
**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): August 6, 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 August 6, 2020, Axonics Modulation Technologies, Inc. (the Company) issued a press release announcing its financial results for the quarter ended June 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 August 6, 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.

Date: August 6, 2020

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics® Reports Second Quarter 2020 Results

IRVINE, CA – August 6, 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 second quarter 2020 and provided an update on operational initiatives.

Financial Highlights

- Net revenue was \$15.2 million in the second quarter ended June 30, 2020 as compared to net revenue of \$1.5 million for the same period of the prior year. Net revenue for the first half of 2020 was \$41.5 million as compared to \$2.6 million for the first half of 2019.
 - As previously disclosed, new order flow was de minimis in April due to COVID-19 related restrictions on elective procedures and began a gradual recovery in early May as restrictions were lifted in certain states. New orders in June continued to improve. Average weekly new order flow in June was approximately 70% of the weekly average achieved in the first quarter of 2020 prior to the COVID-19 related postponement of elective procedures in mid-March.
- Axonics raised \$140 million of net proceeds in a public equity offering in May 2020. As of June 30, 2020, cash and cash equivalents were \$288 million.

Business and Clinical Highlights

- Through the end of July 2020, over 540 unique accounts (hospitals and ambulatory surgery centers) in the U.S. have implanted the Axonics r-SNM System® in patients on an outpatient basis since the product launched in November 2019.
- Since the U.S. launch, over 135 corporate agreements have been signed with national and regional integrated delivery networks (IDN) as well as large urology groups and ambulatory surgery centers. Included in this group are agreements with 12 of the largest 17 national IDNs in the U.S.
- Axonics recently reported 2-year topline clinical results from its ARTISAN-SNM pivotal study. At 2-years post-implant, 88% of all patients were therapy responders, consistent with the 89% therapy responder rate reported at 1-year. The 2-year results demonstrate that patients continue to experience clinically meaningful and statistically significant improvements in urinary urgency incontinence symptoms and quality of life. Eighty percent of patients achieved >75% reduction in symptoms, with 37% being completely dry. There were no serious or unanticipated device related events.

Regulatory Approvals

- In April 2020, the U.S. Food & Drug Administration (FDA) approved a next generation rechargeable implantable neurostimulator (INS) for the Axonics r-SNM System under a premarket approval (PMA) supplement. The new INS extends the recharge interval for patients to only once a month for about one hour and for some patients, only once every two months. The next generation Axonics INS is shipping to U.S. customers this week.
- In June 2020, the FDA approved a new wireless patient remote control with SmartMRI™ technology for the Axonics r-SNM System under a PMA supplement. The new remote control simplifies the process by which patients can receive a full-body MRI. An MRI technician can perform a simple check using a patient's remote control immediately prior to an MRI, avoiding the need for the patient to visit their implanting physician's office or involving personnel from Axonics.

- In July 2020, the FDA approved 3T full-body MRI conditional labeling for the Axonics r-SNM System under a PMA supplement. With this incremental approval, the Axonics device is MRI compatible for both 1.5T and 3T full-body scans.

Raymond W. Cohen, Axonics CEO, commented, “Axonics was exceptionally productive in the second quarter, having built a significant quantity of finished goods inventory, signed numerous IDN agreements, added over 110 new accounts, and gained several FDA approvals. Despite COVID-19 flare-ups in certain geographies, based on the number of accounts that have switched to Axonics and the trajectory of new order flow in July, we are confident that Axonics is well positioned for continued strong growth in the second half of 2020.”

Mr. Cohen continued, “The responder rate from the ARTISAN-SNM pivotal study is the highest success rate ever reported in SNM clinical literature and will soon appear in print in a peer-reviewed journal. More importantly, these results are being replicated by hundreds of physicians in commercial cases all over the U.S. These clinical results, when combined with other key features of our SNM System such as a 15+ year life, recharging only once per month for an hour, full-body MRI compatibility, and ease of use create significant and distinct advantages over the competitive offering. The overwhelmingly positive feedback from physicians, their staff and patients on their experience with Axonics supports our conviction that SNM is poised for significant market expansion in the years ahead.”

