
**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 5, 2019

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 5, 2019, Axonics Modulation Technologies, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 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 August 5, 2019</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: August 5, 2019

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics® Announces Second Quarter 2019 Financial Results and Operational Update

IRVINE, CA – August 5, 2019 – Axonics Modulation Technologies, Inc. (NASDAQ: AXNX), a medical technology company that has developed and is commercializing a novel implantable Sacral Neuromodulation (“SNM”) device for the treatment of urinary and bowel dysfunction, reported today financial results for the second quarter ended June 30, 2019, and provided an update on operational initiatives.

Recent Business Highlights

- Net sales of the Axonics r-SNM® System¹ from international markets totaled \$1.5 million in the second quarter of 2019 a sequential increase of \$0.4 million in sales or approximately 38% from the 2019 first quarter. This compares to \$12 thousand in revenue in the same period last year.
- Hiring and training of the U.S. commercial team is complete, now numbering 146 individuals, including 100 sales professionals, 11 regional sales managers and 35 clinical specialists.
- Commercial efforts in Europe were focused in England, the Netherlands and Germany, gaining an estimated 30% of the market for new patient SNM implants in England in the second quarter of 2019. A total of 25 hospitals in these markets are now implanting the Axonics r-SNM System.
- European commercial team expanded by three clinical specialists to support cases in England and the Netherlands and one sales representative in Switzerland.
- ARTISAN-SNM pivotal clinical study results were published in the Journal of Urology. The results provide the highest response rate for SNM therapy published in clinical literature to date.
- The U.S. Food and Drug Administration (“FDA”) approved full-body magnetic resonance imaging (“MRI”) scans for ARTISAN-SNM study patients in the U.S.
- Announced top-line results from one-year follow-up on patients in the ARTISAN-SNM pivotal clinical study. At one year, 89% of implanted subjects were therapy responders, consistent with the 90% therapy responder rate reported at six months. These data demonstrate durable, statistically significant improvements in urinary urgency incontinence symptoms and quality of life.

Raymond W. Cohen, CEO of Axonics, commented, “The generation of \$1.5 million of revenue in the second quarter demonstrates continued progress and satisfaction with our product from patients and physician implanters. During this quarter, we expanded our market reach in England and had a meaningful contribution from a hospital in Germany. We estimate that one center in Western Canada, that is exclusively implanting Axonics devices, accounted for nearly one-third of all new patient implants in all of Canada in the second quarter.”

Cohen continued, “With respect to FDA approval, we have been engaged in regular and productive interactions with our reviewers at FDA for both for the urinary and fecal incontinence PMAs. Interactions with the reviewers over the past weeks have been focused on the Summary of Safety and Effectiveness Data (“SSED”) and details relating to the print content that will appear in the various instruction manuals for our product upon regulatory approval. Since we have completed all aspects of the technical, clinical and literature review, inclusive of full-body MRI and inspection of our quality system and manufacturing facility, it is our view that we are nearing the end of the FDA review process. Accordingly, we are confident that FDA approval will come toward the end of the third quarter or early fourth quarter of 2019. In the interim, we continue to build inventory in anticipation of our U.S. launch. We are fully staffed and ready to aggressively compete upon approval.”

¹ The Axonics r-SNM System is currently under PMA review and designated as an investigational medical device in the United States

Second Quarter 2019 Financial Results

Net revenue was \$1.5 million in the second quarter ended June 30, 2019, derived from the sale of the Company's r-SNM Systems to customers in Europe and Canada, as compared to minimal net revenue for the same period of last year.

Gross margin was 48.1% in the second quarter.

Operating expense was \$20.0 million for the second quarter of 2019, as compared to \$8.6 million in the prior-year quarter. This increase was primarily due to higher personnel costs for the U.S. commercial team and across the organization related to increased headcount in anticipation of the commercial launch of the Company's r-SNM System in the U.S., as well as the higher costs associated with operating as a public company.

Net loss for the second quarter of 2019 was \$19.1 million, as compared to \$8.6 million in the prior-year quarter. Net loss per share was \$0.68 per share.

As of June 30, 2019, cash, cash equivalents and short-term investments were \$125.7 million.

Webcast and Conference Call

Today, on Monday August 5, 2019, 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 6687965.

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, CA, has developed and is commercializing a novel implantable SNM device for patients with urinary and bowel dysfunction. 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. SNM therapy is a well-established treatment that has been widely used and reimbursed in the U.S. and Europe for the past two decades. The Axonics r-SNM System is the first rechargeable SNM system approved for sale in Europe, Canada and Australia, and the first SNM system to gain CE mark for full-body MRI conditional labeling. PMA for the r-SNM System is currently pending with the U.S. FDA. For more information, visit the Company's website at www.axonicsmodulation.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.

Contacts:**Axonics' Contact**

Axonics Modulation Technologies, Inc.

Dan Dearen, +1-949-396-6320

President & Chief Financial Officer

ir@axonics.com

Investor & Media Contact

W2Opure

Matt Clawson, +1-949-370-8500

mclawson@w2ogroup.com

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

	June 30, 2019	December 31, 2018
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 82,680	\$ 98,306
Short-term investments	43,001	59,218
Accounts receivable	1,286	427
Inventory	7,975	3,673
Prepaid expenses and other current assets	3,074	3,716
Total current assets	138,016	165,340
Property and equipment, net	3,000	2,784
Intangible asset, net	368	426
Other assets	5,068	3,356
Total assets	\$ 146,452	\$ 171,906
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 3,185	\$ 3,436
Accrued liabilities	3,630	1,683
Lease liability, current portion	588	768
Debt, net of unamortized debt issuance costs, current portion	3,897	—
Total current liabilities	11,300	5,887
Lease liability, net of current portion	4,739	3,281
Debt, net of unamortized debt issuance costs, net of current portion	16,000	19,463
Total liabilities	32,039	28,631
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock, par value \$0.0001, 50,000,000 shares authorized at June 30, 2019 and December 31, 2018; 28,480,743 and 27,806,934 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	3	3
Additional paid-in capital	246,706	243,337
Accumulated deficit	(131,827)	(99,649)
Accumulated other comprehensive loss	(469)	(416)
Total stockholders' equity	114,413	143,275
Total liabilities and stockholders' equity	\$ 146,452	\$ 171,906

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,	
	2019	2018	2019	2018
Net revenue	\$ 1,488	\$ 12	\$ 2,565	\$ 12
Cost of goods sold	772	5	1,320	5
Gross profit	716	7	1,245	7
Operating Expenses				
Research and development	4,874	6,178	9,093	10,721
General and administrative	4,362	1,636	8,377	3,071
Sales and marketing	10,750	811	16,664	1,359
Total operating expenses	19,986	8,625	34,134	15,151
Loss from operations	(19,270)	(8,618)	(32,889)	(15,144)
Other Income (Expense)				
Interest income	839	205	1,873	276
Interest and other expense	(629)	(234)	(1,161)	(383)
Other income (expense), net	210	(29)	712	(107)
Loss before income tax expense	(19,060)	(8,647)	(32,177)	(15,251)
Income tax expense	1	1	1	1
Net loss	(19,061)	(8,648)	(32,178)	(15,252)
Foreign currency translation adjustment	(43)	(2)	(53)	(3)
Comprehensive loss	\$ (19,104)	\$ (8,650)	\$ (32,231)	\$ (15,255)
Net loss per share, basic and diluted	\$ (0.68)	\$ (3.07)	\$ (1.15)	\$ (5.43)
Weighted-average shares used to compute basic and diluted net loss per share	27,945,393	2,819,270	27,887,121	2,811,183