

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): March 5, 2024

AXOGEN, INC.
(Exact Name of Registrant as Specified in Charter)

Minnesota
(State or Other Jurisdiction of
Incorporation or Organization)

001-36046
(Commission File Number)

41-1301878
(I.R.S. Employer Identification No.)

13631 Progress Boulevard, Suite 400 Alachua, Florida
(Address of principal executive offices)

32615
(Zip Code)

(386) 462-6800
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- 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 Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, \$0.01 par value	AXGN	The Nasdaq Stock 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 March 5, 2024 Axogen, Inc. (the “Company”) issued a press release announcing its fourth quarter and full year 2023 financial results. A copy of the press release is furnished as Exhibit 99.1.

The information furnished pursuant to Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, 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 liability of such section, nor shall it be incorporated by reference into future filings by the Company under the Securities Act of 1933, as amended (the “Securities Act”), or under the Exchange Act, unless the Company expressly sets forth in such future filing that such information is to be considered “filed” or incorporated by reference therein.

Item 7.01 Regulation FD Disclosure

On March 5, 2024, the Company issued a press release announcing its fourth quarter and full year 2023 financial results. A copy of the press release is furnished as Exhibit 99.1.

The information in this Item 7.01, including 99.1 is being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section and shall not be deemed incorporated by reference into any filing under the Securities Act or Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Axogen Inc. Press Release, dated March 5, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AXOGEN, INC.

Dated: March 5, 2024

By: /s/ Marc Began

Marc Began

Executive Vice President, General Counsel and Chief Compliance Officer



Axogen, Inc Reports 2023 Fourth Quarter and Full-Year Financial Results

ALACHUA and TAMPA, FL –March 5, 2024 –Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today reported financial results and business highlights for the fourth quarter and full-year ended December 31, 2023.

Fourth Quarter 2023 Financial Results and Business Highlights

- Fourth quarter revenue was \$42.9 million, an 18.7% increase compared to the fourth quarter of 2022.
- The Company estimates that revenues from emergent trauma procedures represented approximately half of total revenues during the fourth quarter and grew mid-single digits versus the fourth quarter of 2022.
- The Company estimates that revenues from scheduled non-trauma procedures represented approximately half of total revenues during the fourth quarter and grew more than 25% versus the fourth quarter of 2022.
- Gross margin was 78.7% for the fourth quarter compared to 83.0% in the fourth quarter of 2022.
- Net loss for the quarter was \$3.9 million, or \$0.09 per share, compared to net loss of \$5.4 million, or \$0.13 per share in the fourth quarter of 2022.
- Adjusted net loss for the quarter was \$2.6 million, or \$0.06 per share, compared to adjusted net loss of \$1.1 million, or \$0.03 per share in the fourth quarter of 2022.
- Adjusted EBITDA was \$0.6 million for the quarter, compared to an adjusted EBITDA loss of \$0.7 million in the fourth quarter of 2022.
- The balance of all cash, cash equivalents, and investments on December 31, 2023 was \$37.0 million, as compared to a balance of \$38.6 million on September 30, 2023.

“We are pleased with our solid performance in the fourth quarter, and we are encouraged by the continued momentum we’ve seen in this first quarter,” commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “Looking ahead, we remain focused on further penetrating core accounts by leveraging our growing body of clinical evidence and expanding use cases with our innovative new products and applications. Additionally, we are excited to expand our leadership position in nerve repair with the 2024 Q2 launch of Avive+ Sofit Tissue Matrix, supporting our mission of restoring nerve function and quality of life to patients with peripheral nerve injuries.”

Full-Year Financial Results and Business Highlights

- Full-year 2023 revenue was \$159.0 million, a 14.7% increase compared to 2022 revenue of \$138.6 million.
- Revenue from Core Accounts represents approximately 65% of total revenue.
- Gross margin was 80.4% for the full-year, compared to 82.6% in 2022.
- Net loss for the year was \$21.7 million, or \$0.51 per share, compared to net loss of \$28.9 million, or \$0.69 per share in 2022.
- Adjusted net loss was \$7.3 million for the full-year, or \$0.17 per share, compared to 12.6 million for the full-year, or \$0.30 per share in 2022.
- Adjusted EBITDA loss was \$1.1 million for the full-year, compared to an adjusted EBITDA loss of \$9.3 million for 2022.
- Core Accounts totaled 376, a 13.3% growth over the prior year level of 332.
- Ended the fourth quarter with 116 direct sales representatives compared to 116 at the end of the third quarter and 115 on December 31, 2022.

