
**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): May 6, 2021

Axonics, 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))

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

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.

Item 2.02. Results of Operations and Financial Condition.

On May 6, 2021, Axonics, Inc. (the Company) issued a press release announcing its financial results for the quarter ended March 31, 2021. 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, 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, 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	Press release of Axonics, Inc., dated May 6, 2021
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

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, INC.

Date: May 6, 2021

By:

/s/ Raymond W. Cohen

Raymond W. Cohen
Chief Executive Officer

Axonics® Reports First Quarter 2021 Financial Results

IRVINE, Calif – May 6, 2021 – Axonics, Inc. (Nasdaq: AXNX), a global medical technology company that is developing and commercializing novel products for the treatment of bladder and bowel dysfunction, today reported financial results for the first quarter ended March 31, 2021.

“This quarter’s revenue result reflects growing demand for our long-lived r-SNM® system and Bulkamid® despite the resurgence of COVID cases in the U.S. in early 2021 and ongoing lockdowns in Europe,” said Raymond W. Cohen, CEO of Axonics. “Physician and patient satisfaction remains high and Axonics is poised to take full advantage of the strong growth outlook for sacral neuromodulation as the vaccine rollout continues and we return to a more normalized elective procedure environment.”

Cohen continued, “Response to our recent acquisition of Bulkamid has been overwhelmingly positive. As anticipated, the expanded offering has elevated Axonics’ value proposition to the urology and urogynecology community. Clinicians are enthusiastic to offer this safe and efficacious next-generation bulking agent to women suffering from stress urinary incontinence. Physicians working with Axonics now have a complete set of tools to treat patients presenting with stress urinary incontinence, urge urinary incontinence, mixed incontinence, urge urinary frequency as well as bowel incontinence. Integration and training is ongoing and anticipated to be completed during the second quarter, allowing us to leverage our 250-person field team and position Axonics for a strong second half of 2021.”

First Quarter 2021 Financial Results

- Net revenue was \$34.4 million in the first quarter 2021, an increase of 31% compared to \$26.3 million in the prior year period.
 - Sacral neuromodulation revenue was \$32.9 million, of which \$31.7 million was generated in the U.S. and the remainder in select international markets.
 - Bulkamid revenue for March¹ was \$1.5 million, of which \$0.6 million was generated in the U.S. and the remainder in international markets.
- Gross margin was 59.3% in the first quarter 2021 compared to 62.4% in the prior year period.
- Operating expenses were \$42.0 million in the first quarter 2021 compared to \$31.1 million in the prior year period. Excluding one-time acquisition-related costs and amortization of intangibles, operating expenses were \$36.9 million.
- Net loss was \$22.5 million in the first quarter 2021 compared to a net loss of \$14.6 million in the prior year period.
- As of March 31, 2021, cash and cash equivalents were \$131.0 million.

¹The acquisition of Bulkamid was completed on February 25, 2021. Reported revenue includes sales from February 26, 2021 onwards.

First Quarter 2021 Corporate Highlights

- On January 28, 2021, a manuscript was published online in Neurourology and Urodynamics discussing the two-year outcomes of the ARTISAN-SNM study.
- On February 16, 2021, Axonics announced FDA approval of its third-generation implantable neurostimulator.
- On March 2, 2021, Axonics announced a strategic alliance for the manufacture of its new non-rechargeable implantable sacral neuromodulation device.

Fiscal Year 2021 Financial Outlook

Axonics anticipates fiscal year 2021 net revenue to be in the range of \$176 million to \$180 million, which would represent growth of approximately 58% to 61% compared to fiscal year 2020 net revenue of \$111.5 million.

Webcast and Conference Call

Axonics will host a conference call today, May 6, 2021, at 4:30 p.m. Eastern Time, to discuss financial results and recent business developments. The live teleconference may be accessed by dialing 866-687-5771 (U.S.) or 409-217-8725 (International) and using passcode 3749952.

The live webcast of the conference call may be accessed by visiting the Events & Presentations section of the Axonics investor relations website. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the Axonics website.

About Axonics

Based in Irvine, Calif., Axonics is a global medical technology company that is developing and commercializing novel products for the treatment of bladder and bowel dysfunction. The company's rechargeable sacral neuromodulation (SNM) system provides patients suffering from overactive bladder and/or fecal incontinence with long-lived, easy to use, safe, clinically effective therapy. In addition, Axonics' best-in-class urethral bulking agent, Bulkamid®, provides women suffering from stress urinary incontinence (SUI) with safe and durable symptom relief.

Overactive bladder affects an estimated 87 million adults in the U.S. and Europe, with an additional 40 million adults estimated to suffer from fecal incontinence. SUI affects an estimated 20 million women in the U.S. alone. Axonics' clinically proven products are offered at hundreds of medical centers across the U.S. and abroad. Reimbursement coverage is well established in the U.S. and is a covered service in most European countries. For more information, visit 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.

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

	Three Months Ended	
	March 31,	
	2021	2020
Sacral neuromodulation net revenue	\$ 32,903	\$ 26,296
Bulkamid net revenue	1,470	—
Total net revenue	34,373	26,296
Cost of goods sold	13,974	9,895
Gross profit	20,399	16,401
Operating Expenses		
Research and development	9,369	6,855
General and administrative	6,626	7,653
Sales and marketing	20,928	16,569
Amortization of intangible assets	678	29
Acquisition-related costs	4,414	—
Total operating expenses	42,015	31,106
Loss from operations	(21,616)	(14,705)
Other Income (Expense)		
Interest income	8	642
Interest and other expense	(1,450)	(552)
Other (expense) income, net	(1,442)	90
Loss before income tax expense	(23,058)	(14,615)
Income tax (benefit) expense	(555)	1
Net loss	(22,503)	(14,616)
Foreign currency translation adjustment	(2,202)	(177)
Comprehensive loss	<u>\$ (24,705)</u>	<u>\$ (14,793)</u>
Net loss per share, basic and diluted	\$ (0.57)	\$ (0.43)
Weighted-average shares used to compute basic and diluted net loss per share	39,613,964	33,637,646

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

	March 31, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	\$ 130,962	\$ 241,181
Accounts receivable, net of allowance for doubtful accounts of \$412 and \$465 at March 31, 2021 and December 31, 2020, respectively	21,509	18,270
Inventory, net	71,243	63,060
Prepaid expenses and other current assets	4,658	5,435
Total current assets	228,372	327,946
Property and equipment, net	6,048	6,328
Intangible assets, net	115,023	196
Other assets	8,145	7,736
Goodwill	87,382	—
Total assets	\$ 444,970	\$ 342,206
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 11,446	\$ 10,660
Accrued liabilities	5,868	6,684
Accrued compensation and benefits	5,348	5,948
Operating lease liability, current portion	1,362	1,280
Debt, net of unamortized debt issuance costs, current portion	22	21,110
Total current liabilities	24,046	45,682
Operating lease liability, net of current portion	8,849	9,154
Debt, net of unamortized debt issuance costs, net of current portion	75,171	—
Other long-term liabilities	6,750	—
Total liabilities	114,816	54,836
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock, par value \$0.0001, 50,000,000 shares authorized at March 31, 2021 and December 31, 2020; 41,827,068 and 39,931,030 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	4	4
Additional paid-in capital	589,785	522,296
Accumulated deficit	(257,002)	(234,499)
Accumulated other comprehensive loss	(2,633)	(431)
Total stockholders' equity	330,154	287,370
Total liabilities and stockholders' equity	\$ 444,970	\$ 342,206