Second Quarter 2020 Financial Results

- Net revenue was \$15.2 million in the second quarter 2020, as compared to net revenue of \$1.5 million for the same period of the prior year. Net revenue from the U.S. accounted for \$14.6 million, with select European markets and Canada accounting for the balance of second quarter 2020 revenue.
- Gross margin was 44.4% in the second quarter 2020, as compared to 48.1% for the same period of the prior year. The decrease in gross margin was primarily due to lower overhead absorption related to the COVID-19 pandemic in second quarter 2020. Management anticipates gross margin will return to the low to mid sixty percent range in the second half of 2020 and anticipates the low to mid seventy percent range over the longer-term.
- Operating expenses were \$26.2 million in the second quarter 2020, as compared to \$20.0 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 \$19.8 million in the second quarter 2020, as compared to a net loss of \$19.1 million for the same period of the prior year. Cash used in operating activities in the second quarter 2020 was \$13.0 million.
- As of June 30, 2020, cash and cash equivalents were \$288 million.

Webcast and Conference Call

Axonics will host a conference call today, August 6, 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 2397731.

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.

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

	June 30, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	\$ 287,679	\$ 171,082
Short-term investments	—	12,592
Accounts receivable, net of allowance for doubtful accounts of \$589 and \$75 at June 30, 2020 and December 31, 2019, respectively	14,115	7,879
Inventory, net	30,138	15,659
Prepaid expenses and other current assets	3,573	4,468
Total current assets	335,505	211,680
Property and equipment, net	5,562	3,047
Intangible asset, net	254	311
Other assets	7,415	4,784
Total assets	\$ 348,736	\$ 219,822
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 10,728	\$ 5,882
Accrued liabilities	3,961	2,174
Accrued compensation and benefits	5,289	3,375
Operating lease liability, current portion	851	602
Debt, current portion	10,000	—
Total current liabilities	30,829	12,033
Operating lease liability, net of current portion	9,261	4,450
Debt, net of unamortized debt issuance costs, net of current portion	10,750	20,336
Total liabilities	50,840	36,819
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Common stock, par value \$0.0001, 50,000,000 shares authorized at June 30, 2020 and December 31, 2019; 39,462,405 and 34,110,995 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	4	3
Additional paid-in capital	512,588	363,012
Accumulated deficit	(213,983)	(179,584)
Accumulated other comprehensive loss	(713)	(428)
Total stockholders' equity	297,896	183,003
Total liabilities and stockholders' equity	\$ 348,736	\$ 219,822

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net revenue	\$ 15,213	\$ 1,488	\$ 41,509	\$ 2,565
Cost of goods sold	8,463	772	18,358	1,320
Gross profit	6,750	716	23,151	1,245
Operating Expenses				
Research and development	6,398	4,874	13,282	9,093
General and administrative	5,537	4,362	13,190	8,377
Sales and marketing	14,220	10,750	30,789	16,664
Total operating expenses	26,155	19,986	57,261	34,134
Loss from operations	(19,405)	(19,270)	(34,110)	(32,889)
Other Income (Expense)				
Interest income	65	839	707	1,873
Interest and other expense	(443)	(629)	(995)	(1,161)
Other income (expense), net	(378)	210	(288)	712
Loss before income tax expense	(19,783)	(19,060)	(34,398)	(32,177)
Income tax expense	—	1	1	1
Net loss	(19,783)	(19,061)	(34,399)	(32,178)
Foreign currency translation adjustment	(108)	(43)	(285)	(53)
Comprehensive loss	\$ (19,891)	\$ (19,104)	\$ (34,684)	\$ (32,231)
Net loss per share, basic and diluted	\$ (0.54)	\$ (0.68)	\$ (0.98)	\$ (1.15)
Weighted-average shares used to compute basic and diluted net loss per share	36,440,846	27,945,393	35,040,180	27,887,121