
**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 5, 2022

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 5, 2022, Axonics, Inc. (the Company) issued a press release announcing its financial results for the quarter ended March 31, 2022. 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 5, 2022
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 5, 2022

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics® Reports First Quarter 2022 Financial Results

IRVINE, Calif. – May 5, 2022 – 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 three months ended March 31, 2022.

“We are pleased with this quarter’s revenue result considering the significant impact the Omicron surge had on elective procedures in January and February,” said Raymond W. Cohen, chief executive officer of Axonics. “Sacral neuromodulation procedure volumes recovered nicely in March and continued to trend favorably in April. Bulkamid® generated yet another quarter of record revenue and we are delighted to report that over 32,000 women have had their stress urinary incontinence symptoms treated with Bulkamid from the time we acquired the product last year.”

Cohen continued, “In April, we commenced the broad commercial launch of the Axonics F15™, our newly developed, long-lived, recharge-free sacral neuromodulation system. Physician response has been overwhelmingly positive, and we are confident this new recharge-free option will expand the sacral neuromodulation market while also accelerating the conversion of accounts to Axonics. We also recently launched our direct-to-consumer television advertising campaign, which aims to reduce stigma, increase awareness for Axonics therapies, and encourage women to consult and seek treatment from a physician who specializes in bladder and bowel dysfunction. With a full portfolio of incontinence solutions, increased public awareness for our innovative products, and a keen focus on execution, Axonics is well positioned to achieve its mission of treating more adults suffering from incontinence.”

First Quarter 2022 Financial Results

- Net revenue was \$48.4 million in first quarter 2022, an increase of 41% compared to \$34.4 million in the prior year period.
 - Sacral neuromodulation revenue was \$39.1 million, of which \$37.7 million was generated in the U.S. and the remainder in international markets.
 - Bulkamid revenue was \$9.4 million, of which \$6.6 million was generated in the U.S. and the remainder in international markets.
- Gross margin was 68.7% in first quarter 2022 compared to 59.3% in the prior year period.
- Operating expenses were \$56.8 million in first quarter 2022 compared to \$42.0 million in the prior year period.
- Net loss was \$22.7 million in first quarter 2022 compared to net loss of \$22.5 million in the prior year period.
- Cash and cash equivalents were \$213.2 million as of March 31, 2022.

Fiscal Year 2022 Revenue Guidance

Axonics has updated its fiscal year 2022 revenue guidance as follows:

- Total company revenue of \$238 million, an increase of 32% compared to fiscal year 2021. This compares to prior revenue guidance of \$234 million.
- Sacral neuromodulation revenue of \$199 million, an increase of 26% compared to fiscal year 2021.
- Bulkamid revenue of \$39 million, an increase of 72% compared to fiscal year 2021.

Webcast and Conference Call

Axonics will host a conference call today 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 6152315.

A 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 adults with bladder and bowel dysfunction. Axonics recently ranked No. 1 on the 2021 Deloitte Technology Fast 500™ and the 2022 Financial Times ranking of the 500 fastest growing companies in the Americas.

Axonics' sacral neuromodulation (SNM) systems provide patients suffering from overactive bladder and/or fecal incontinence with long-lived, easy to use, safe, clinically effective therapy. In addition, the company's best-in-class urethral bulking hydrogel, Bulkamid®, provides safe and durable symptom relief to women with stress urinary incontinence (SUI). 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 29 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.

Axonics contact:

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

	<u>March 31, 2022</u>	<u>December 31, 2021</u>
	<u>(unaudited)</u>	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 213,180	\$ 220,878
Accounts receivable, net of allowance for credit losses of \$316 and \$355 at March 31, 2022 and December 31, 2021, respectively	27,425	29,044
Inventory, net	61,876	64,946
Prepaid expenses and other current assets	4,952	6,449
Total current assets	<u>307,433</u>	<u>321,317</u>
Property and equipment, net	6,907	6,915
Intangible assets, net	101,179	106,469
Other assets	7,494	7,734
Goodwill	102,558	105,510
Total assets	<u>\$ 525,571</u>	<u>\$ 547,945</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 10,390	\$ 7,654
Accrued liabilities	6,246	5,435
Accrued compensation and benefits	7,480	12,413
Operating lease liability, current portion	1,403	1,366
Total current liabilities	<u>25,519</u>	<u>26,868</u>
Operating lease liability, net of current portion	8,686	9,052
Deferred tax liabilities, net	17,564	19,217
Other long-term liabilities	10,370	10,370
Total liabilities	<u>62,139</u>	<u>65,507</u>
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock, par value \$0.0001, 50,000,000 shares authorized at March 31, 2022 and December 31, 2021; 47,002,862 and 46,330,167 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	5	5
Additional paid-in capital	812,141	803,559
Accumulated deficit	(337,234)	(314,566)
Accumulated other comprehensive loss	(11,480)	(6,560)
Total stockholders' equity	<u>463,432</u>	<u>482,438</u>
Total liabilities and stockholders' equity	<u>\$ 525,571</u>	<u>\$ 547,945</u>

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

	Three Months Ended	
	March 31,	
	2022	2021
Net revenue	\$ 48,420	\$ 34,373
Cost of goods sold	15,178	13,974
Gross profit	33,242	20,399
Operating expenses		
Research and development	11,236	9,369
General and administrative	10,013	6,626
Sales and marketing	33,063	20,928
Amortization of intangible assets	2,463	678
Acquisition-related costs	—	4,414
Total operating expenses	56,775	42,015
Loss from operations	(23,533)	(21,616)
Other income (expense)		
Interest income	43	8
Interest and other expense	(289)	(1,450)
Other expense, net	(246)	(1,442)
Loss before income tax benefit	(23,779)	(23,058)
Income tax benefit	(1,111)	(555)
Net loss	(22,668)	(22,503)
Foreign currency translation adjustment	(4,920)	(2,202)
Comprehensive loss	\$ (27,588)	\$ (24,705)
Net loss per share, basic and diluted	\$ (0.50)	\$ (0.57)
Weighted-average shares used to compute basic and diluted net loss per share	45,139,038	39,613,964

Axonics, Inc.
Net Revenue by Product and Region
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2022	2021
Sacral neuromodulation		
United States	\$ 37,715	\$ 31,745
International	1,355	1,158
Sacral neuromodulation total	\$ 39,070	\$ 32,903
Bulkamid		
United States	\$ 6,569	\$ 578
International	2,781	892
Bulkamid total	\$ 9,350	\$ 1,470
Total net revenue	\$ 48,420	\$ 34,373