Summary of Operational and Business Highlights

- We recently completed a productive Pre-BLA meeting with FDA. We have aligned with FDA on a rolling submission process and the content of the modules for submission. We anticipate the filing to be completed in the third quarter of 2024. Subject to ongoing engagement with FDA, we currently believe the submission timetable will allow for a potential approval in mid-2025.
 - In August 2023, we began processing tissue in the new, state-of-the-art biologics processing facility, which provides for up to three times the previous capacity and was designed for long-term growth and expansion.
 - During 2023, we surpassed 100,000 Avance nerve graft implants since launch in 2007.
 - We are continuing to expand our offering in the nerve protection market with the national launch of Axoguard HA+ Nerve Protector™ in 2023 and expect to launch Avive+ Soft Tissue Matrix™ in the second quarter of 2024.
 - We launched Resensation® for implant-based reconstruction allowing us to access an additional 10-15% of the overall breast reconstruction market. As part of this launch, we have established a comprehensive training program to support the adoption of this innovative approach to bring sensation to more patients undergoing mastectomy.
 - We ended the year with 245 peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio.
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2024 Financial Guidance

We expect revenue to be in the range of \$177 million to \$181 million, which represents an annual growth rate of approximately 11% to 14%. Additionally, we anticipate gross margin for the full year to be in the range of 76% to 79%.

Conference Call

The Company will host a conference call and webcast for the investment community today at 8:00 a.m. ET. Investors interested in participating in the conference call by phone may do so by dialing toll free at (877) 407-0993 or use the direct dial-in number at (201) 689-8795. Those interested in listening to the conference call live via the Internet may do so by visiting the Investors page of the Company's website at www.axogeninc.com and clicking on the webcast link.

Following the conference call, a replay will be available in the Investors section of the Company's website at www.axogeninc.com under Investors.

About Axogen

Axogen (AXGN) is the leading Company focused specifically on the science, development, and commercialization of technologies for peripheral nerve regeneration and repair. Axogen employees are passionate about helping to restore peripheral nerve function and quality of life to patients with physical damage or transection to peripheral nerves by providing innovative, clinically proven, and economically effective repair solutions for surgeons and health care providers. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body. Every day, people suffer traumatic injuries or undergo surgical procedures that impact the function of their peripheral nerves. Physical damage to a peripheral nerve, or the inability to properly reconnect peripheral nerves, can result in the loss of muscle or organ function, the loss of sensory feeling, or the initiation of pain.

Axogen's platform for peripheral nerve repair features a comprehensive portfolio of products that are used across two primary application categories: scheduled, non-trauma procedures and emergent trauma procedures. Scheduled procedures are generally characterized as those where a patient is seeking relief from conditions caused by a nerve defect or surgical procedure. These procedures include providing sensation for women seeking breast reconstruction following a mastectomy, nerve reconstruction following the surgical removal of painful neuromas, oral and maxillofacial procedures, and nerve decompression. Emergent procedures are generally characterized as procedures resulting from injuries that are initially present in an ER. These procedures are typically referred to and completed by a specialist either immediately or within a few days following the initial injury.

Axogen's product portfolio includes Avance[®] nerve graft, a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site; Axoguard Nerve Connector[®], a porcine submucosa ECM coaptation aid for tensionless repair of severed peripheral nerves; Axoguard Nerve Protector[®], a porcine submucosa ECM product used to wrap and protect damaged peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments; Axoguard HA+ Nerve Protector[™], a porcine submucosa ECM base layer coated with a proprietary hyaluronate-alginate gel, a next-generation technology designed to enhance nerve gliding and provide short- and long-term protection for peripheral nerve injuries; and Axoguard Nerve Cap[®], a porcine submucosa ECM product used to protect a peripheral nerve end and separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma. The Axogen portfolio of products is available in the

United States, Canada, Germany, the United Kingdom, Spain, South Korea, and several other countries.

