
**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 1, 2023

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 1, 2023, Axonics, Inc. (the Company) issued a press release announcing its financial results for the quarter ended March 31, 2023. 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 1, 2023
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 1, 2023

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics Reports First Quarter 2023 Financial Results

Generated quarterly revenue of \$70.7 million, an increase of 46% year over year

Fiscal year 2023 revenue guidance increased to \$348 million

IRVINE, Calif. – May 1, 2023 – 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, 2023.

“Our commercial team continues to execute at a high level, generating revenue growth of 46% year over year in the first quarter,” said Raymond W. Cohen, chief executive officer. “Our sacral neuromodulation growth was driven by higher utilization and share gains while Bulkamid® continues to benefit from physicians enthusiastically adopting our durable hydrogel to treat their stress urinary incontinence patients. Based on the strong results generated in the first quarter, we are raising our fiscal year 2023 revenue guidance to \$348 million, representing 27% growth year over year.”

Cohen continued, “We continue to focus on bringing new innovations to the incontinence market, with the goal of increasing the penetration of advanced therapies for this vastly undertreated patient population. In the first quarter, we received FDA approval and commercially launched the Axonics R20™, our fourth-generation rechargeable SNM system that requires recharging just once every six to ten months for one hour. In addition, last week we announced the acquisition of a technology to facilitate easier and faster lead placement during the SNM external trial. We are confident that this commitment to innovation, increasing public awareness, and providing physicians and patients strong clinical support will continue to drive market expansion and advance Axonics on its path to incontinence market leadership.”

1Q23 Financial Results

- Net revenue was \$70.7 million in 1Q23, an increase of 46% compared to the prior year period.
 - Sacral neuromodulation revenue was \$55.2 million, of which \$53.9 million was generated in the U.S. and the remainder in international markets.
 - Bulkamid revenue was \$15.5 million, of which \$11.6 million was generated in the U.S. and the remainder in international markets.
- Gross margin was 74.3% in 1Q23 compared to 68.7% in the prior year period.
- Operating expenses were \$66.9 million in 1Q23 and included a \$1.8 million non-cash charge for the change in fair value of contingent consideration related to the Bulkamid acquisition. Operating expenses were \$56.8 million in the prior year period.
 - Excluding acquisition-related charges, adjusted operating expenses were \$65.1 million in 1Q23.
- Adjusted EBITDA was \$0.9 million in 1Q23 compared to an adjusted EBITDA loss of \$13.4 million in the prior year period.
- Net loss was \$9.2 million in 1Q23 compared to a net loss of \$22.7 million in the prior year period.
- Cash, cash equivalents and short-term investments were \$357 million as of March 31, 2023.

Fiscal Year 2023 Revenue Guidance

Axonics has updated its fiscal year 2023 revenue guidance as follows:

- Total company revenue of \$348 million, an increase of 27% compared to fiscal year 2022.
 - This compares to initial fiscal year 2023 revenue guidance of \$342 million.
- Sacral neuromodulation revenue of \$280.5 million, an increase of 26% compared to fiscal year 2022.
- Bulkamid revenue of \$67.5 million, an increase of 31% compared to fiscal year 2022.

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. To access the conference call by telephone, interested parties may register at the following link: [Axonics 1Q23 registration](#).

For those not planning to ask a question, the company recommends accessing the conference call by webcast at the following link: [Axonics 1Q23 webcast](#). A replay of the webcast will be archived in the Events section of the Axonics investor relations website.

About Axonics

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. 2 on the 2023 Financial Times ranking of the fastest growing companies in the Americas and No. 4 on the 2022 Deloitte Technology Fast 500.

Axonics® sacral neuromodulation systems provide adults with 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. In the U.S., moderate to severe urinary incontinence affects an estimated 28 million women and fecal incontinence affects an estimated 19 million adults. 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 "plans," "expects," "believes," "anticipates," "designs," 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.

Use of Non-GAAP Financial Measures

To supplement Axonics' consolidated financial statements prepared in accordance with generally accepted accounting principles (GAAP), Axonics provides certain non-GAAP financial measures in this release as supplemental financial metrics.

