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): May 9, 2023

AXOGEN, INC.

(Exact Name of Registrant as Specified in Charter)

Minnesota	**001-36046**	**41-1301878**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

13631 Progress Boulevard, Suite 400 Alachua, Florida	**32615**
(Address of principal executive offices)	(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 May 9, 2023, Axogen, Inc. (the "Company") issued a press release announcing its first quarter 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 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated May 9, 2023
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: May 9, 2023

By: /s/ Marc Began

Marc Began

Executive Vice President, General Counsel and Chief Compliance Officer

Axogen, Inc Reports 2023 First Quarter Financial Results

ALACHUA and TAMPA, FL – May 9, 2023 – 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 first quarter ended March 31, 2023.

First Quarter Financial Results and Business Highlights

- Net revenue was $36.7 million, an increase of 18% over the first quarter of 2022.
- Gross margin was 81.7%, compared to 82.1% in the first quarter of 2022.
- Net loss of $7.1 million, or $0.17 per share, compared to net loss of $11.5 million, or $0.27 per share in the first quarter of 2022.
- Adjusted net loss of $4.1 million, or $0.10 per share, compared to adjusted net loss of $8.5 million, or $0.20 per share, in the first quarter of 2022.
- Adjusted EBITDA loss of $3.8 million, compared to an adjusted EBITDA loss of $7.4 million in the first quarter of 2022.
- The balance of all cash and cash equivalents and investments on March 31, 2023, was $44.1 million, as compared to $55.0 million on December 31, 2022. The net change includes capital expenditures of $3.3 million related to the construction of the Company's new processing facility in Dayton, OH, and $7.6 million of other cash burn, including approximately $7.2 million of items which typically occur in the first quarter, including bonuses, sales meetings and awards, and insurance premiums.
- In early April, a new comprehensive study was published that analyzed all-payor data of 1,300 procedural costs of nerve injury repairs. The authors' findings indicated that there were no significant differences in procedure cost between autograft and allograft repair. Additionally, the study concluded that there was significant operating room time savings of 41 minutes on average, for allograft compared to autograft in the outpatient setting, where the majority of nerve repairs are performed.

Additionally, on April 7th, the Company received FDA 510(k) clearance for the Axoguard HA+ Nerve Protector™. The category of nerve protection covers a wide range of nerve injuries including compression, crush injuries, complex traumatic injuries where the nerve remains intact, and protecting the coaptation sites of nerve transections. The Company believes that these injury types and their anatomical locations present diverse challenges requiring unique targeted solutions. Axoguard HA+ Nerve Protector adds new proprietary design features, including the benefits of a hyaluronate-alginate

gel layer, which facilitates enhanced nerve gliding to aid in minimizing soft tissue attachments, while the base layer is remodeled into a long-term protective tissue layer. Axoguard HA+ will undergo a pilot launch in the second quarter, followed by a full product launch in the third quarter.

“The strong revenue growth and operational execution of this quarter continues the momentum we achieved in the second half of last year with improved consistency of hospital staffing and surgical capacity," commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “We continue to drive innovation across the broad spectrum of nerve repair solutions. We believe our new Axoguard HA+ Nerve Protector provides enhanced design features and improves our access to the nerve protection category.”

Additional Operational and Business Highlights

- Core Accounts totaled 350, an increase of 5% sequentially, and 23% over an adjusted* prior year level of 285. Revenue from Core Accounts continued to represent approximately 60% of total revenue.
- Active Accounts totaled 994, up 3% sequentially, and 9% over an adjusted* prior year level of 916. Revenue from the top 10% of Active Accounts represents approximately 35% of total revenue.
- Ended the quarter with a total of 220 peer-reviewed clinical publications featuring Axogen’s nerve repair product portfolio, up from 215 the previous quarter.
- Ended the quarter with 116 direct sales representatives, compared to 115 at the end of the fourth quarter of 2022, and compared to 116 one year ago.

2023 Financial Guidance

Management continues to expect full-year 2023 revenue to be in the range of $154 million to $159 million. The Company continues to anticipate that gross margin will be reduced with the transition to its new processing facility and expects gross margins will return to approximately 80% by the fourth quarter of 2023.

