
**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): March 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))

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.

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

Item 2.02. Results of Operations and Financial Condition.

On March 1, 2023, Axonics, Inc. (the Company) issued a press release announcing its financial results for the quarter and fiscal year ended December 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 (the Exchange Act), 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, or the Exchange Act, 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 March 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: March 1, 2023

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics Reports Fourth Quarter and Fiscal Year 2022 Financial Results

Generated record quarterly revenue of \$86 million, an increase of 62% y/y

Reported fiscal year 2022 revenue of \$274 million, an increase of 52% y/y

Reiterated fiscal year 2023 revenue guidance of \$342 million, an increase of 25% y/y

IRVINE, Calif – (BUSINESS WIRE) – 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 and fiscal year ended December 31, 2022.

“This quarter’s record results reflect the growing demand for our best-in-class incontinence products,” said Raymond W. Cohen, chief executive officer of Axonics. “Our U.S. commercial team is continuing to take advantage of increased patient awareness and the overwhelmingly positive physician response to the Axonics F15™ recharge-free sacral neuromodulation system while leveraging cross selling opportunities with Bulkamid®. Our unique hydrogel generated another record revenue quarter and during 2022, Bulkamid was used to treat over 50,000 women with stress urinary incontinence.”

Cohen continued, “In addition to strong commercial execution, we are encouraged by the measurable operating leverage in our business which produced adjusted EBITDA of \$10 million in the quarter. We continue to make progress on several key initiatives, including our direct-to-consumer advertising campaign, expansion of our in-house manufacturing capabilities that has benefited gross margin, and the recent FDA approval of the Axonics R20™, our fourth-generation rechargeable sacral neuromodulation system. We remain confident that our commitment to innovation, quality and providing physicians and patients strong clinical support will continue to drive market expansion and advance Axonics on its path to incontinence market leadership.”

Fourth Quarter 2022 Financial Results

- Net revenue was \$85.9 million in fourth quarter 2022, an increase of 62% compared to the prior year period.
 - Sacral neuromodulation revenue was \$70.3 million, of which \$69.1 million was generated in the U.S. and the remainder in international markets.
 - Bulkamid revenue was \$15.6 million, of which \$12.3 million was generated in the U.S. and the remainder in international markets.
- Gross margin was 73.3% in fourth quarter 2022 compared to 66.6% in the prior year period.
- Operating expenses were \$66.6 million in fourth quarter 2022 and included a \$2.1 million non-cash charge for the change in fair value of contingent consideration related to the Bulkamid acquisition. Operating expenses were \$53.1 million in the prior year period.
 - Excluding acquisition-related charges, adjusted operating expenses were \$64.5 million in fourth quarter 2022 and \$51.6 million in the prior year period.
- Adjusted EBITDA was \$10.1 million in fourth quarter 2022 compared to an adjusted EBITDA loss of \$6.7 million in the prior year period.
- Net income was \$0.7 million in fourth quarter 2022 compared to a net loss of \$15.2 million in the prior year period.

- Net income in fourth quarter 2022 benefited from \$3.8 million of interest and other income, net.
- Cash, cash equivalents and short-term investments were \$357 million as of December 31, 2022.

Fiscal Year 2022 Financial Results

- Net revenue was \$273.7 million in fiscal year 2022, an increase of 52% compared to the prior year.
 - SNM revenue was \$222.0 million, of which \$216.9 million was generated in the U.S. and the remainder in international markets.
 - Bulkamid revenue was \$51.7 million, of which \$40.2 million was generated in the U.S. and the remainder in international markets.
- Gross margin was 72.2% in fiscal year 2022 compared to 64.2% in the prior year.
- Operating expenses were \$262.6 million in fiscal year 2022 and included \$22.6 million of non-cash charges for the change in fair value of contingent consideration related to the Bulkamid acquisition. Operating expenses were \$187.5 million in the prior year.
 - Excluding acquisition-related charges, adjusted operating expenses were \$240.1 million in fiscal year 2022 and \$180.4 million in the prior year.
- Adjusted EBITDA was \$1.6 million in fiscal year 2022 compared to an adjusted EBITDA loss of \$30.4 million in the prior year.
- Net loss was \$59.7 million in fiscal year 2022 compared to net loss of \$80.1 million in the prior year.

Fiscal Year 2023 Revenue Guidance

Axonics is reiterating its previously announced fiscal year 2023 revenue guidance of \$342 million, which is based on sacral neuromodulation and Bulkamid revenue each growing 25% compared to fiscal year 2022.

- Sacral neuromodulation revenue of \$277.5 million.
- Bulkamid revenue of \$64.5 million.

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. Interested parties may join the conference call by telephone by registering at the following link: [Axonics 4Q22 registration](#). After registering, a confirmation email will be sent that includes the dial-in number and unique access code required to join the conference call by telephone.

For those not planning to ask a question on the conference call, the company recommends joining the live webcast, which can be accessed by visiting the following link: [Axonics 4Q22 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. 1 on the 2022 Financial Times ranking of the 500 fastest growing companies in the Americas and No. 4 on the 2022 Deloitte Technology Fast 500™ following its No. 1 ranking in 2021.

