
**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): November 7, 2024

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 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 November 7, 2024, Axonics, Inc. (the Company) issued a press release announcing its financial results for the quarter ended September 30, 2024. 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 November 7, 2024
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: November 7, 2024

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics Reports Third Quarter 2024 Financial Results

IRVINE, Calif. – November 7, 2024 – Axonics, Inc. (Nasdaq: AXNX), a medical technology company that develops, manufactures and commercializes innovative and minimally invasive products to treat bladder and bowel dysfunction, today reported financial results for the three months ended September 30, 2024.

“Axonics continued to execute at a high level in the third quarter, generating revenue growth of 25% year over year,” said Raymond W. Cohen, chief executive officer. “Revenue growth for both sacral neuromodulation and Bulkamid® was driven by higher utilization at existing customers and the onboarding of new accounts.”

Mr. Cohen continued, “Our commitment to innovation, quality, direct-to-consumer advertising and providing strong clinical support continues to expand the market for life-changing incontinence therapies and propel Axonics on its path to market leadership. We look forward to the global impact the Axonics portfolio can make as part of Boston Scientific as we endeavor to treat more patients than ever before.”

Third Quarter 2024 Financial Results

- Net revenue was \$116.2 million, an increase of 25% compared to the prior year period.
 - Sacral neuromodulation revenue was \$92.3 million, an increase of 25% compared to the prior year period.
 - Bulkamid revenue was \$23.8 million, an increase of 25% compared to the prior year period.
- Gross margin was 77.2% compared to 74.2% in the prior year period.
- Loss from operations was \$6.3 million and includes \$8 million of one-time legal and acquisition-related costs. This compares to a loss from operations of \$0.7 million in the prior year period.
- Net loss was \$21,000 compared to net income of \$3.9 million in the prior year period.
- Adjusted EBITDA was \$23.6 million compared to \$14.0 million in the prior year period.
- Cash, cash equivalents, short-term investments and restricted cash were \$367 million as of September 30, 2024.

About Axonics

Axonics is a global medical technology company that is developing and commercializing novel products for adults with bladder and bowel dysfunction. Axonics ranked No. 2 on the 2023 Financial Times ranking of the fastest growing companies in the Americas after being ranked No. 1 in 2022.

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, Axonics’ 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.

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 loss before other income/expense (including interest), income tax expense (benefit), depreciation and amortization expense, stock-based compensation expense, acquisition-related costs, cash compensation in lieu of equity compensation due to pending merger, one-time litigation-related expense, 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 (Loss) Income 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.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words like "may," "will," "likely," "should," "expect," "anticipate," "future," "plan," "believe," "intend," "goal," "seek," "endeavor," "estimate," "project," "continue," and variations of such words and similar expressions. These forward-looking statements are not guarantees of future performance and involve risks, assumptions, and uncertainties, including, but not limited to, risks related to: Axonics' ability to consummate the transactions contemplated by the Agreement and Plan of Merger, dated January 8, 2024 (the "Merger Agreement"), by and among Axonics, Boston Scientific Corporation ("Boston Scientific"), and Sadie Merger Sub, Inc., a wholly owned subsidiary of Boston Scientific ("Merger Sub"), providing for the merger of Merger Sub with and into Axonics with Axonics continuing as the surviving company and a wholly owned subsidiary of Boston Scientific (the "Merger"), in a timely manner or at all; the risk that the Merger Agreement may be terminated in circumstances requiring the payment by Axonics of a termination fee; the satisfaction (or waiver) of the conditions to the closing of the Merger; potential delays in consummating the Merger; the occurrence of any event, change or other circumstance or condition that could give rise to termination of the Merger Agreement; Axonics' ability to timely and successfully realize the anticipated benefits of the Merger; the ability to successfully integrate the businesses of Axonics and Boston Scientific; the effect of the announcement or pendency of the Merger on Axonics' current plans, business relationships, operating results and business generally; the effect of limitations placed on Axonics' business under the Merger Agreement; significant transaction costs and unknown liabilities; litigation or regulatory actions related to the Merger Agreement or Merger; FDA or other U.S. or foreign regulatory or legal actions or changes affecting Axonics or Axonics' industry; the results of any ongoing or future legal proceedings, including the litigation with Medtronic, Inc., Medtronic Puerto Rico Operations Co., Medtronic Logistics LLC and Medtronic USA, Inc. (the "Medtronic Litigation"); any termination or loss of intellectual property rights, including as a result of the

Medtronic Litigation; introductions and announcements of new technologies by Axonics, any commercialization partners or Axonics' competitors, and the timing of these introductions and announcements; changes in macroeconomic and market conditions and volatility, including the risk of recession, inflation, supply chain constraints or disruptions and rising interest rates; and economic and market conditions in general and in the medical technology industry specifically, including the size and growth, if any, of Axonics' markets, and risks related to other factors described under "Risk Factors" in other reports and statements filed with the U.S. Securities and Exchange Commission ("SEC"), including Axonics' most recent Annual Report on Form 10-K, which is available on the investor relations section of Axonics' website at www.axonics.com and on the SEC's website at www.sec.gov. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those indicated or anticipated by these forward-looking statements. Therefore, you should not rely on any of these forward-looking statements.

