Axonics® Announces Fourth Quarter and Full Year 2018 Financial Results and Operational Update

March 5, 2019

IRVINE, Calif.--(BUSINESS WIRE)--Mar. 5, 2019-- 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 fourth quarter and year ended December 31, 2018, and provided an update on operational initiatives.

Recent Business Highlights

- In Q4, commercial sales of the miniaturized rechargeable Axonics r-SNM® System totaled $0.5 million.
- On February 11, filed full-body magnetic resonance imaging ("MRI") data with the U.S. Food and Drug Administration ("FDA") seeking conditional labeling for the miniaturized rechargeable Axonics r-SNM System.
- On February 19, disclosed top-line six-month clinical results on the full cohort of patients for the ARTISAN-SNM pivotal clinical study of the Axonics r-SNM System which indicated 90% of all implanted subjects met the efficacy endpoint and that the study met all primary and secondary endpoints.
- On February 21, filed a detailed six-month clinical study report with the FDA on the results of the ARTISAN-SNM pivotal clinical study.
- On February 22, announced CE Mark approval for full-body MRI conditional labeling in Europe for the Axonics r-SNM System, making the Axonics system the first SNM device that allows a safe full-body MRI scan while implanted.
- On March 4, appointed Michael H. Carrel to the Board of Directors.

Raymond W. Cohen, CEO of Axonics, commented, "We view the generation of $0.5 million of revenue in the fourth quarter, serving a handful of customers with a small team of sales professionals, to be a harbinger of things to come. We are seeking measurable market share gains in 2019 from our two primary markets in Europe, the United Kingdom and the Netherlands. The accounts we have secured in these markets are exceeding our expectations in terms of the percentage of SNM implants using the Axonics system. Moreover, we now have the only SNM device with full-body MRI labeling, an advantage that should aid us in gaining further traction."

Cohen continued, "Our primary focus continues to be gaining FDA approval in the shortest possible timeframe. To that end, and based on interaction with the FDA, we determined our best course of action was to further enrich our current literature-based PMA with the full cohort of ARTISAN-SNM study data as well as the full-body MRI data. As we advance our regulatory strategy, we continue to press forward on our initiative to be fully prepared to execute a broad, fully staffed U.S. launch upon FDA approval. We are building a world-class team and have been pleased that many experienced neuromodulation and urology professionals view Axonics as an attractive place to work that represents an exciting career opportunity. Overall, we are making excellent progress on our key operational objectives."

Fourth Quarter 2018 Financial Results

Net revenue was $0.5 million in the fourth quarter ended December 31, 2018, derived from the sale of the Company's r-SNM Systems to customers in Europe and Canada, as compared to no net revenue for the same period of last year.

Gross margin was 50.4% in the fourth quarter of 2018.

Operating expense was $9.7 million for the fourth quarter of 2018, as compared to $4.9 million in the prior-year quarter. This increase was primarily due to higher personnel costs across the organization as well as the costs of operating as a public company.

Net loss for the fourth quarter of 2018 was $9.7 million as compared to $4.9 million in the prior-year quarter. Net loss per share for the fourth quarter of 2018 was $0.50 per share.

As of December 31, 2018, cash, cash equivalents and short-term investments were $157.5 million.

Dan L. Dearen, Axonics President and CFO, said, "We have been actively hiring commercial, operations, regulatory, and quality personnel to ensure we execute on our strategy of fielding a full complement of sales and marketing professionals with sufficient inventory on hand to support a U.S. launch upon FDA approval. To date, we have hired 60 well-qualified sales professionals, 11 regional sales directors and 12 clinical specialists, putting us ahead of schedule and in a good position with the build out of our team and its ability to execute if the approval were to come before our initial projection. The accelerated costs associated with that shift puts us in the best position to achieve our commercial goals when approved."

Full Year 2018 Financial Results

Net revenue was $0.7 million in fiscal year 2018, derived from the sale of the Company's r-SNM Systems to customers in Europe and Canada, as compared to $0.1 million in fiscal year 2017.

Gross margin was 49.7% in fiscal year 2018, compared to 7.9% gross margin in fiscal year 2017. The increase in gross margin is primarily due to country and product mix.

Operating expense was $32.5 million in fiscal year 2018, as compared to $18.2 million in fiscal year 2017. This increase was primarily due to increases in personnel, regulatory submissions and clinical development, contract fabrication and manufacturing, and legal costs.

Net loss for the year was $32.5 million as compared to $18.1 million in the prior year. Net loss per share for fiscal year 2018 was $4.64 per share.