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:

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

	December 31,	
	2022	2021
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 238,846	\$ 220,878
Short-term investments	118,365	—
Accounts receivable, net of allowance for credit losses of \$321 and \$355 at December 31, 2022 and 2021, respectively	44,817	29,044
Inventory, net	55,765	64,946
Prepaid expenses and other current assets	7,282	6,449
Total current assets	465,075	321,317
Property and equipment, net	6,798	6,915
Intangible assets, net	86,253	106,469
Other assets	6,813	7,734
Goodwill	94,414	105,510
Total assets	\$ 659,353	\$ 547,945
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 9,070	\$ 7,654
Accrued liabilities	6,520	5,435
Accrued compensation and benefits	15,495	12,413
Operating lease liability, current portion	1,562	1,366
Other current liabilities	32,600	—
Total current liabilities	65,247	26,868
Operating lease liability, net of current portion	7,555	9,052
Deferred tax liabilities, net	16,412	19,217
Other long-term liabilities	—	10,370
Total liabilities	89,214	65,507
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, par value \$0.0001 per share, 75,000,000 and 50,000,000 shares authorized at December 31, 2022 and 2021, respectively; 49,546,727 and 46,330,167 shares issued and outstanding at December 31, 2022 and 2021, respectively	5	5
Additional paid-in capital	969,545	803,559
Accumulated deficit	(374,264)	(314,566)
Accumulated other comprehensive loss	(25,147)	(6,560)
Total stockholders' equity	570,139	482,438
Total liabilities and stockholders' equity	\$ 659,353	\$ 547,945

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

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
	(unaudited)	(unaudited)	(unaudited)	
Net revenue	\$ 85,918	\$ 53,135	\$ 273,702	\$ 180,290
Cost of goods sold	22,951	17,744	76,037	64,572
Gross profit	62,967	35,391	197,665	115,718
Operating expenses				
Research and development	8,103	10,182	34,410	37,297
General and administrative	10,264	7,937	40,238	30,041
Sales and marketing	43,824	31,338	156,019	105,789
Amortization of intangible assets	2,271	2,147	9,383	7,241
Acquisition-related costs	2,114	1,467	22,561	7,158
Total operating expenses	66,576	53,071	262,611	187,526
Loss from operations	(3,609)	(17,680)	(64,946)	(71,808)
Other income (expense)				
Interest and other income	3,229	16	5,133	40
Loss on disposal of property and equipment	(69)	(91)	(69)	(91)
Interest and other expense	592	102	(2,434)	(7,426)
Other income (expense), net	3,752	27	2,630	(7,477)
Income (loss) before income tax (benefit) expense	143	(17,653)	(62,316)	(79,285)
Income tax (benefit) expense	(522)	(2,487)	(2,618)	782
Net income (loss)	665	(15,166)	(59,698)	(80,067)
Foreign currency translation adjustment	11,038	352	(18,587)	(6,129)
Comprehensive income (loss)	\$ 11,703	\$ (14,814)	\$ (78,285)	\$ (86,196)
Net income (loss) per share, basic	\$ 0.01	\$ (0.29)	\$ (1.28)	\$ (1.86)
Weighted-average shares used to compute basic net income (loss) per share	48,166,003	38,971,859	46,684,478	43,072,298
Net income (loss) per share, diluted	\$ 0.01	\$ (0.29)	\$ (1.28)	\$ (1.86)
Weighted-average shares used to compute basic net income (loss) per share	50,460,039	38,971,859	46,684,478	43,072,298

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

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
SNM				
United States	\$ 69,068	\$ 43,702	\$ 216,861	\$ 153,837
International	1,236	722	5,130	3,753
SNM total	<u>\$ 70,304</u>	<u>\$ 44,424</u>	<u>\$ 221,991</u>	<u>\$ 157,590</u>
Bulkamid				
United States	\$ 12,341	\$ 5,790	\$ 40,178	\$ 12,660
International	3,273	2,921	11,533	10,040
Bulkamid total	<u>\$ 15,614</u>	<u>\$ 8,711</u>	<u>\$ 51,711</u>	<u>\$ 22,700</u>
Total net revenue	<u>\$ 85,918</u>	<u>\$ 53,135</u>	<u>\$ 273,702</u>	<u>\$ 180,290</u>

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

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
GAAP Net income (loss)	\$ 665	\$ (15,166)	\$ (59,698)	\$ (80,067)
Non-GAAP Adjustments:				
Interest and other income	(3,229)	(16)	(5,133)	(40)
Interest and other expense	(592)	(102)	2,434	7,426
Income tax (benefit) expense	(522)	(2,487)	(2,618)	782
Depreciation and amortization expense	2,880	2,643	11,721	9,126
Stock-based compensation expense	8,757	6,844	32,018	25,164
Acquisition-related costs	2,114	1,467	22,561	7,158
Loss on disposal of property and equipment	69	91	69	91
Impairment expense	—	—	287	—
Adjusted EBITDA	<u>\$ 10,142</u>	<u>\$ (6,726)</u>	<u>\$ 1,641</u>	<u>\$ (30,360)</u>