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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): December 11, 2018**

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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.

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

On December 11, 2018, Axonics Modulation Technologies, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2018. 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="#"><u>Press release of Axonics Modulation Technologies, Inc., dated December 11, 2018</u></a>

**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.**

Dated: December 11, 2018

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

# Axonics® Announces Third Quarter 2018 Financial Results and Operational Update

IRVINE, CA – December 11, 2018 – Axonics Modulation Technologies, Inc. (NASDAQ: AXNX), a medical technology company focused on the development and commercialization of novel implantable Sacral Neuromodulation (“SNM”) devices for the treatment of urinary and bowel dysfunction, reported today financial results for the quarter ended September 30, 2018 and provided an update on operational initiatives.

## Recent Business Highlights

- On November 2, completed the initial public offering of Axonics common stock, receiving net proceeds of approximately \$126.3 million after deducting underwriting discounts, commissions and offering expenses.
- On November 29, announced its r-SNM® System was listed on the U.K.’s National Health Service (“NHS”) Supply Chain online catalogue.
- On December 3, submitted a literature-based premarket approval application (“PMA”) to the U.S. Food and Drug Administration (“FDA”) for the Axonics r-SNM System.
- On December 7, the FDA approved an Investigational Device Exemption (“IDE”) supplement regarding the ARTISAN-SNM pivotal clinical study of the Axonics r-SNM System. The ARTISAN-SNM clinical study is intended to serve as primary clinical support for the Company's traditional PMA filing. The supplement proposed, among other things, changing the primary endpoint to an Intent to Treat (“ITT”) analysis on all implanted subjects. In addition, the FDA provided certain feedback with respect to an early analysis of a partial cohort of subjects that have reached their six-month post-implant time point.
- On December 10, announced the U.K.’s National Institute for Health and Care Excellence (“NICE”) published a Medtech Innovation Briefing on the r-SNM System.

Raymond W. Cohen, CEO of Axonics commented, “First and foremost, we are focused on concluding our ARTISAN-SNM pivotal clinical study where we expect all subjects will reach their six-month post-implant endpoint in early January 2019. Gaining FDA approval is the single most important objective for Axonics and, as such, we are aggressively pursuing the literature-based PMA and also continuing to gather clinical data using our IDE study in order to obtain U.S. marketing approval in the shortest possible timeframe.”

Cohen continued, “We are also actively and carefully recruiting and securing talented and experienced sales managers and sales field professionals with approximately 30 of these individuals planning to attend our first formal training program scheduled for mid-January 2019. We have also been opening new accounts and securing both initial and repeat orders for commercial implants of our r-SNM System in Europe and Canada. The NICE briefing indicates key features and benefits of the system and should further aid us in gaining traction in the U.K. following our listing on the NHS online catalogue. Overall, we are making excellent progress on our key operational and clinical initiatives.”

## Third Quarter 2018 Financial Results

Net revenue was \$0.2 million in the third quarter ended September 30, 2018, derived from the sale of the Company's r-SNM Systems to customers in Europe and Canada as compared to net revenue of \$0.1 million for the same period of last year.

Gross margin was 47.5% in the third quarter of 2018 compared to 7.9% gross margin in the prior year period.

Operating expense was \$7.6 million for the third quarter of 2018, as compared to \$4.6 million in the prior-year quarter. This increase was primarily due to increases in legal, personnel, regulatory submissions and clinical development costs.

Net loss for the period was \$7.6 million as compared to \$4.5 million in the prior-year quarter. The net loss per share for the third quarter of 2018 was \$2.67 per share.

As of September 30, 2018, cash and cash equivalents and short-term investments were \$31.2 million.

### **Webcast and Conference Call**

On Tuesday, December 11, 2018, at 4:30 p.m. Eastern Time, the Company will host a conference call with the investment community to discuss the 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 5087907.

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](http://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, is focused on development and commercialization of novel implantable Sacral Neuromodulation devices for patients with urinary and bowel dysfunction. Overactive bladder affects an estimated 87 million adults in the U.S. and Europe. Another approximately 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 Europe and the U.S. for the past two decades. The Axonics r-SNM System is the first rechargeable Sacral Neuromodulation system approved for sale in Europe, Canada and Australia. For more information, visit the Company's website at [www.axonicsmodulation.com](http://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](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.