*The Company voluntarily suspended market availability of Avive® Soft Tissue Membrane on June 1, 2021; and therefore no Avive revenue was recorded in 2022. Core and Active Account metrics for prior periods were adjusted for Avive revenue. For a reconciliation of adjusted Core and Active Account numbers, please see our Corporate Presentation on the investors page on www.axogeninc.com.

Axoguard HA+ Nerve Protector

The Axoguard HA+ Nerve Protector is a proprietary nerve protection device designed to provide short- and long-term protection for peripheral nerve injuries. The device is comprised of a processed porcine submucosa extracellular matrix (ECM) base layer with a hyaluronate-alginate gel coating. The gel layer facilitates enhanced nerve gliding to aid in minimizing soft tissue attachments, while the base layer is remodeled into a long-term protective tissue layer. It is available in a variety of sizes to meet patient’s and surgeon’s needs.

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 (866) 682-6100 or use the direct dial-in number at (862) 298-0702. 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 atwww.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, including 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; 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.

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 statement on benefits and market opportunities, market launch timetable for Axoguard HA+, as well as statements under the subheading "2023 Financial Guidance." Actual results or events could differ materially from those described in any forward-looking statements as a result of various factors, including, without limitation, statements related to the continued impact of COVID-19, global supply chain issues, record inflation, hospital staffing issues, product development, product potential, expected

clinical enrollment timing and outcomes, regulatory process and approvals, APC renovation timing and expense, 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, 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, and 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 Loss and Adjusted Net 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.
Ed Joyce, Director, Investor Relations
InvestorRelations@axogeninc.com

Axogen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share amounts)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 7,707	$ 15,284
Restricted cash	6,252	6,251
Investments	30,160	33,505
Accounts receivable, net of allowance for doubtful accounts of $383 and $650, respectively	22,278	22,186
Inventory	19,849	18,905
Prepaid expenses and other	2,453	1,944
Total current assets	88,699	98,075
Property and equipment, net	83,049	79,294
Operating lease right-of-use assets	13,868	14,369
Intangible assets, net	3,858	3,649
Total assets	$ 189,474	$ 195,387
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 20,188	$ 22,443
Current maturities of long-term lease obligations	1,050	1,310
Total current liabilities	21,238	23,753
Long-term debt, net of debt discount and financing fees	45,931	45,712
Long-term lease obligations	20,089	20,405
Debt derivative liabilities	4,703	4,518
Total liabilities	91,961	94,388
Commitments and contingencies - see Note 12		
Shareholders' equity:		
Common stock, $0.01 par value per share; 100,000,000 shares authorized; 42,809,994 and 42,445,517 shares issued and outstanding	428	424
Additional paid-in capital	363,739	360,155
Accumulated deficit	(266,654)	(259,580)
Total shareholders' equity	97,513	100,999
Total liabilities and shareholders' equity	$ 189,474	$ 195,387

Axogen, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands, except per share amounts)

	Three Months Ended	
	March 31, 2023	**March 31, 2022**
Revenues	$ 36,664	$ 31,007
Cost of goods sold	6,709	5,546
Gross profit	29,955	25,461
Costs and expenses:		
Sales and marketing	21,618	20,888
Research and development	6,679	6,275
General and administrative	8,999	9,618
Total costs and expenses	37,296	36,781
Loss from operations	(7,341)	(11,320)
Other income (expense):		
Investment income (loss)	549	(46)
Interest expense	(16)	(354)
Change in fair value of derivatives	(185)	252
Other expense	(81)	(7)
Total other income (expense), net	267	(155)
Net loss	$ (7,074)	$ (11,475)
Weighted average common shares outstanding — basic and diluted	42,571,021	41,804,330
Loss per common share — basic and diluted	$ (0.17)	$ (0.27)

Axogen, Inc.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three Months Ended March 31, 2023 and 2022
(unaudited)
(In thousands, except per share amounts)