For more information, visit www.axogeninc.com.

Cautionary Statements Concerning Forward-Looking Statements

This press release contains “forward-looking” statements as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations or predictions of future conditions, events, or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates,” “projects,” “forecasts,” “continue,” “may,” “should,” “will,” “goals,” and variations of such words and similar expressions are intended to identify such forward-looking statements. Forward-looking statements include the Company's estimates regarding the revenues from scheduled non-trauma procedures and emergent trauma procedures as a portion of the total revenues, Ms. Zaderej's statements on the Company's future focus, the Company's portfolio of clinical data supports the products' efficacy, cost and time savings, the anticipated timing of the full BLA submission and our expectations that the BLA will be approved in mid-2025, the expected timing of the launch of Avive+ Soft Tissue Matrix, our expectations regarding our ability to access an additional 10-15% of the overall breast reconstruction market, as well as statements related to the 2024 financial outlook, including revenue range and gross margins. Actual results or events could differ materially from those described in any forward-looking statements as a result of various factors, including, without limitation, global supply chain issues, hospital staffing issues, product development, product potential, clinical outcomes, regulatory process and approvals, financial performance, sales growth, surgeon and product adoption, market awareness of our products, data validation, our visibility at and sponsorship of conferences and educational events, global business disruption caused by Russia's invasion of Ukraine and related sanctions, recent geopolitical conflicts in the Middle East, potential disruptions due to management transitions, as well as those risk factors described under Part I, Item 1A., “Risk Factors,” of our Annual Report on Form 10-K for the most recently ended fiscal year. Forward-looking statements are not a guarantee of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made and, except as required by applicable law, we assume no responsibility to publicly update or revise any forward-looking statements.

About Non-GAAP Financial Measures

To supplement our consolidated financial statements, we use the non-GAAP financial measures of EBITDA, which measures earnings before interest, income taxes, depreciation and amortization, and Adjusted EBITDA which further excludes non-cash stock compensation expense and litigation and related expenses. We also use the non-GAAP financial measures of Adjusted Net Income or Loss and Adjusted Net Income or Loss Per Common Share - basic and diluted which excludes non-cash stock compensation expense and litigation and related expenses from Net Loss and Net Loss Per Common Share - basic and diluted, respectively. These non-GAAP measures are not based on any comprehensive set of accounting rules or principles and should not be considered a substitute for, or superior to, financial measures calculated in accordance with GAAP, and may be different from non-GAAP measures used by other companies. In addition, these non-GAAP measures should be read in conjunction with our financial statements prepared in accordance with GAAP. The reconciliations of the non-GAAP measures to the most directly comparable financial measures calculated and presented in accordance with GAAP should be carefully evaluated.

We use these non-GAAP financial measures for financial and operational decision-making and as a means to evaluate period-to-period comparisons. We believe that these non-GAAP financial measures provide meaningful supplemental information regarding our performance and that both management and investors benefit from referring to these non-GAAP financial measures in assessing our performance and when planning, forecasting, and analyzing future periods. We believe these non-GAAP financial measures are useful to investors because (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making and (2) they are used by our institutional investors and the analyst community to help them analyze the performance of our business, the Company's cash available for operations, and the Company's ability to meet future capital expenditure and working capital requirements.

Contact:

Axogen, Inc.

