
**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 31, 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 October 31, 2022, Axonics, Inc. (the Company) issued a press release announcing its financial results for the quarter ended September 30, 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 October 31, 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: October 31, 2022

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics® Reports Third Quarter 2022 Financial Results

Generated record quarterly revenue of \$70 million, an increase of 50% year over year

Fiscal year 2022 revenue guidance raised to \$262 million, an increase of 45% year over year

IRVINE, Calif. – October 31, 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 September 30, 2022.

“This quarter’s record revenue result reflects growing demand from physicians and their patients for our best-in-class incontinence products,” said Raymond W. Cohen, chief executive officer of Axonics. “In the third quarter, total revenue increased by 50% compared to the prior year period. Sacral neuromodulation revenue grew 42% year over year, benefiting from the overwhelmingly positive physician response to the commercial launch of the Axonics F15™ recharge-free SNM system. Bulkamid® generated another record revenue quarter and we now expect this product to generate \$50 million of revenue in 2022, which is two years ahead of our original forecast at the time of the acquisition in February 2021.”

Cohen continued, “In addition to strong commercial execution, 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 FDA review for approval of our fourth-generation rechargeable SNM 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.”

Third Quarter 2022 Financial Results

- Net revenue was \$70.4 million in third quarter 2022, an increase of 50% compared to \$46.9 million in the prior year period.
 - Sacral neuromodulation revenue was \$56.9 million, of which \$55.6 million was generated in the U.S. and the remainder in international markets.
 - Bulkamid revenue was \$13.5 million, of which \$11.0 million was generated in the U.S. and the remainder in international markets.
- Gross margin was 72.8% in third quarter 2022 compared to 66.5% in the prior year period.
- Operating expenses were \$67.6 million in third quarter 2022 and includes \$8.2 million of non-cash costs for the change in fair value of contingent consideration related to the acquisition of Bulkamid. Operating expenses were \$47.7 million in the prior year period.
 - Excluding acquisition-related costs, adjusted operating expenses were \$59.4 million in third quarter 2022.
- Net loss was \$16.3 million in third quarter 2022 compared to net loss of \$17.3 million in the prior year period.
- Cash, cash equivalents and short-term investments were \$350 million as of September 30, 2022.

Fiscal Year 2022 Revenue Guidance

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

- Total company revenue of \$262 million, an increase of 45% compared to fiscal year 2021. This compares to prior revenue guidance of \$253 million.

- Sacral neuromodulation revenue of \$212 million, an increase of 35% compared to fiscal year 2021.
- Bulkamid revenue of \$50 million, an increase of 120% 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. To join the conference call by telephone, interested parties are required to register in advance by using the following link: Axonics 3Q22 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 using the following link: Axonics 3Q22 webcast. A replay of the webcast will be available shortly after the conclusion of the conference call and will be archived in the Events section of the Axonics investor relations 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 adults 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 "plans," "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.

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

	September 30, 2022	December 31, 2021
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 241,331	\$ 220,878
Short-term investments	108,682	—
Accounts receivable, net of allowance for credit losses of \$298 and \$355 at September 30, 2022 and December 31, 2021, respectively	36,960	29,044
Inventory, net	57,827	64,946
Prepaid expenses and other current assets	4,561	6,449
Total current assets	449,361	321,317
Property and equipment, net	7,103	6,915
Intangible assets, net	81,787	106,469
Other assets	7,085	7,734
Goodwill	86,942	105,510
Total assets	<u>\$ 632,278</u>	<u>\$ 547,945</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 9,972	\$ 7,654
Accrued liabilities	7,106	5,435
Accrued compensation and benefits	11,742	12,413
Operating lease liability, current portion	1,523	1,366
Other current liabilities	30,500	—
Total current liabilities	60,843	26,868
Operating lease liability, net of current portion	7,960	9,052
Deferred tax liabilities, net	13,957	19,217
Other long-term liabilities	—	10,370
Total liabilities	82,760	65,507
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, par value \$0.0001, 75,000,000 and 50,000,000 shares authorized at September 30, 2022 and December 31, 2021, respectively; 49,479,594 and 46,330,167 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	5	5
Additional paid-in capital	960,627	803,559
Accumulated deficit	(374,929)	(314,566)
Accumulated other comprehensive loss	(36,185)	(6,560)
Total stockholders' equity	549,518	482,438
Total liabilities and stockholders' equity	<u>\$ 632,278</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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net revenue	\$ 70,384	\$ 46,913	\$ 187,784	\$ 127,155
Cost of goods sold	19,124	15,719	53,086	46,828
Gross profit	51,260	31,194	134,698	80,327
Operating expenses				
Research and development	7,936	8,648	26,307	27,115
General and administrative	9,389	7,443	29,974	22,104
Sales and marketing	39,751	28,112	112,195	74,451
Amortization of intangible assets	2,317	2,216	7,112	5,094
Acquisition-related costs	8,242	1,277	20,447	5,691
Total operating expenses	67,635	47,696	196,035	134,455
Loss from operations	(16,375)	(16,502)	(61,337)	(54,128)
Other income (expense)				
Interest income	1,501	9	1,904	24
Interest and other expense	(1,898)	(229)	(3,026)	(7,528)
Other expense, net	(397)	(220)	(1,122)	(7,504)
Loss before income tax (benefit) expense	(16,772)	(16,722)	(62,459)	(61,632)
Income tax (benefit) expense	(520)	528	(2,096)	3,269
Net loss	(16,252)	(17,250)	(60,363)	(64,901)
Foreign currency translation adjustment	(12,057)	(5,138)	(29,625)	(6,481)
Comprehensive loss	\$ (28,309)	\$ (22,388)	\$ (89,988)	\$ (71,382)
Net loss per share, basic and diluted	\$ (0.34)	\$ (0.38)	\$ (1.31)	\$ (1.53)
Weighted-average shares used to compute basic and diluted net loss per share	47,208,192	44,848,023	46,185,209	42,436,061

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Sacral neuromodulation				
United States	\$ 55,610	\$ 39,147	\$ 147,793	\$ 110,135
International	1,249	922	3,894	3,031
Sacral neuromodulation total	\$ 56,859	\$ 40,069	\$ 151,687	\$ 113,166
Bulkamid				
United States	\$ 11,045	\$ 3,921	\$ 27,837	\$ 6,870
International	2,480	2,923	8,260	7,119
Bulkamid total	\$ 13,525	\$ 6,844	\$ 36,097	\$ 13,989
Total net revenue	\$ 70,384	\$ 46,913	\$ 187,784	\$ 127,155