
**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): August 5, 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 August 5, 2021, Axonics, Inc. (the Company) issued a press release announcing its financial results for the quarter ended June 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 August 5, 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: August 5, 2021

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics® Reports Second Quarter 2021 Financial Results

Total revenue of \$45.9 million in 2Q21, including record SNM revenue of \$40.2 million

Bulkamid® revenue of \$5.7 million in first full quarter since acquisition

Fiscal year 2021 revenue guidance increased to a range of \$186 million to \$188 million

IRVINE, Calif – August 5, 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 second quarter ended June 30, 2021.

“This quarter’s record revenue result reflects the growing demand for our best-in-class incontinence solutions,” said Raymond W. Cohen, chief executive officer of Axonics. “Clinical outcomes and satisfaction with our rechargeable sacral neuromodulation (SNM) system remain high, with over 12,000 patients having been implanted since our U.S. commercial launch in late 2019. Given the strong commercial momentum for both SNM and Bulkamid, we have increased our fiscal year 2021 revenue guidance to be in the range of \$186 million to \$188 million.”

Cohen continued, “During the second quarter, we trained our entire U.S. field team on Bulkamid and are now executing a broad rollout to physicians across the United States. Physician enthusiasm to incorporate this next-generation bulking agent into their practices to treat female stress urinary incontinence is significant as evidenced by our second quarter results and the six fully booked regional seminars we are hosting this summer to provide Bulkamid wet-lab training. In late June, we filed a PMA supplement with the FDA for our new long-lived, non-rechargeable implantable neurostimulator. We anticipate the 10-year life and fully recharge-free system will be a very attractive proposition for patients and physicians. The progress on these key initiatives and the continued expansion of our U.S. commercial team gives us confidence in achieving our ambitious long-term growth objectives.”

Second Quarter 2021 Financial Results

- Net revenue was \$45.9 million in the second quarter 2021, an increase of 202% compared to \$15.2 million in the prior year period.
 - Sacral neuromodulation revenue was \$40.2 million, of which \$39.2 million was generated in the U.S. and the remainder in select international markets.
 - Bulkamid revenue was \$5.7 million, of which \$2.4 million was generated in the U.S. and the remainder in international markets.
- Gross margin was 62.6% in the second quarter 2021 compared to 44.4% in the prior year period.
- Operating expenses were \$44.7 million in the second quarter 2021 compared to \$26.2 million in the prior year period.
- Net loss was \$25.1 million in the second quarter 2021 compared to a net loss of \$19.8 million in the prior year period.
- As of June 30, 2021, cash and cash equivalents were \$231.1 million. In mid-June, Axonics prepaid and terminated its \$75 million term loan with Silicon Valley Bank.

Second Quarter 2021 Corporate Highlights

- On May 14, 2021, Axonics completed a public stock offering of 4,025,000 shares at \$50 per share, generating gross proceeds of \$201.3 million.
- On May 18, 2021, Axonics announced CE Mark approval for its second generation rechargeable INS and wireless patient remote control with *SmartMRI*[™] technology.
- On May 20, 2021, Axonics announced FDA approval allowing the use of detachable extremity coils for patients undergoing 1.5T and 3.0T MRI scans.
- On June 24, 2021, Axonics announced the filing of a PMA supplement with the FDA for its non-rechargeable INS.

Fiscal Year 2021 Revenue Guidance

Axonics is increasing its fiscal year 2021 revenue guidance as follows:

- Total net revenue to be in the range of \$186 million to \$188 million, representing growth of approximately 67% to 69% over fiscal year 2020 net revenue of \$111.5 million. This compares to the prior net revenue outlook of \$176 million to \$180 million.
- Sacral neuromodulation (SNM) net revenue to be in the range of \$166 million to \$168 million.
- Bulkamid net revenue of \$20 million.

Webcast and Conference Call

Axonics will host a conference call today, August 5, 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 3072186.

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 the treatment of 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 women suffering from stress urinary incontinence (SUI) with safe and durable symptom relief.

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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Sacral neuromodulation net revenue	\$ 40,194	\$ 15,213	\$ 73,097	\$ 41,509
Bulkamid net revenue	5,675	—	7,145	—
Total net revenue	45,869	15,213	80,242	41,509
Cost of goods sold	17,135	8,463	31,109	18,358
Gross profit	28,734	6,750	49,133	23,151
Operating Expenses				
Research and development	9,098	6,370	18,467	13,225
General and administrative	8,035	5,537	14,661	13,190
Sales and marketing	25,411	14,220	46,339	30,789
Amortization of intangible assets	2,200	28	2,878	57
Acquisition-related costs	—	—	4,414	—
Total operating expenses	44,744	26,155	86,759	57,261
Loss from operations	(16,010)	(19,405)	(37,626)	(34,110)
Other Income (Expense)				
Interest income	7	65	15	707
Interest and other expense	(5,849)	(443)	(7,299)	(995)
Other expense, net	(5,842)	(378)	(7,284)	(288)
Loss before income tax expense	(21,852)	(19,783)	(44,910)	(34,398)
Income tax expense	3,296	—	2,741	1
Net loss	(25,148)	(19,783)	(47,651)	(34,399)
Foreign currency translation adjustment	859	(108)	(1,343)	(285)
Comprehensive loss	\$ (24,289)	\$ (19,891)	\$ (48,994)	\$ (34,684)
Net loss per share, basic and diluted	\$ (0.59)	\$ (0.54)	\$ (1.16)	\$ (0.98)
Weighted-average shares used to compute basic and diluted net loss per share	42,788,678	36,440,846	41,210,091	35,040,180

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

	June 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	\$ 231,140	\$ 241,181
Accounts receivable, net of allowance for doubtful accounts of \$385 and \$465 at June 30, 2021 and December 31, 2020, respectively	25,646	18,270
Inventory, net	70,391	63,060
Prepaid expenses and other current assets	5,006	5,435
Total current assets	332,183	327,946
Property and equipment, net	5,958	6,328
Intangible assets, net	113,416	196
Other assets	7,324	7,736
Goodwill	106,631	—
Total assets	\$ 565,512	\$ 342,206
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 9,447	\$ 10,660
Accrued liabilities	6,305	6,684
Accrued compensation and benefits	7,198	5,948
Operating lease liability, current portion	1,407	1,280
Debt, net of unamortized debt issuance costs, current portion	30	21,110
Total current liabilities	24,387	45,682
Operating lease liability, net of current portion	8,481	9,154
Debt, net of unamortized debt issuance costs, net of current portion	89	—
Deferred tax liabilities, net	20,626	—
Other long-term liabilities	7,664	—
Total liabilities	61,247	54,836
Stockholders' equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized, no shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Common stock, par value \$0.0001, 50,000,000 shares authorized at June 30, 2021 and December 31, 2020; 46,090,964 and 39,931,030 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	5	4
Additional paid-in capital	788,184	522,296
Accumulated deficit	(282,150)	(234,499)
Accumulated other comprehensive loss	(1,774)	(431)
Total stockholders' equity	504,265	287,370
Total liabilities and stockholders' equity	\$ 565,512	\$ 342,206