Harold D. Tamayo, Vice President of Finance and Investor Relations

htamayo@axogeninc.com

AXOGEN, INC.
CONSOLIDATED BALANCE SHEETS
(unaudited)
December 31, 2023 and 2022
(In Thousands, Except Share and Per Share Amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 31,024	\$ 15,284
Restricted cash	6,002	6,251
Investments	—	33,505
Accounts receivable, net of allowance for doubtful accounts of \$337 and \$650, respectively	25,147	22,186
Inventory	23,020	18,905
Prepaid expenses and other	2,811	1,944
Total current assets	88,004	98,075
Property and equipment, net	88,730	79,294
Operating lease right-of-use assets	15,562	14,369
Intangible assets, net	4,531	3,649
Total assets	\$ 196,827	\$ 195,387
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	28,883	22,443
Current maturities of long-term lease obligations	1,547	1,310
Total current liabilities	30,430	23,753
Long-term debt, net of debt discount and financing fees	46,603	45,712
Long-term lease obligations	21,142	20,405
Debt derivative liabilities	2,987	4,518
Total liabilities	101,162	94,388
Commitments and contingencies - see Note 14		
Shareholders' equity:		
Common stock, \$0.01 par value per share; 100,000,000 shares authorized; 43,124,496 and 42,445,517 shares issued and outstanding	431	424
Additional paid-in capital	376,530	360,155
Accumulated deficit	(281,296)	(259,580)
Total shareholders' equity	95,665	100,999
Total liabilities and shareholders' equity	\$ 196,827	\$ 195,387

AXOGEN, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
Years ended December 31, 2023 , 2022 and 2021
(In Thousands, Except Share and Per Share Amounts)

	2023	2022	2021
Revenues	\$ 159,012	\$ 138,584	\$ 127,358
Cost of goods sold	31,138	24,147	22,931
Gross profit	127,874	114,437	104,427
Costs and expenses:			
Sales and marketing	86,060	80,228	73,328
Research and development	28,333	27,158	24,177
General and administrative	34,943	36,758	32,338
Total costs and expenses	149,336	144,144	129,843
Loss from operations	(21,462)	(29,707)	(25,416)
Other (expense) income:			
Investment income	1,487	569	93
Interest expense	(2,835)	(624)	(1,356)
Change in fair value of derivatives	1,531	1,044	(28)
Other expense	(437)	(230)	(278)
Total other income (expense), net	(254)	759	(1,569)
Net loss	\$ (21,716)	\$ (28,948)	\$ (26,985)
Weighted average common shares outstanding — basic and diluted	42,879,000	42,083,000	41,215,000
Loss per common share — basic and diluted	\$ (0.51)	\$ (0.69)	\$ (0.65)

AXOGEN INC.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three Months and Year Ended December 31, 2023 and 2022
(unaudited)
(In Thousands, Except Per Share Amounts)

	Three Months Ended		Year Ended	
	December 31, 2023	December 31, 2022	December 31, 2023	December 31, 2022
Net loss	\$ (3,893)	\$ (5,415)	\$ (21,716)	\$ (28,948)
Depreciation and amortization expense	1,617	713	4,491	3,093
Investment income	(336)	(397)	(1,487)	(569)
Income tax expense	9	125		189
Interest expense	1,843	(40)	2,835	624
EBITDA - non GAAP	<u>\$ (760)</u>	<u>\$ (5,014)</u>	<u>\$ (15,538)</u>	<u>\$ (25,611)</u>
Non cash stock-based compensation expense	1,327	4,154	14,418	15,591
Litigation and related costs	—	177	—	761
Adjusted EBITDA - non GAAP	<u>\$ 567</u>	<u>\$ (683)</u>	<u>\$ (1,120)</u>	<u>\$ (9,259)</u>
Net loss	\$ (3,893)	\$ (5,415)	\$ (21,716)	\$ (28,948)
Non cash stock-based compensation expense	1,327	4,154	14,418	15,591
Litigation and related costs	—	177	—	761
Adjusted net loss - non GAAP	<u>\$ (2,566)</u>	<u>\$ (1,083)</u>	<u>\$ (7,298)</u>	<u>\$ (12,596)</u>
Weighted average common shares outstanding basic and diluted	<u>43,048,446</u>	<u>42,306,012</u>	<u>42,878,542</u>	<u>42,083,125</u>
Loss per common share — basic and diluted	\$ (0.09)	\$ (0.13)	\$ (0.51)	\$ (0.69)
Non cash stock-based compensation expense	\$ 0.03	\$ 0.10	\$ 0.34	\$ 0.37
Litigation and related costs	\$ —	\$ —	\$ —	\$ 0.02
Adjusted net loss per common share - basis and diluted - non GAAP	<u>\$ (0.06)</u>	<u>\$ (0.03)</u>	<u>\$ (0.17)</u>	<u>\$ (0.30)</u>

