
**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): May 5, 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 May 5, 2020, Axonics Modulation Technologies, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 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.

Exhibit No.	Description
99.1	Press release of Axonics Modulation Technologies, Inc., dated May 5, 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.

Date: May 5, 2020

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics® Reports First Quarter 2020 Results

IRVINE, CA – May 5, 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 financial results for the first quarter 2020 and provided an update on operational initiatives.

Recent Business & Financial Highlights

- Net revenue was \$26.3 million in the first quarter of 2020, the first full quarter of commercial results following U.S. Food & Drug Administration (“FDA”) approval of the Axonics r-SNM® System in November 2019. Sales momentum accelerated throughout the first quarter, peaking in mid-March prior to COVID-19 related postponement of elective procedures.
- Over 350 unique accounts (hospitals and ambulatory surgery centers) in the United States implanted patients with the Axonics r-SNM System in the first quarter of 2020.
- Over 110 facility agreements with national and regional IDNs as well as large urology groups and ambulatory surgery centers have been signed since the U.S. launch. Included in this group are agreements with three of the largest national IDNs in the U.S. which were executed in March. Another 85 agreements are currently in process.
- In January 2020, the FDA approved an enhanced, second-generation programmer for the Axonics r-SNM System under a premarket approval (“PMA”) supplement. The new programmer features, among other things, a predictive programming algorithm that translates intra-operative responses and suggests how to program the patient for optimum therapy, thereby reducing the need to adjust post-implant therapy.
- In April 2020, Axonics submitted a PMA supplement to the FDA for the purpose of gaining full-body MRI conditional labeling for 3.0T MRI scans. Both 1.5T and 3.0T labeling is approved in Europe under the CE Mark. In September 2019, the FDA approved full-body labeling for 1.5T MR scanners. Axonics has since performed all the required tests to support the rationale for full-body 3.0T labeling.
- In April 2020, the FDA approved a next generation rechargeable implantable neurostimulator (“INS”) for the Axonics r-SNM System under a PMA supplement. The new INS decreases how frequently a patient needs to recharge their implanted device to once a month for about one hour and for some patients, once every other month. The next generation Axonics INS is expected to begin shipping to U.S. customers early in the third quarter of 2020.

Raymond W. Cohen, CEO of Axonics, commented, “We are quite proud of this quarter’s exceptional revenue result considering we had only been in the market for two months prior to the start of 2020. Moreover, we believe that this result ranks among the highest revenue total generated in the history of the medical device industry for a company’s first full quarter of sales in the U.S. following FDA approval. The results are a testament to the quality of our 170 person U.S. commercial team and were driven by the overwhelmingly positive response from the SNM implanting community and their patients to the introduction of a bespoke SNM device that is intuitive, fuss-free, long-lived, MRI compatible, safe and clinically effective. This quarter’s results reinforce our confidence that the SNM market is poised for meaningful expansion in the years ahead, driven to a large extent by Axonics’ continuous innovation and commitment to increasing patient awareness. As elective procedures are rescheduled, we expect to be very active in the months ahead as more patients say ‘yes’ to Axonics and SNM therapy. Despite the setback from COVID-19, we remain bullish about our prospects for continued growth in 2020 and beyond.”

Mr. Cohen continued, “The Axonics team would like to express its gratitude to the courageous and selfless healthcare workers providing care for those impacted by COVID-19. At Axonics, we remain focused on supporting our customers and their patients as well as protecting the health of our employees and their families.”

First Quarter 2020 Financial Results

- Net revenue was \$26.3 million in the first quarter 2020, as compared to net revenue of \$1.1 million for the same period of the prior year.
- Net revenue from the United States accounted for \$25.0 million, with select European markets and Canada accounting for the balance of first quarter 2020 revenue.
- Gross margin was 62.4% in the first quarter 2020, as compared to 49.2% for the same period of the prior year.
- Operating expenses were \$31.1 million in the first quarter 2020, as compared to \$14.1 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 \$14.6 million in the first quarter 2020, as compared to \$13.1 million for the same period of the prior year.
- As of March 31, 2020, cash, cash equivalents and short-term investments were \$159.8 million, as compared to \$183.7 million at December 31, 2019.

Webcast and Conference Call

Axonics will host a conference call with the investment community today, May 5, 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 6654699.

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.axonics.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.

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

	March 31, 2020	December 31, 2019
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 159,820	\$ 171,082
Short-term investments	—	12,592
Accounts receivable, net of allowance for doubtful accounts of \$589 and \$75 at March 31, 2020 and December 31, 2019, respectively	20,770	7,879
Inventory, net	19,230	15,659
Prepaid expenses and other current assets	4,245	4,468
Total current assets	204,065	211,680
Property and equipment, net	5,406	3,047
Intangible asset, net	282	311
Other assets	7,626	4,784
Total assets	\$ 217,379	\$ 219,822
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 7,440	\$ 5,882
Accrued liabilities	3,110	2,174
Accrued compensation and benefits	3,503	3,375
Operating lease liability, current portion	794	602
Debt, current portion	5,000	—
Total current liabilities	19,847	12,033
Operating lease liability, net of current portion	9,485	4,450
Debt, net of unamortized debt issuance costs, net of current portion	15,571	20,336
Total liabilities	44,903	36,819
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2020 and December 31, 2019	—	—
Common stock, par value \$0.0001, 50,000,000 shares authorized at March 31, 2020 and December 31, 2019; 34,510,662 and 34,110,995 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	3	3
Additional paid-in capital	367,278	363,012
Accumulated deficit	(194,200)	(179,584)
Accumulated other comprehensive loss	(605)	(428)
Total stockholders' equity	172,476	183,003
Total liabilities and stockholders' equity	\$ 217,379	\$ 219,822

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

	Three Months Ended March 31,	
	2020	2019
Net revenue	\$ 26,296	\$ 1,077
Cost of goods sold	9,895	548
Gross profit	16,401	529
Operating Expenses		
Research and development	6,884	4,219
General and administrative	7,653	4,015
Sales and marketing	16,569	5,914
Total operating expenses	31,106	14,148
Loss from operations	(14,705)	(13,619)
Other Income (Expense)		
Interest income	642	1,034
Interest and other expense	(552)	(532)
Other income, net	90	502
Loss before income tax expense	(14,615)	(13,117)
Income tax expense	1	—
Net loss	(14,616)	(13,117)
Foreign currency translation adjustment	(177)	(10)
Comprehensive loss	\$ (14,793)	\$ (13,127)
Net loss per share, basic and diluted	\$ (0.43)	\$ (0.47)
Weighted-average shares used to compute basic and diluted net loss per share	33,637,646	27,828,201