Webcast and Conference Call

Today, on Tuesday, March 5, 2019, 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 3386378.

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, is focused on the 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 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 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, and the first SNM system to gain CE mark for full-body MRI conditional labeling. Premarket Approval (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.

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

	December 31,	
	2018	**2017**
ASSETS		
Current assets		
Cash and cash equivalents	$ 98,306	$ 24,398
Short-term investments	59,218	—
Accounts receivable	427	—
Inventory	3,673	1,541
Prepaid expenses and other current assets	3,716	980
Total current assets	165,340	26,919
Property and equipment, net	2,784	1,530
Intangible asset, net	426	541
Other assets	3,356	422
Total assets	$ 171,906	$ 29,412
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 3,436	$ 1,616
Accrued liabilities	1,683	789
Lease liability, current portion	768	—
Total current liabilities	5,887	2,405
Lease liability, net of current portion	3,281	135
Debt, net of unamortized debt issuance costs	19,463	—
Total liabilities	28,631	2,540
Mezzanine Equity		

Convertible Preferred Stock

Series A Convertible Preferred Stock, par value $0.0001, no shares authorized, issued, and outstanding at December 31, 2018; 1,030,000 shares authorized, 719,500 shares issued and outstanding at December 31, 2017; aggregate liquidation preference of $0 and $15,829 at December 31, 2018 and 2017, respectively	—	14,021
Series B-1 Convertible Preferred Stock, par value $0.0001, no shares authorized, issued, and outstanding at December 31, 2018; 2,529,862 shares authorized, 1,925,302 shares issued and outstanding at December 31, 2017; aggregate liquidation preference of $0 and $15,248 at December 31, 2018 and 2017, respectively	—	13,757
Series B-2 Convertible Preferred Stock, par value $0.0001, no shares authorized, issued, and outstanding at December 31, 2018; 2,537,231 shares authorized, 2,213,794 shares issued and outstanding at December 31, 2017; aggregate liquidation preference of $0 and $19,481 at December 31, 2018 and 2017, respectively	—	17,572
Series C Convertible Preferred Stock, par value $0.0001, no shares authorized, issued, and outstanding at December 31, 2018; 3,888,889 shares authorized, 1,898,213 shares issued and outstanding at December 31, 2017; aggregate liquidation preference of $0 and $17,084 at December 31, 2018 and 2017, respectively	—	16,877
Noncontrolling interest in Axonics Europe, S.A.S.	—	31,066
Stockholders' Equity (Deficit)		
Preferred Stock, par value $0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2018; no shares authorized, issued, and outstanding at December 31, 2017	—	—
Common Stock, par value $0.0001, 50,000,000 and 15,000,000 shares authorized at December 31, 2018 and December 31, 2017, respectively; 27,806,934 and 2,776,583 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	3	—
Additional paid-in capital	243,337	2,900
Stock subscriptions receivable	—	(1,753)
Accumulated deficit	(99,649)	(67,166)
Accumulated other comprehensive loss	(416)	(402)
Total stockholders' equity (deficit)	143,275	(66,421)
Total liabilities, mezzanine equity and stockholders' equity (deficit)	$ 171,906	$ 29,412

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

	Three Months Ended December 31,		Years Ended December 31,	
	2018	2017	2018	2017
Net revenue	$ 494	$ —	$ 707	$ 128
Cost of goods sold	245	—	356	118
Gross profit	249	—	351	10
Operating Expenses				
Research and development	4,783	3,373	19,402	12,332
General and administrative	3,501	1,303	9,362	4,823
Sales and marketing	1,416	262	3,724	1,029
Total operating expenses	9,700	4,938	32,488	18,184
Loss from operations	(9,451)	(4,938)	(32,137)	(18,174)
Other Income (Expense)				
Interest income	550	80	998	201
Loss on disposal of property and equipment	—	(65)	—	(65)
Interest and other expense	(764)	(9)	(1,343)	(22)
Other income (expense), net	(214)	6	(345)	114
Loss before income tax expense	(9,665)	(4,932)	(32,482)	(18,060)
Income tax expense	—	—	1	1
Net loss	(9,665)	(4,932)	(32,483)	(18,061)
Foreign currency translation adjustment	(10)	—	(14)	588
Comprehensive loss	$ (9,675)	$ (4,932)	$ (32,497)	$ (17,473)
Net loss per share, basic and diluted	$ (0.50)	$ (1.78)	$ (4.64)	$ (7.04)
Weighted-average shares used to compute basic and diluted net loss per share	19,402,008	2,776,583	6,997,777	2,564,964

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