AXOGEN, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
Years ended December 31, 2023 2022 and 2021
(In Thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
Balance, December 31, 2020	40,619	\$ 406	\$ 326,390	\$ (203,647)	\$ 123,149
Stock-based compensation	—	—	10,919	—	10,919
Issuance of restricted and performance stock units	254	2	(2)	—	—
Shares surrendered by employees to pay tax withholdings	—	—	—	—	\$ —
Exercise of stock options and employee stock purchase plan	864	9	5,458	—	5,467
Net loss	—	—	—	(26,985)	\$ (26,985)
Balance, December 31, 2021	41,737	417	342,765	(230,632)	112,550
Stock-based compensation	—	—	15,591	—	15,591
Issuance of restricted and performance stock units	343	3	(3)	—	—
Exercise of stock options and employee stock purchase plan	365	4	1,802	—	1,806
Net loss	—	—	—	(28,948)	(28,948)
Balance, December 31, 2022	42,445	424	360,155	(259,580)	100,999
Stock-based compensation	—	—	14,418	—	14,418
Issuance of restricted and performance stock units	369	4	(4)	—	—
Exercise of stock options and employee stock purchase plan	310	3	1,961	—	1,964
Net loss	—	—	—	(21,716)	(21,716)
Balance, December 31, 2023	<u>43,124</u>	<u>\$ 431</u>	<u>\$ 376,530</u>	<u>\$ (281,296)</u>	<u>\$ 95,665</u>

AXOGEN, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2023, 2022 and 2021
(In Thousands)

	2023	2022	2021
Cash flows from operating activities:			
Net loss	\$ (21,716)	\$ (28,948)	\$ (26,985)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	4,218	2,827	2,744
Amortization of right-of-use assets	1,062	1,761	1,795
Amortization of intangible assets	273	265	202
Amortization of debt discount and deferred financing fees	891	891	831
Loss on disposal of equipment	56	—	—
Loss on extinguishment of debt			
Provision for bad debt	(271)	612	(41)
Provision for inventory write-down	1,939	1,769	3,314
Investment losses (gains)	(666)	(228)	68
Change in fair value of derivatives	(1,531)	(1,044)	28
Stock-based compensation	14,418	15,591	10,919
Change in operating assets and liabilities:			
Accounts receivable	(2,691)	(4,639)	(499)
Inventory	(6,054)	(3,656)	(7,478)
Prepaid expenses and other	(867)	(84)	2,435
Accounts payable and accrued expenses	6,509	660	(270)
Operating lease obligations	(1,269)	(1,841)	(463)
Cash paid for interest portion of finance leases	(3)	(2)	(2)
Contract and other liabilities	(14)	—	(3)
Net cash used in operating activities	(5,716)	(16,066)	(13,405)
Cash flows from investing activities:			
Purchase of property and equipment	(13,872)	(20,078)	(27,811)
Economic development grant proceeds	—	—	950
Purchase of investments	(10,203)	(39,247)	(68,699)
Proceeds from sale of investments	44,374	57,300	72,500
Cash payments for intangible assets	(1,046)	(1,175)	(589)
Net cash provided by (used in) investing activities	19,253	(3,200)	(23,649)
Cash flows from financing activities:			
Proceeds from issuance of long-term debt	—	—	15,000
Cash paid for debt portion of finance leases	(10)	(12)	(15)
Proceeds from exercise of stock options and ESPP stock purchases	1,964	1,806	5,467
Net cash provided by financing activities	1,954	1,794	20,452
Net increase (decrease) in cash, cash equivalents, and restricted cash	15,491	(17,472)	(16,602)
Cash, cash equivalents, and restricted cash, beginning of period	21,535	39,007	55,609
Cash, cash equivalents, and restricted cash, end of period	\$ 37,026	\$ 21,535	\$ 39,007