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

	September 30, 2018 <u>(unaudited)</u>	December 31, 2017
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 20,148	\$ 24,398
Short-term investments	11,069	—
Accounts receivable	219	—
Inventory	2,148	1,541
Prepaid expenses and other current assets	1,751	980
Total current assets	35,335	26,919
Property and equipment, net	2,817	1,530
Intangible asset, net	455	541
Other assets	3,712	422
Total assets	\$ 42,319	\$ 29,412
<b>LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities		
Accounts payable	\$ 1,983	\$ 1,616
Accrued liabilities	2,713	789
Lease liability, current portion	800	—
Total current liabilities	5,496	2,405
Lease liability, net of current portion	3,453	135
Debt, net of unamortized debt issuance costs	9,056	—
Total liabilities	18,005	2,540
Mezzanine Equity		
Convertible Preferred Stock		
Series A Convertible Preferred Stock, par value \$0.0001, 1,030,000 shares authorized, 719,500 shares issued and outstanding at September 30, 2018 and December 31, 2017; aggregate liquidation preference of \$15,829 at September 30, 2018 and December 31, 2017	14,021	14,021
Series B-1 Convertible Preferred Stock, par value \$0.0001, 2,529,862 shares authorized, 1,925,302 shares issued and outstanding at September 30, 2018 and December 31, 2017; aggregate liquidation preference of \$15,248 at September 30, 2018 and December 31, 2017	13,757	13,757
Series B-2 Convertible Preferred Stock, par value \$0.0001, 2,537,231 shares authorized, 2,213,794 shares issued and outstanding at September 30, 2018 and December 31, 2017; aggregate liquidation preference of \$19,481 at September 30, 2018 and December 31, 2017	17,572	17,572

Series C Convertible Preferred Stock, par value \$0.0001, 6,188,888 and 3,888,889 shares authorized at September 30, 2018 and December 31, 2017, respectively; 4,131,546 and 1,898,213 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively; aggregate liquidation preference of \$37,184 and \$17,084 at September 30, 2018 and December 31, 2017, respectively	36,776	16,877
Noncontrolling interest in Axonics Europe, S.A.S.	31,066	31,066
Stockholders' Deficit		
Common Stock, par value \$0.0001, 17,500,000 and 15,000,000 shares authorized at September 30, 2018 and December 31, 2017, respectively; 2,830,591 and 2,776,583 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	—	—
Additional paid-in capital	3,336	2,900
Stock subscriptions receivable	(1,824)	(1,753)
Accumulated deficit	(89,984)	(67,166)
Accumulated other comprehensive loss	(406)	(402)
Total stockholders' deficit	(88,878)	(66,421)
Total liabilities, mezzanine equity and stockholders' deficit	\$ 42,319	\$ 29,412

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Net revenue	\$ 201	\$ 128	\$ 213	\$ 128
Cost of goods sold	106	118	111	118
Gross profit	95	10	102	10
Operating Expenses				
Research and development	3,898	3,132	14,619	8,959
General and administrative	2,790	1,103	5,861	3,520
Sales and marketing	949	368	2,308	767
Total operating expenses	7,637	4,603	22,788	13,246
Loss from operations	(7,542)	(4,593)	(22,686)	(13,236)
Other Income (Expense)				
Interest income	172	79	448	121
Other expense	(196)	(8)	(579)	(13)
Other income (expense), net	(24)	71	(131)	108
Loss before income tax expense	(7,566)	(4,522)	(22,817)	(13,128)
Income tax expense	—	—	1	1
Net loss	(7,566)	(4,522)	(22,818)	(13,129)
Foreign currency translation adjustment	(1)	519	(4)	588
Comprehensive loss	\$ (7,567)	\$ (4,003)	\$ (22,822)	\$ (12,541)
Net loss per share, basic and diluted	\$ (2.67)	\$ (1.67)	\$ (8.10)	\$ (5.26)
Weighted-average shares used to compute basic and diluted net loss per share	2,830,591	2,705,138	2,817,652	2,494,424