
**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 4, 2021

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 November 4, 2021, Axonics, Inc. (the Company) issued a press release announcing its financial results for the quarter ended September 30, 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, 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 4, 2021
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 4, 2021

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics® Reports Third Quarter 2021 Financial Results

IRVINE, Calif – November 4, 2021 – 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 third quarter ended September 30, 2021.

“We are pleased with this quarter’s revenue result considering the significant impact the surge in Covid-19 Delta variant cases had on elective procedure volumes in August and September, in addition to staffing shortages at hospitals and seasonality from summer vacations,” said Raymond W. Cohen, chief executive officer of Axonics. “Bulkamid® posted its highest revenue quarter to date and has proven to be more insulated from Covid-19 impact due to physicians having the option to perform the procedure in their offices.”

Cohen continued, “Over the last four months, we have had the pleasure of hosting 325 physicians at six regional seminars to introduce Bulkamid and provide proctored wet lab training. The programs also provided us with an opportunity to introduce our sacral neuromodulation system to physicians who are less familiar with Axonics and have them hear firsthand from their peers who have already experienced the difference of working with Axonics. The overwhelmingly positive feedback from physicians at these seminars reinforces our confidence that the SNM market will grow considerably once Covid-19 subsides and that Axonics’ best-in-class incontinence solutions will drive durable growth for years to come.”

Third Quarter 2021 Financial Results

- Net revenue was \$46.9 million in third quarter 2021, an increase of 33% compared to \$35.2 million in the prior year period.
 - Sacral neuromodulation (SNM) revenue was \$40.1 million, of which \$39.1 million was generated in the U.S. and the remainder in select international markets.
 - Bulkamid revenue was \$6.8 million, of which \$3.9 million was generated in the U.S. and the remainder in international markets.
- Gross margin was 66.5% in third quarter 2021 compared to 61.9% in the prior year period.
- Operating expenses were \$47.7 million in third quarter 2021 compared to \$30.6 million in the prior year period.
- Net loss was \$17.3 million in third quarter 2021 compared to a net loss of \$9.2 million in the prior year period.
- As of September 30, 2021, cash and cash equivalents were \$228.8 million.

2021 Revenue Guidance

Axonics continues to closely monitor the impact that the Covid-19 pandemic has had, and continues to have, on elective procedure volumes. Based on third quarter results as well as continuing disruptions from Covid-19 and hospital staffing shortages potentially slowing the recovery in elective procedure volumes, Axonics is updating its 2021 guidance as follows:

- Fiscal year 2021 total company revenue of \$177.0 million, an increase of 59% compared to fiscal year 2020.
 - 4Q21 total company revenue of \$49.8 million, an increase of 43% compared to 4Q20.

- Fiscal year 2021 SNM revenue of \$155.2 million, an increase of 39% compared to fiscal year 2020.
 - 4Q21 SNM revenue of \$42.0 million, an increase of 21% compared to 4Q20.
- Fiscal year 2021 Bulkamid revenue of \$21.8 million.
 - 4Q21 Bulkamid revenue of \$7.8 million.

Webcast and Conference Call

Axonics will host a conference call today, November 4, 2021, 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 8798817.

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. 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 agent, 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 20 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.

Axonics contact:

Neil Bhalodkar
Investor Relations
949-336-5293
IR@axonics.com

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

	September 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	\$ 228,797	\$ 241,181
Accounts receivable, net of allowance for doubtful accounts of \$385 and \$465 at September 30, 2021 and December 31, 2020, respectively	26,641	18,270
Inventory, net	70,358	63,060
Prepaid expenses and other current assets	4,433	5,435
Total current assets	330,229	327,946
Property and equipment, net	6,168	6,328
Intangible assets, net	108,302	196
Other assets	7,041	7,736
Goodwill	109,565	—
Total assets	\$ 561,305	\$ 342,206
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 10,512	\$ 10,660
Accrued liabilities	6,424	6,684
Accrued compensation and benefits	9,305	5,948
Operating lease liability, current portion	1,401	1,280
Debt, net of unamortized debt issuance costs, current portion	109	21,110
Total current liabilities	27,751	45,682
Operating lease liability, net of current portion	8,152	9,154
Deferred tax liabilities, net	26,432	—
Other long-term liabilities	8,880	—
Total liabilities	71,215	54,836
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, par value \$0.0001, 50,000,000 shares authorized at September 30, 2021 and December 31, 2020; 46,258,758 and 39,931,030 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	5	4
Additional paid-in capital	796,397	522,296
Accumulated deficit	(299,400)	(234,499)
Accumulated other comprehensive loss	(6,912)	(431)
Total stockholders' equity	490,090	287,370
Total liabilities and stockholders' equity	\$ 561,305	\$ 342,206

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,	
	2021	2020	2021	2020
Net revenue	\$ 46,913	\$ 35,243	\$ 127,155	\$ 76,752
Cost of goods sold	15,719	13,434	46,828	31,792
Gross profit	31,194	21,809	80,327	44,960
Operating Expenses				
Research and development	8,648	7,719	27,115	20,944
General and administrative	8,720	5,773	23,381	18,963
Sales and marketing	28,112	17,057	74,451	47,846
Amortization of intangible assets	2,216	29	5,094	86
Acquisition-related costs	—	—	4,414	—
Total operating expenses	47,696	30,578	134,455	87,839
Loss from operations	(16,502)	(8,769)	(54,128)	(42,879)
Other Expense				
Interest income	9	35	24	742
Interest and other expense	(229)	(434)	(7,528)	(1,429)
Other expense, net	(220)	(399)	(7,504)	(687)
Loss before income tax expense	(16,722)	(9,168)	(61,632)	(43,566)
Income tax expense	528	—	3,269	1
Net loss	(17,250)	(9,168)	(64,901)	(43,567)
Foreign currency translation adjustment	(5,138)	99	(6,481)	(186)
Comprehensive loss	\$ (22,388)	\$ (9,069)	\$ (71,382)	\$ (43,753)
Net loss per share, basic and diluted	\$ (0.38)	\$ (0.24)	\$ (1.53)	\$ (1.20)
Weighted-average shares used to compute basic and diluted net loss per share	44,848,023	38,830,924	42,436,061	36,312,984

Axonics, Inc.
Net Revenue Growth by Product and Geographic Region
(in thousands, except percentages)
(unaudited)

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	% Change	2021	2020	% Change
SNM						
United States	\$ 39,147	\$ 34,139	14.7%	\$ 110,135	\$ 73,833	49.2%
International	922	1,104	(16.5)%	3,031	2,919	3.8%
SNM Total	\$ 40,069	\$ 35,243	13.7%	\$ 113,166	\$ 76,752	47.4%
Bulkamid						
United States	\$ 3,921	\$ —	N/A	\$ 6,870	\$ —	N/A
International	2,923	—	N/A	7,119	—	N/A
Bulkamid Total	\$ 6,844	\$ —	N/A	\$ 13,989	\$ —	N/A
Total net revenue	\$ 46,913	\$ 35,243	33.1%	\$ 127,155	\$ 76,752	65.7%