Adjusted EBITDA is calculated as net income (loss) before other income/expense (including interest), income tax expense (benefit), depreciation and amortization expense, stock-based compensation expense, acquisition-related costs, loss on disposal of property and equipment, and expense related to impairment of intangible assets. Management believes that in order to properly understand short-term and long-term financial trends, investors may want to consider the impact of these excluded items in addition to GAAP measures. The excluded items vary in frequency and/or impact on our results of operations and management believes that the excluded items are typically not reflective of our ongoing core business operations and financial condition. Further, management uses adjusted EBITDA for both strategic and annual operating planning. A reconciliation of adjusted EBITDA reported in this release to the most comparable GAAP measure for the respective periods appears in the table captioned "Reconciliation of GAAP Net Income (Loss) to Adjusted EBITDA" later in this release.

The non-GAAP financial measures used by Axonics may not be the same or calculated in the same manner as those used and calculated by other companies. Non-GAAP financial measures have limitations as analytical tools and should not be considered in isolation or as a substitute for Axonics' financial results prepared and reported in accordance with GAAP. We urge investors to review the reconciliation of these non-GAAP financial measures to the comparable GAAP financial measures included in this press release, and not to rely on any single financial measure to evaluate our business.

Axonics contact:

Neil Bhalodkar

949-336-5293

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

	<u>March 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
	<u>(unaudited)</u>	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 240,105	\$ 238,846
Short-term investments	116,957	118,365
Accounts receivable, net of allowance for credit losses of \$322 and \$321 at March 31, 2023 and December 31, 2022, respectively	40,200	44,817
Inventory, net	66,067	55,765
Prepaid expenses and other current assets	6,342	7,282
Total current assets	469,671	465,075
Property and equipment, net	7,017	6,798
Intangible assets, net	85,888	86,253
Other assets	6,534	6,813
Goodwill	96,581	94,414
Total assets	<u>\$ 665,691</u>	<u>\$ 659,353</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 14,737	\$ 9,070
Accrued liabilities	6,640	6,520
Accrued compensation and benefits	8,836	15,495
Operating lease liability, current portion	1,557	1,562
Other current liabilities	34,400	32,600
Total current liabilities	66,170	65,247
Operating lease liability, net of current portion	7,178	7,555
Deferred tax liabilities, net	15,737	16,412
Total liabilities	89,085	89,214
Commitments and contingencies		
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, par value \$0.0001, 75,000,000 shares authorized at March 31, 2023 and December 31, 2022; 50,110,667 and 49,546,727 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	5	5
Additional paid-in capital	982,189	969,545
Accumulated deficit	(383,512)	(374,264)
Accumulated other comprehensive loss	(22,076)	(25,147)
Total stockholders' equity	576,606	570,139
Total liabilities and stockholders' equity	<u>\$ 665,691</u>	<u>\$ 659,353</u>

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

	Three Months Ended March 31,	
	2023	2022
Net revenue	\$ 70,650	\$ 48,420
Cost of goods sold	18,150	15,178
Gross profit	52,500	33,242
Operating expenses		
Research and development	8,056	11,236
General and administrative	12,168	10,013
Sales and marketing	42,654	33,063
Amortization of intangible assets	2,222	2,463
Acquisition-related costs	1,766	—
Total operating expenses	66,866	56,775
Loss from operations	(14,366)	(23,533)
Other income (expense)		
Interest and other income	3,628	43
Interest and other expense	683	(289)
Other income (expense), net	4,311	(246)
Loss before income tax benefit	(10,055)	(23,779)
Income tax benefit	(807)	(1,111)
Net loss	(9,248)	(22,668)
Foreign currency translation adjustment	3,071	(4,920)
Comprehensive loss	\$ (6,177)	\$ (27,588)
Net loss per share, basic and diluted	\$ (0.19)	\$ (0.50)
Weighted-average shares used to compute basic and diluted net loss per share	48,579,084	45,139,038

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

	Three Months Ended March 31,	
	2023	2022
Sacral neuromodulation		
United States	\$ 53,853	\$ 37,715
International	1,305	1,355
Sacral neuromodulation total	\$ 55,158	\$ 39,070
Bulkamid		
United States	\$ 11,613	\$ 6,569
International	3,879	2,781
Bulkamid total	\$ 15,492	\$ 9,350
Total net revenue	\$ 70,650	\$ 48,420

Axonics, Inc.
Reconciliation of GAAP Net Loss to Adjusted EBITDA
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2023	2022
GAAP Net loss	\$ (9,248)	\$ (22,668)
Non-GAAP Adjustments:		
Interest and other income	(3,628)	(43)
Interest and other expense	(683)	289
Income tax benefit	(807)	(1,111)
Depreciation and amortization expense	2,813	3,029
Stock-based compensation expense	10,714	7,138
Acquisition-related costs	1,766	—
Adjusted EBITDA	\$ 927	\$ (13,366)