. launch clearly exceeded our expectations. These results were achieved based not only on the quality of our product and the demand from SNM implanters for a long-lived innovative product, but also can be attributed to the investment of time and capital we made to recruit, hire and train over 145 U.S. sales and clinical specialists during 2019 in advance of FDA approval.”

Cohen continued, “The velocity of sales in the U.S. has continued in Q1 of 2020 with over 300 U.S. institutions now implanting our r-SNM System nationwide in the first quarter. Physician feedback has been very positive regarding patient outcomes and the support they are receiving from the Axonics team. We expect our momentum to continue throughout 2020 as more institutions begin implanting our device. We fully expect the U.S. market for SNM to increase based on the notion that more patients are choosing SNM given the

attractive proposition of a 15+ year implant that does not require explant in the event that an MRI scan is needed.”

Fourth Quarter 2019 Financial Results

- Net revenue was \$9.9 million in the fourth quarter ended December 31, 2019, as compared to net revenue of \$0.5 million for the same period of the prior year.
- Net revenue from the United States accounted for \$8.4 million, with net revenue from certain select European markets accounting for \$1.5 million.
- Gross margin was 54.4%.
- Operating expense was \$28.1 million for the fourth quarter of 2019, as compared to \$9.7 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 across the organization related to increased headcount to support the commercial launch of the Company’s r-SNM System in the U.S.
- Net loss for the fourth quarter of 2019 was \$22.8 million, as compared to \$9.7 million for the same period of the prior year. Net loss per share was \$0.75 per share.
- As of December 31, 2019, cash, cash equivalents and short-term investments were \$183.7 million as compared to \$157.5 million at December 31, 2018.

2019 Fiscal Year Financial Results

- Net revenue was \$13.8 million in fiscal year 2019 and was derived from the sale of the Company’s r-SNM System to customers in the U.S., Europe and Canada. This compares to net revenue of \$0.7 million in fiscal year 2018, which was derived from sales to customers in Europe and Canada.
- Gross margin was 53.0% in fiscal year 2019, compared to 49.7% gross margin in fiscal year 2018. The increase in gross margin is primarily due to country and product mix.
- Operating expense was \$87.9 million for 2019, as compared to \$32.5 million in fiscal year 2018. This increase was primarily due to higher personnel costs across the organization related to increased headcount to support the commercial launch of the Company’s r-SNM System in the U.S.

Webcast and Conference Call

Today, on Wednesday March 4, 2020, at 4:30 p.m. Eastern Time, the Company will host a conference call with the investment community to discuss its financial results and recent business developments.

Interested parties may access the live call via telephone by dialing 866-687-5771 (U.S.) or 409-217-8725 (International) and using conference ID 8582626.

A live webcast of the call may be accessed by visiting the Events & Presentations page of the investors section of the Company’s website at ir.axonicsmodulation.com. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the Company’s 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 impact 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.

Axonics Contact:

Neil Bhalodkar
Vice President, Investor Relations
949-336-5293
ir@axonics.com

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

	December 31,	
	2019	2018
ASSETS		
Current assets		
Cash and cash equivalents	\$ 171,082	\$ 98,306
Short-term investments	12,592	59,218
Accounts receivable, net of allowance for doubtful accounts of \$75 and \$0 at December 31, 2019 and 2018, respectively	7,879	427
Inventory, net	15,659	3,673
Prepaid expenses and other current assets	4,468	3,716
Total current assets	211,680	165,340
Property and equipment, net	3,047	2,784
Intangible asset, net	311	426
Other assets	4,784	3,356
Total assets	\$ 219,822	\$ 171,906
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 5,882	\$ 3,436
Accrued liabilities	2,174	1,019
Accrued compensation and benefits	3,375	664
Operating lease liability, current portion	602	768
Total current liabilities	12,033	5,887
Operating lease liability, net of current portion	4,450	3,281
Debt, net of unamortized debt issuance costs	20,336	19,463
Total liabilities	36,819	28,631
Stockholders' Equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2019 and 2018	—	—
Common stock, par value \$0.0001, 50,000,000 shares authorized at December 31, 2019 and 2018; 34,110,995 and 27,806,934 shares issued and outstanding at December 31, 2019 and 2018, respectively	3	3
Additional paid-in capital	363,012	243,337
Accumulated deficit	(179,584)	(99,649)
Accumulated other comprehensive loss	(428)	(416)
Total stockholders' equity	183,003	143,275
Total liabilities and stockholders' equity	\$ 219,822	\$ 171,906

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,	
	2019	2018	2019	2018
	(unaudited)	(unaudited)		
Net revenue	\$ 9,946	\$ 494	\$ 13,820	\$ 707
Cost of goods sold	4,538	245	6,490	356
Gross profit	5,408	249	7,330	351
Operating Expenses				
Research and development	6,233	4,783	20,181	19,402
General and administrative	5,537	3,501	19,076	9,362
Sales and marketing	16,301	1,416	48,672	3,724
Total operating expenses	28,071	9,700	87,929	32,488
Loss from operations	(22,663)	(9,451)	(80,599)	(32,137)
Other Income (Expense)				
Interest income	474	550	2,974	998
Interest and other expense	(562)	(764)	(2,309)	(1,343)
Other income (expense), net	(88)	(214)	665	(345)
Loss before income tax expense	(22,751)	(9,665)	(79,934)	(32,482)
Income tax expense	—	—	1	1
Net loss	(22,751)	(9,665)	(79,935)	(32,483)
Foreign currency translation adjustment	153	(10)	(12)	(14)
Comprehensive loss	\$ (22,598)	\$ (9,675)	\$ (79,947)	\$ (32,497)
Net loss per share, basic and diluted	\$ (0.75)	\$ (0.50)	\$ (2.80)	\$ (4.64)
Weighted-average shares used to compute basic and diluted net loss per share	30,374,223	19,402,008	28,567,302	6,997,777