Axonics® Announces First Quarter 2019 Financial Results and Operational Update

May 8, 2019

IRVINE, Calif.--(BUSINESS WIRE)--May 8, 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 first quarter ended March 31, 2019, and provided an update on operational initiatives.

Recent Business Highlights

- Net sales of the Axonics r-SNM® System[1] from international markets totaled $1.1 million in the first quarter of 2019, sequentially doubling sales from the 2018 fourth quarter. This compares to no revenue in the same period last year.
- Commercial efforts in Europe were focused in England and the Netherlands, gaining an estimated 25% of the SNM market in England and approximately 30% in the Netherlands of new patient implants in the first quarter of 2019. A total of 23 hospitals in these markets are now implanting the Axonics r-SNM System.
- Presented at the American Urology Association (AUA) Annual Meeting on May 5 the ARTISAN-SNM pivotal clinical study results on the full cohort of patients implanted with the Axonics r-SNM System. The pivotal study results indicated 90% of all implanted subjects met the efficacy endpoint and that the study met all primary and secondary endpoints.
- Achieved CE Mark approval for full-body magnetic resonance imaging ("MRI") conditional labeling in Europe making the Axonics system the first SNM device to allow a full-body MRI scan without being first explanted.
- Filed full-body MRI data with the U.S. Food and Drug Administration ("FDA") seeking conditional labeling upon pre-market approval ("PMA") for the Axonics r-SNM System.
- Filed, during the first week of March 2019, a PMA with the FDA seeking approval for expansion of the market labeling to include the clinical indication of fecal incontinence ("FI").
- Completed an FDA pre-PMA audit and inspection of the Axonics quality system and its manufacturing processes and facility resulting in zero observations.
- Was informed by the FDA, there will be no formal "90-day substantive review letter" issued to Axonics because there are no outstanding deficiencies.
- Appointed Michael H. Carrel, Jane E. Kiernan and Nancy L. Snyderman, M.D. to the Board of Directors.

[1] The Axonics r-SNM System is currently designated as an investigational medical device in the United States

Raymond W. Cohen, CEO of Axonics, commented, "The generation of $1.1 million of revenue in the first quarter shows strong progress and reflects the growing number of centers adopting our r-SNM product. We anticipate continued market share gains from our two primary markets in Europe in 2019, England and the Netherlands, and view those countries as models for engaging and earning market share in the United States upon FDA regulatory approval. While we are clear that the prize is the U.S. market which represents nearly 90 percent of the overall volume in SNM, based on this encouraging start, we do plan to expand our footprint in Europe during 2019 and into 2020. Achieving CE Mark for full-body MRI labeling, along with the unique features of our long-lived neurostimulator, has provided important differentiators as compared to the legacy provider, aiding our modestly-sized field team in gaining access to the most active implanting centers."

Cohen continued, "On the regulatory front, we are engaged in regular and productive interactions with the FDA with our primary focus on gaining approval in the shortest possible timeframe. We have enriched our current PMA with the full cohort of ARTISAN-SNM study data as well as the full-body MRI data. We believe that a significant portion of the FDA review is complete and are confident that FDA approval will come during the second half of 2019. While we push forward for clearance to market in the U.S., we continue to put all the operational, manufacturing and commercial pieces in place to support a broad, fully staffed and immediate U.S. launch upon approval. The internal and U.S. commercial teams continue to be rounded out. Overall, we are making excellent progress on our key operational objectives."

First Quarter 2019 Financial Results

Net revenue was $1.1 million in the first quarter ended March 31, 2019, 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 49.2% in the first quarter of 2019.

Operating expense was $14.1 million for the first quarter of 2019, as compared to $6.5 million in the prior-year quarter. This increase was primarily due to higher personnel costs 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 higher costs associated with operating as a public company.

Net loss for the first quarter of 2019 was $13.1 million as compared to $6.6 million in the prior-year quarter. Net loss per share for the first quarter of 2019 was $0.47 per share.

As of March 31, 2019, cash, cash equivalents and short-term investments were $144.2 million.

Webcast and Conference Call

Today, on Wednesday, May 8, 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 7475517. 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.

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

	March 31, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 89,334	$ 98,306
Short-term investments	54,819	59,218
Accounts receivable	804	427
Inventory	5,064	3,673
Prepaid expenses and other current assets	2,778	3,716
Total current assets	152,799	165,340
Property and equipment, net	2,887	2,784
Intangible asset, net	397	426
Other assets	3,344	3,356
Total assets	$ 159,427	$ 171,906
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,102	$ 3,436
Accrued liabilities	2,364	1,683
Lease liability, current portion	523	768
Debt, net of unamortized debt issuance costs, current portion	1,705	—
Total current liabilities	6,694	5,887
Lease liability, net of current portion	3,476	3,281
Debt, net of unamortized debt issuance costs, net of current portion	17,923	19,463
Total liabilities	28,093	28,631
Stockholders' equity		
Preferred stock, par value $0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Common stock, par value $0.0001, 50,000,000 shares authorized at March 31, 2019 and December 31, 2018; 28,201,091 and 27,806,934 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	3	3
Additional paid-in capital	244,523	243,337
Accumulated deficit	(112,766)	(99,649)
Accumulated other comprehensive loss	(426)	(416)

Total stockholders' equity	131,334	143,275
Total liabilities and stockholders' equity	$ 159,427	$ 171,906

Axonics Modulation Technologies, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Net revenue	$ 1,077	$ —
Cost of goods sold	548	—
Gross profit	529	—
Operating Expenses		
Research and development	4,219	4,543
General and administrative	4,015	1,435
Sales and marketing	5,914	548
Total operating expenses	14,148	6,526
Loss from operations	(13,619)	(6,526)
Other Income (Expense)		
Interest income	1,034	71
Interest and other expense	(532)	(149)
Other income (expense), net	502	(78)
Loss before income tax expense	(13,117)	(6,604)
Income tax expense	—	—
Net loss	(13,117)	(6,604)
Foreign currency translation adjustment	(10)	(1)
Comprehensive loss	$ (13,127)	$ (6,605)
Net loss per share, basic and diluted	$ (0.47)	$ (2.36)
Weighted-average shares used to compute basic and diluted net loss per share	27,828,201	2,802,622

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