
**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): February 24, 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))

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 February 24, 2022, Axonics, Inc. (the Company) issued a press release announcing its financial results for the quarter and fiscal year ended December 31, 2021. 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 February 24, 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: February 24, 2022

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics® Reports Fourth Quarter and Fiscal Year 2021 Financial Results

Total revenue of \$53.1 million in 4Q21, an increase of 53% year over year

Fiscal year 2022 revenue outlook of \$234 million, an increase of 30% year over year

IRVINE, Calif – February 24, 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 and fiscal year ended December 31, 2021.

“We are proud of our fourth quarter and fiscal year 2021 results considering the disruption Covid-19 has had on elective procedures in the U.S. and around the world,” said Raymond W. Cohen, chief executive officer of Axonics. “In 2021, in addition to strong commercial execution, Axonics made important progress on several strategic initiatives, including the successful acquisition and launch of Bulkamid® in the U.S., growth of our commercial field team, expansion of our in-house manufacturing capabilities, and the FDA submission of our recharge-free SNM system.”

Cohen continued, “We expect to begin shipping our long-lived, recharge-free SNM system in early second quarter following FDA approval. We believe this new device will set a new standard for what is possible in the SNM category. We are also in the final stages of launching a national television direct-to-consumer advertising campaign to broaden awareness for Axonics therapies that treat all forms of incontinence. We remain confident that our commitment to innovation, quality and providing physicians and patients strong support will continue to drive market expansion and advance Axonics on its path to market leadership.”

Fourth Quarter 2021 Financial Results

- Net revenue was \$53.1 million in fourth quarter 2021, an increase of 53% compared to \$34.8 million in the prior year period.
 - Sacral neuromodulation (SNM) revenue was \$44.4 million, of which \$43.7 million was generated in the U.S. and the remainder in select international markets.
 - Bulkamid revenue was \$8.7 million, of which \$5.8 million was generated in the U.S. and the remainder in international markets.
- Gross margin was 66.6% in fourth quarter 2021 compared to 63.6% in the prior year period.
- Operating expenses were \$53.1 million in fourth quarter 2021 compared to \$33.0 million in the prior year period.
- Net loss was \$15.2 million in fourth quarter 2021 compared to a net loss of \$11.3 million in the prior year period.
- As of December 31, 2021, cash and cash equivalents were \$220.9 million.

Fiscal Year 2021 Financial Results

- Net revenue was \$180.3 million in fiscal year 2021, an increase of 62% compared to \$111.5 million in the prior year.
 - SNM revenue was \$157.6 million, an increase of 41% compared to \$111.5 million in the prior year.

- Bulkamid revenue was \$22.7 million. ⁽¹⁾
- Gross margin was 64.2% in fiscal year 2021 compared to 60.2% in the prior year.
- Operating expenses were \$187.5 million in fiscal year 2021 compared to \$120.9 million in the prior year.
- Net loss was \$80.1 million in fiscal year 2021 compared to a net loss of \$54.9 million in the prior year.

⁽¹⁾ The acquisition of Bulkamid was completed on February 25, 2021. Reported revenue includes sales from February 26, 2021 onwards.

Fiscal Year 2022 Revenue Outlook

Axonics continues to closely monitor the impact that the Covid-19 pandemic has had, and continues to have, on elective procedure volumes.

Axonics' fiscal year 2022 revenue outlook is as follows:

- Total company revenue of \$234 million, an increase of 30% compared to fiscal year 2021.
- SNM revenue of \$197 million, an increase of 25% compared to fiscal year 2021.
- Bulkamid revenue of \$37 million, an increase of 63% compared to fiscal year 2021.

Webcast and Conference Call

Axonics will host a conference call today, February 24, 2022, at 4:30 p.m. Eastern Time, to discuss financial results and recent business developments. The live teleconference may be accessed by dialing 866-687-5771 (U.S.) or 409-217-8725 (international) and using passcode 6189042.