	Three Months Ended	
	March 31, 2023	**March 31, 2022**
Net loss	$ (7,074)	$ (11,475)
Depreciation and amortization expense	780	773
Investment (income) loss	(549)	46
Income tax expense	83	—
Interest expense	16	354
EBITDA - non GAAP	$ (6,744)	$ (10,302)
Non cash stock-based compensation expense	2,954	2,678
Litigation and related costs	—	267
Adjusted EBITDA - non GAAP	$ (3,790)	$ (7,357)
Net loss	$ (7,074)	$ (11,475)
Non cash stock-based compensation expense	2,954	2,678
Litigation and related costs	—	267
Adjusted net loss - non GAAP	$ (4,120)	$ (8,530)
Weighted average common shares outstanding — basic and diluted	42,571,021	41,804,330
Loss per common share — basic and diluted	$ (0.17)	$ (0.27)
Non cash stock-based compensation expense	0.07	0.06
Litigation and related costs	—	0.01
Adjusted net loss per common share — basic and diluted - non GAAP	$ (0.10)	$ (0.20)

Axogen, Inc.
Condensed Consolidated Statements of Changes in Shareholders' Equity
(unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
Three Months Ended March 31, 2023					
Balance at December 31, 2022	42,445,517	$ 424	$ 360,155	$ (259,580)	$ 100,999
Net loss	—	—	—	(7,074)	(7,074)
Stock-based compensation	—	—	2,954	—	2,954
Issuance of restricted and performance stock units	238,719	3	(3)	—	—
Exercise of stock options and employee stock purchase plan	125,758	1	633	—	634
Balance at March 31, 2023	42,809,994	$ 428	$ 363,739	$ (266,654)	$ 97,513
Three Months Ended March 31, 2022					
Balance at December 31, 2021	41,736,950	$ 417	$ 342,765	$ (230,632)	$ 112,550
Net loss	—	—	—	(11,475)	(11,475)
Stock-based compensation	—	—	2,678	—	2,678
Issuance of restricted and performance stock units	215,287	2	(2)	—	—
Exercise of stock options and employee stock purchase plan	20,750	1	97	—	98
Balance at March 31, 2022	41,972,987	$ 420	$ 345,538	$ (242,107)	$ 103,851

Axogen, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(InThousands)

	Three Months Ended	
	March 31, 2023	**March 31, 2022**
Cash flows from operating activities:		
Net loss	$ (7,074)	$ (11,475)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	709	704
Amortization of right-of-use assets	464	427
Amortization of intangible assets	71	69
Amortization of debt discount and deferred financing fees	219	220
Provision for bad debt	(267)	267
Provision for inventory write-down	581	459
Change in fair value of derivatives	185	(252)
Investment (income) loss	(426)	96
Stock-based compensation	2,954	2,678
Change in operating assets and liabilities:		
Accounts receivable	175	(624)
Inventory	(1,525)	(1,166)
Prepaid expenses and other	(509)	(1,030)
Accounts payable and accrued expenses	(2,442)	(1,104)
Operating lease obligations	(537)	(320)
Cash paid for interest portion of finance leases	(1)	—
Net cash used in operating activities	(7,423)	(11,051)
Cash flows from investing activities:		
Purchase of property and equipment	(4,304)	(5,037)
Purchase of investments	(10,203)	(6,024)
Proceeds from sale of investments	13,974	4,400
Cash payments for intangible assets	(253)	(580)
Net cash used in investing activities	(786)	(7,241)
Cash flows from financing activities:		
Cash paid for debt portion of finance leases	(1)	(2)
Proceeds from exercise of stock options and ESPP stock purchases	634	97
Net cash provided by financing activities	633	95
Net decrease in cash, cash equivalents, and restricted cash	(7,576)	(18,197)
Cash, cash equivalents, and restricted cash, beginning of period	21,535	39,007
Cash, cash equivalents, and restricted cash, end of period	$ 13,959	$ 20,810
Supplemental disclosures of cash flow activity:		
Cash paid for interest, net of capitalized interest	$ —	$ —
Supplemental disclosure of non-cash investing and financing activities:		
Acquisition of fixed assets in accounts payable and accrued expenses	$ 1,026	$ 1,119
Obtaining a right-of-use asset in exchange for a lease liability	$ —	$ 641
Acquisition of intangible assets in accounts payable and accrued expenses	$ 326	$ 239