
**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): October 30, 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 October 30, 2023, Axonics, Inc. (the Company) issued a press release announcing its financial results for the quarter ended September 30, 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 October 30, 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: October 30, 2023

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics Reports Third Quarter 2023 Financial Results

Generated quarterly revenue of \$93.1 million, an increase of 32% year over year

Fiscal year 2023 revenue guidance increased to \$362 million

IRVINE, Calif. – October 30, 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 September 30, 2023.

“Our commercial team continues to execute at a high level, generating over 30% revenue growth in the third quarter,” said Raymond W. Cohen, chief executive officer. “Our growth was driven by higher utilization and share of wallet at existing customers and the onboarding of new accounts. Based on the strong results generated in the third quarter, we are raising our fiscal year 2023 revenue guidance to \$362 million, representing growth of 32% year over year.”

Mr. Cohen continued, “In the third quarter, the company also generated adjusted EBITDA of \$14 million and GAAP net income of \$4 million, demonstrating the significant operating leverage of our business. Axonics is growing rapidly and profitably as we advance on our path to incontinence market leadership.”

3Q23 Financial Results

- Net revenue was \$93.1 million in 3Q23, an increase of 32% compared to the prior year period.
 - Sacral neuromodulation revenue was \$73.9 million, of which \$72.2 million was generated in the U.S. and the remainder in international markets.
 - Bulkamid revenue was \$19.2 million, of which \$15.6 million was generated in the U.S. and the remainder in international markets.
- Gross margin was 74.2% in 3Q23 compared to 72.8% in the prior year period.
- Operating expenses were \$69.8 million in 3Q23 compared to \$67.6 million in the prior year period.
 - Excluding acquisition-related costs, adjusted operating expenses were \$59.4 million in the prior year period.
- Adjusted EBITDA was \$14.0 million in 3Q23 compared to \$3.3 million in the prior year period.
- Net income was \$3.9 million in 3Q23 compared to a net loss of \$16.3 million in the prior year period.
- Cash, cash equivalents and short-term investments were \$344.7 million as of September 30, 2023, an increase of \$13.2 million compared to June 30, 2023.

Fiscal Year 2023 Revenue Guidance

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

- Total company revenue of \$362 million, an increase of 32% compared to fiscal year 2022. This compares to prior fiscal year 2023 revenue guidance of \$358 million.
 - Sacral neuromodulation revenue of \$288.5 million, an increase of 30% compared to fiscal year 2022.

- Bulkamid revenue of \$73.5 million, an increase of 42% 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 3Q23 registration](#).

For those not planning to ask a question, the company recommends accessing the conference call by webcast at the following link: [Axonics 3Q23 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. 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, acquired in-process research and development expense, 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)

	September 30, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 147,323	\$ 238,846
Short-term investments	197,393	118,365
Accounts receivable, net of allowance for credit losses of \$380 and \$321 at September 30, 2023 and December 31, 2022, respectively	48,944	44,817
Inventory, net	74,909	55,765
Prepaid expenses and other current assets	6,816	7,282
Total current assets	475,385	465,075
Property and equipment, net	6,556	6,798
Intangible assets, net	80,274	86,253
Other assets	3,245	6,813
Goodwill	95,287	94,414
Total assets	<u>\$ 660,747</u>	<u>\$ 659,353</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 14,666	\$ 9,070
Accrued liabilities	5,962	6,520
Accrued compensation and benefits	12,994	15,495
Operating lease liabilities, current portion	1,971	1,562
Other current liabilities	—	32,600
Total current liabilities	35,593	65,247
Operating lease liabilities, net of current portion	876	7,555
Deferred tax liabilities, net	13,658	16,412
Total liabilities	50,127	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 September 30, 2023 and December 31, 2022	—	—
Common stock, par value \$0.0001, 75,000,000 shares authorized at September 30, 2023 and December 31, 2022; 50,669,203 and 49,546,727 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	5	5
Additional paid-in capital	1,022,052	969,545
Accumulated deficit	(386,926)	(374,264)
Accumulated other comprehensive loss	(24,511)	(25,147)
Total stockholders' equity	610,620	570,139
Total liabilities and stockholders' equity	<u>\$ 660,747</u>	<u>\$ 659,353</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net revenue	\$ 93,100	\$ 70,384	\$ 256,644	\$ 187,784
Cost of goods sold	23,996	19,124	64,850	53,086
Gross profit	69,104	51,260	191,794	134,698
Operating expenses				
Research and development	8,167	7,936	25,172	26,307
General and administrative	11,778	9,389	34,659	29,974
Sales and marketing	47,544	39,751	134,468	112,195
Amortization of intangible assets	2,302	2,317	6,803	7,112
Acquisition-related costs	—	8,242	2,368	20,447
Acquired in-process research & development	—	—	15,447	—
Total operating expenses	69,791	67,635	218,917	196,035
Loss from operations	(687)	(16,375)	(27,123)	(61,337)
Other income (expense)				
Interest and other income	4,271	1,501	12,149	1,904
Interest and other expense	(83)	(1,898)	774	(3,026)
Other income (expense), net	4,188	(397)	12,923	(1,122)
Income (loss) before income tax benefit	3,501	(16,772)	(14,200)	(62,459)
Income tax benefit	(427)	(520)	(1,538)	(2,096)
Net income (loss)	3,928	(16,252)	(12,662)	(60,363)
Foreign currency translation adjustment	(6,185)	(12,057)	636	(29,625)
Comprehensive loss	\$ (2,257)	\$ (28,309)	\$ (12,026)	\$ (89,988)
Net income (loss) per share, basic	\$ 0.08	\$ (0.34)	\$ (0.26)	\$ (1.31)
Weighted-average shares used to compute basic net income (loss) per share	49,244,981	47,208,192	48,973,252	46,185,209
Net income (loss) per share, diluted	\$ 0.08	\$ (0.34)	\$ (0.26)	\$ (1.31)
Weighted-average shares used to compute diluted net income (loss) per share	50,086,491	47,208,192	48,973,252	46,185,209

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Sacral neuromodulation				
United States	\$ 72,212	\$ 55,610	\$ 198,270	\$ 147,793
International	1,737	1,249	5,025	3,894
Sacral neuromodulation total	\$ 73,949	\$ 56,859	\$ 203,295	\$ 151,687
Bulkamid				
United States	\$ 15,579	\$ 11,045	\$ 41,998	\$ 27,837
International	3,572	2,480	11,351	8,260
Bulkamid total	\$ 19,151	\$ 13,525	\$ 53,349	\$ 36,097
Total net revenue	\$ 93,100	\$ 70,384	\$ 256,644	\$ 187,784

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP Net income (loss)	\$ 3,928	\$ (16,252)	\$ (12,662)	\$ (60,363)
Non-GAAP Adjustments:				
Interest and other income	(4,271)	(1,501)	(12,149)	(1,904)
Interest and other expense	83	1,898	(774)	3,026
Income tax benefit	(427)	(520)	(1,538)	(2,096)
Depreciation and amortization expense	3,254	2,921	9,295	8,841
Stock-based compensation expense	11,470	8,218	33,388	23,261
Acquisition-related costs	—	8,242	2,368	20,447
Acquired in-process research & development	—	—	15,447	—
Impairment expense	—	287	—	287
Adjusted EBITDA	\$ 14,037	\$ 3,293	\$ 33,375	\$ (8,501)