The forward-looking statements included in this press release are made only as of the date of this press release, and except as otherwise required by federal securities law, Axonics does not assume any obligation nor does it intend to publicly update or revise any forward-looking statements to reflect new information, changed circumstances or unanticipated events.

Axonics contact:

Neil Bhalodkar

IR@axonics.com

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

	September 30, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	\$ 239,452	\$ 104,811
Short-term investments	105,773	240,149
Accounts receivable, net of allowance for credit losses of \$1,198 and \$442 at September 30, 2024 and December 31, 2023, respectively	62,644	57,243
Inventory, net	113,861	79,940
Prepaid expenses and other current assets	4,184	9,279
Total current assets	525,914	491,422
Restricted cash	22,082	12,714
Property and equipment, net	20,698	10,760
Intangible assets, net	78,454	81,375
Other assets	22,478	24,235
Goodwill	104,545	99,417
Total assets	\$ 774,171	\$ 719,923
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 20,109	\$ 18,452
Accrued liabilities	5,701	10,527
Accrued compensation and benefits	35,998	15,060
Operating lease liabilities, current portion	2,611	1,777
Total current liabilities	64,419	45,816
Operating lease liabilities, net of current portion	29,900	25,840
Deferred tax liabilities, net	15,363	10,703
Total liabilities	109,682	82,359
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, 2024 and December 31, 2023	—	—
Common stock, par value \$0.0001, 75,000,000 shares authorized at September 30, 2024 and December 31, 2023; 51,110,021 and 50,770,520 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	5	5
Additional paid-in capital	1,063,185	1,033,778
Accumulated deficit	(392,586)	(380,352)
Accumulated other comprehensive loss	(6,115)	(15,867)
Total stockholders' equity	664,489	637,564
Total liabilities and stockholders' equity	\$ 774,171	\$ 719,923

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net revenue	\$ 116,193	\$ 93,100	\$ 322,167	\$ 256,644
Cost of goods sold	26,542	23,996	74,120	64,850
Gross profit	89,651	69,104	248,047	191,794
Operating expenses				
Research and development	13,491	8,167	37,339	25,172
General and administrative	23,761	11,778	55,192	34,659
Sales and marketing	52,972	47,544	160,607	134,468
Amortization of intangible assets	2,221	2,302	6,722	6,803
Acquisition-related costs	3,474	—	9,953	2,368
Acquired in-process research & development	—	—	—	15,447
Total operating expenses	95,919	69,791	269,813	218,917
Loss from operations	(6,268)	(687)	(21,766)	(27,123)
Other income (expense)				
Interest and other income	4,704	4,271	13,379	12,149
Interest and other expense	8	(83)	(83)	774
Other income, net	4,712	4,188	13,296	12,923
(Loss) income before income tax (benefit) expense	(1,556)	3,501	(8,470)	(14,200)
Income tax (benefit) expense	(1,535)	(427)	3,764	(1,538)
Net (loss) income	(21)	3,928	(12,234)	(12,662)
Foreign currency translation adjustment	10,438	(6,185)	9,752	636
Comprehensive income (loss)	\$ 10,417	\$ (2,257)	\$ (2,482)	\$ (12,026)
Net (loss) income per share, basic	\$ (0.00)	\$ 0.08	\$ (0.24)	\$ (0.26)
Weighted-average shares used to compute basic net (loss) income per share	51,088,073	49,244,981	51,010,885	48,973,252
Net (loss) income per share, diluted	\$ (0.00)	\$ 0.08	\$ (0.24)	\$ (0.26)
Weighted-average shares used to compute diluted net (loss) income per share	51,088,073	50,086,491	51,010,885	48,973,252

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Sacral neuromodulation				
United States	\$ 90,072	\$ 72,212	\$ 248,988	\$ 198,270
International	2,277	1,737	6,255	5,025
Sacral neuromodulation total	\$ 92,349	\$ 73,949	\$ 255,243	\$ 203,295
Bulkamid				
United States	\$ 19,050	\$ 15,579	\$ 52,575	\$ 41,998
International	4,794	3,572	14,349	11,351
Bulkamid total	\$ 23,844	\$ 19,151	\$ 66,924	\$ 53,349
Total net revenue	\$ 116,193	\$ 93,100	\$ 322,167	\$ 256,644

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
GAAP Net (loss) income	\$ (21)	\$ 3,928	\$ (12,234)	\$ (12,662)
Non-GAAP Adjustments:				
Interest and other income	(4,704)	(4,271)	(13,379)	(12,149)
Interest and other expense	(8)	83	83	(774)
Income tax (benefit) expense	(1,535)	(427)	3,764	(1,538)
Depreciation and amortization expense	3,215	3,254	9,298	9,295
Stock-based compensation expense	8,231	11,470	26,393	33,388
Acquisition-related costs	3,474	—	9,953	2,368
Cash compensation in lieu of equity compensation due to pending merger	10,404	—	21,586	—
One-time litigation-related expense	4,500	—	4,500	—
Acquired in-process research & development	—	—	—	15,447
Adjusted EBITDA	\$ 23,556	\$ 14,037	\$ 49,964	\$ 33,375