A live webcast of the conference call may be accessed by visiting the [Events & Presentations](#) section of the Axonics investor relations website. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the Axonics 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™, a ranking of the 500 fastest-growing technology, media, telecommunications, life sciences, fintech, and energy tech companies in North America.

The company's rechargeable sacral neuromodulation (SNM) system provides patients suffering from 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 (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 "planned," "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.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31,	
	2021	2020
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 220,878	\$ 241,181
Accounts receivable, net of allowance for credit losses of \$355 and \$465 at December 31, 2021 and 2020, respectively	29,044	18,270
Inventory, net	64,946	63,060
Prepaid expenses and other current assets	6,449	5,435
Total current assets	321,317	327,946
Property and equipment, net	6,915	6,328
Intangible assets, net	106,469	196
Other assets	7,734	7,736
Goodwill	105,510	—
Total assets	\$ 547,945	\$ 342,206
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 7,654	\$ 10,660
Accrued liabilities	5,435	6,684
Accrued compensation and benefits	12,413	5,948
Operating lease liability, current portion	1,366	1,280
Debt, net of unamortized debt issuance costs, current portion	—	21,110
Total current liabilities	26,868	45,682
Operating lease liability, net of current portion	9,052	9,154
Deferred tax liabilities, net	19,217	—
Other long-term liabilities	10,370	—
Total liabilities	65,507	54,836
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, par value \$0.0001 per share, 50,000,000 shares authorized at December 31, 2021 and 2020; 46,330,167 and 39,931,030 shares issued and outstanding at December 31, 2021 and 2020, respectively	5	4
Additional paid-in capital	803,559	522,296
Accumulated deficit	(314,566)	(234,499)
Accumulated other comprehensive loss	(6,560)	(431)
Total stockholders' equity	482,438	287,370
Total liabilities and stockholders' equity	\$ 547,945	\$ 342,206

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

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
	(unaudited)	(unaudited)	(unaudited)	
Net revenue	\$ 53,135	\$ 34,783	\$ 180,290	\$ 111,535
Cost of goods sold	17,744	12,652	64,572	44,444
Gross profit	35,391	22,131	115,718	67,091
Operating expenses				
Research and development	10,182	8,111	37,297	29,055
General and administrative	9,404	6,588	32,785	25,551
Sales and marketing	31,338	18,284	105,789	66,130
Amortization of intangible assets	2,147	29	7,241	115
Acquisition-related costs	—	—	4,414	—
Total operating expenses	53,071	33,012	187,526	120,851
Loss from operations	(17,680)	(10,881)	(71,808)	(53,760)
Other income (expense)				
Interest income	16	19	40	761
Loss on disposal of property and equipment	(91)	(41)	(91)	(41)
Interest and other expense	102	(445)	(7,426)	(1,874)
Other income (expense), net	27	(467)	(7,477)	(1,154)
Loss before income tax (benefit) expense	(17,653)	(11,348)	(79,285)	(54,914)
Income tax (benefit) expense	(2,487)	—	782	1
Net loss	(15,166)	(11,348)	(80,067)	(54,915)
Foreign currency translation adjustment	352	183	(6,129)	(3)
Comprehensive loss	\$ (14,814)	\$ (11,165)	\$ (86,196)	\$ (54,918)
Net loss per share, basic and diluted	\$ (0.34)	\$ (0.29)	\$ (1.86)	\$ (1.48)
Weighted-average shares used to compute basic and diluted net loss per share	44,960,262	38,971,859	43,072,298	36,981,335

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

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
	(unaudited)	(unaudited)	(unaudited)	
SNM				
United States	\$ 43,702	\$ 33,709	\$ 153,837	\$ 107,542
International	722	1,074	3,753	3,993
SNM total	\$ 44,424	\$ 34,783	\$ 157,590	\$ 111,535
Bulkamid				
United States	\$ 5,790	\$ —	\$ 12,660	\$ —
International	2,921	—	10,040	—
Bulkamid total	\$ 8,711	\$ —	\$ 22,700	\$ —
Total net revenue	\$ 53,135	\$ 34,783	\$ 180,290	\$ 111,535