Axonics® Announces Third Quarter 2019 Financial Results and Operational Update

November 14, 2019

IRVINE, Calif.--(BUSINESS WIRE)--Nov. 14, 2019-- 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 third quarter ended September 30, 2019, and provided an update on operational initiatives.

Recent Business Highlights

- Net sales of the Axonics r-SNM® System from international markets totaled $1.3 million in the third quarter of 2019 as compared to $0.2 million in revenue in the same period last year.
- Sales in the third quarter were derived primarily from England and the Netherlands along with three hospitals in Germany and three hospitals in Switzerland ordering in the quarter. A total of 32 hospitals in these markets and one in Canada are now implanting the Axonics r-SNM System.
- The first commercial patient was implanted in the United States at the University of California, Irvine on October 29 followed by a few dozen implants primarily for patients with bowel or dual incontinence in the first weeks following the commencement of sales in the U.S.
- During October and November, physician seminars were completed in Orlando, Irvine, Dallas and Boston. These one-day Saturday seminars were attended by 273 U.S.-based SNM implanters. A fifth program has been added in early December to accommodate demand with 46 additional physicians currently registered.
- On November 13, the U.S. Food and Drug Administration ("FDA") approved the Axonics r-SNM ® System for the clinical indication of overactive bladder ("OAB") which includes urinary urge incontinence and urinary urge frequency as well as urinary retention.

Raymond W. Cohen, CEO of Axonics, commented, "We are satisfied with the results of the third quarter considering the fact that a significant number of our small, but growing customer base in Europe did not perform implants in August during the summer holiday season. While we will continue to add new customer accounts in Germany and Switzerland and look to increase implants in England to close out 2019, the Company is now focused on the launch of our product in the U.S. market."

Cohen continued, "Given the attendance at our physician seminar series and enthusiastic response by the SNM implanting community to our product, we have made excellent strides towards establishing Axonics as a serious contender in sacral neuromodulation by bringing innovation and awareness to a therapy that has been underutilized. With respect to FDA approval for urinary clinical indications, we can now begin to communicate the outstanding clinical results of the Axonics r-SNM System. Survey results from the seminar attendees clearly indicate that these physicians place a high value on clinical results and state that when considering what product to offer their patients, efficacy is the single most important factor, followed by a long-lived device. Our 146-person U.S. field team is now able to directly and effectively deliver this message while providing the level of support required to convert customers to Axonics and retain them."

Third Quarter 2019 Financial Results

- Net revenue was $1.3 million in the third quarter ended September 30, 2019 as compared to net revenue of $0.2 million for the same period of last year.
- Gross margin was 51.7%.
- Operating expense was $25.7 million for the third quarter of 2019, as compared to $7.6 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 to support the commercial launch of the Company's r-SNM System in the U.S.
- Net loss for the third quarter of 2019 was $25.0 million, as compared to $7.6 million in the prior-year quarter. Net loss per share was $0.89 per share.
- As of September 30, 2019, cash, cash equivalents and short-term investments were $101.5 million.

Webcast and Conference Call

Today, on Thursday, November 14, 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 4373989.

A live webcast of the call may be accessed by visiting the Events & Presentations page of the Investor Relations 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 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. 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 Modulation Technologies, Inc.

Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

	September 30, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 76,231	$ 98,306
Short-term investments	25,311	59,218
Accounts receivable	954	427
Inventory, net	12,703	3,673
Prepaid expenses and other current assets	2,625	3,716
Total current assets	117,824	165,340
Property and equipment, net	2,952	2,784
Intangible asset, net	340	426
Other assets	4,928	3,356
Total assets	$ 126,044	$ 171,906

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities		
Accounts payable	$ 4,232	$ 3,436
Accrued liabilities	4,304	1,683
Lease liability, current portion	625	768
Debt, net of unamortized debt issuance costs, current portion	6,382	—
Total current liabilities	15,543	5,887
Lease liability, net of current portion	4,573	3,281
Debt, net of unamortized debt issuance costs, net of current portion	13,740	19,463
Total liabilities	33,856	28,631
Stockholders' equity		
Preferred stock, par value $0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, par value $0.0001, 50,000,000 shares authorized at September 30, 2019 and December 31, 2018; 28,633,911 and 27,806,934 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	3	3
Additional paid-in capital	249,599	243,337
Accumulated deficit	(156,833)	(99,649)
Accumulated other comprehensive loss	(581)	(416)
Total stockholders' equity	92,188	143,275
Total liabilities and stockholders' equity	$ 126,044	$ 171,906

Axonics Modulation Technologies, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**

Net revenue	$ 1,309	$ 201	$ 3,874	$ 213
Cost of goods sold	632	106	1,952	111
Gross profit	677	95	1,922	102
Operating Expenses				
Research and development	4,855	3,898	13,948	14,619
General and administrative	5,162	2,790	13,539	5,861
Sales and marketing	15,707	949	32,371	2,308
Total operating expenses	25,724	7,637	59,858	22,788
Loss from operations	(25,047)	(7,542)	(57,936)	(22,686)
Other Income (Expense)				
Interest income	627	172	2,500	448
Interest and other expense	(586)	(196)	(1,747)	(579)
Other income (expense), net	41	(24)	753	(131)
Loss before income tax expense	(25,006)	(7,566)	(57,183)	(22,817)
Income tax expense	—	—	1	1
Net loss	(25,006)	(7,566)	(57,184)	(22,818)
Foreign currency translation adjustment	(112)	(1)	(165)	(4)
Comprehensive loss	$ (25,118)	$ (7,567)	$ (57,349)	$ (22,822)
Net loss per share, basic and diluted	$ (0.89)	$ (2.67)	$ (2.05)	$ (8.10)
Weighted-average shares used to compute basic and diluted net loss per share	28,098,564	2,830,591	27,958,376	2,817,652

Source: Axonics Modulation Technologies, Inc.

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