

May 2, 2024



Axogen, Inc Reports First Quarter 2024 Financial Results

ALACHUA, Fla. and TAMPA, Fla., May 02, 2024 (GLOBE NEWSWIRE) -- 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, 2024.

First Quarter Financial Results

- First quarter revenue was \$41.4 million, a 12.9% increase compared to the first quarter of 2023.
- In the first quarter of 2024, our gross margin increased to 78.8%, up from 77.7%, as reclassified* in the same quarter of the previous year.
- Net loss for the quarter was \$6.6 million, or \$0.15 per share, compared to net loss of \$7.1 million, or \$0.17 per share in the first quarter of 2023.
- Adjusted net loss for the quarter was \$2.7 million, or \$0.06 per share, compared to adjusted net loss of \$4.1 million, or \$0.10 per share in the first quarter of 2023.
- Adjusted EBITDA was \$1.0 million for the quarter, compared to an adjusted EBITDA loss of \$3.8 million in the first quarter of 2023.
- The balance of all cash, cash equivalents, and investments on March 31, 2024, was \$23.6 million, as compared to a balance of \$37.0 million on December 31, 2023.

“We are pleased with the positive trend in the bottom line and continue to focus on higher productivity as we grow revenue. This is in line with our goal of reaching profitability and positive cashflow as we execute on our growth strategy,” commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “We are encouraged by our team’s performance and execution heading into key near-term milestones. We look forward to our national launch for Avive+ Soft Tissue Matrix™ in June, and completion of our rolling BLA submission for Avance Nerve Graft® in the third quarter.”

* See Reclassification section and Reclassification Financial Table below.

Summary of Operational and Business Highlights

- Core Accounts totaled 400, an increase of 14.3% over the prior-year level of 350, and an increase of 6.4% sequentially. Revenue from Core Accounts represents approximately 65% of revenue.

- We ended the first quarter with 115 direct sales representatives compared to 116 at the end of the fourth quarter.
- In February we completed a productive pre-BLA meeting with FDA where we gained alignment on the content on the modules for submission. We received approval of our rolling submission proposal, and we anticipate the BLA filing to be completed in the third quarter of 2024. We believe the submission timeline will allow for a potential approval in mid-2025.
- We are pleased with the adoption of Axoguard HA+ Nerve Protector™ across multiple applications. In the first quarter we initiated a limited market release of Avive+ Soft Tissue Matrix and have completed the first implant. We expect to drive continued growth within the nerve protection category following the full launch of Avive+ Soft Tissue Matrix™ in June.
- We continue to see strong interest in and adoption of the Resensation® neurotization techniques for autologous and implant-based breast reconstructions driven by expanding surgeon education and patient activation.

2024 Financial Guidance

We are maintaining our annual revenue guidance in the range of \$177 million to \$181 million, which represents a growth rate of approximately 11% to 14%. We also reiterate our gross margin guidance for the full year to be in the range of 76% to 79%. Additionally, we expect to be net cashflow positive cumulatively for the period from April 1st through year end.

Reclassifications

Certain reclassifications have been made to the prior period financial information to conform to the presentation used in the condensed consolidated statement of operations for the three months ended March 31, 2024.

Effective as of the first quarter of 2024, the Company voluntarily changed its accounting policy for shipping and handling costs. Under the new accounting policy, these costs are included in Costs of goods sold, whereas they were previously included in Sales and marketing expenses. Including these expenses in Costs of goods sold better aligns these costs with the related revenue in the gross profit calculation. Although the prior method of accounting continues to be an accepted alternative, the new accounting policy is more widely used in the industry and provides improved comparability of the Company's financial statements to its peers. This change in accounting policy has been applied retrospectively. The consolidated statement of operations for the three months ended March 31, 2023, has been reclassified to reflect this change in accounting policy. The impact of this reclassification was an increase of \$1.5 million to cost of goods sold for the three months ended March 31, 2023, and a corresponding decrease to Sales and marketing expenses in the same period.

Effective as of the first quarter of 2024, the Company also ceased allocating certain costs to and from certain departments. Previously such costs had been allocated based on the Company's estimate of the proportionate share of total expense to Cost of goods sold, Sales and marketing, Research and development, and General and administrative. The Company

determined that these changes would better reflect industry practice and would provide more meaningful information as well as increased transparency of its operations. To conform the 2023 presentation to the current quarter's presentation, \$1.1 million was reclassified to General and administrative, of which \$0.4 million was previously included in Research and development, \$0.7 million was previously included in Sales and marketing, and \$0.002 million was previously included in Cost of goods sold for the three months ended March 31, 2023, in the condensed consolidated statement of operations.

These reclassifications had no impact on net revenue, loss from operations, net loss, or loss per common share for prior periods and do not represent a restatement of the Company's previously issued consolidated financial statements.

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 used across various applications and surgical specialties, including traumatic injuries, oral and maxillofacial surgery, breast reconstruction, and the surgical treatment of pain. These applications encompass both scheduled and emergent procedures. Specifically, scheduled procedures are often pursued by patients seeking relief from conditions caused by a nerve defect or previous surgical interventions. Such procedures include providing sensation for women undergoing breast reconstruction following a mastectomy, nerve reconstruction after the surgical removal of painful neuromas, and oral and maxillofacial procedures, as well as nerve decompression. Conversely, emergent procedures typically arise from injuries that initially present in an emergency room, with specialists intervening either immediately or within a few days following the initial injury. This broad range of applications underscores Axogen's vital role in addressing diverse patient needs in peripheral nerve repair.

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 extracellular matrix (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; Avive+ Soft Tissue Matrix[™], a multi-layer amniotic membrane allograft used to protect and separate tissues in the surgical bed during the critical phase of tissue repair; 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, the United Kingdom, South Korea, and several other European and international 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 expectations and estimates regarding the use of the product across various applications and surgical specialties that encompass scheduled and emergent procedures, Ms. Zaderej's statements on the Company's future focus, the anticipated timing of the completion of the rolling BLA submission and potential for approval of the BLA in mid-2025, the expected timing of the full launch of Avive+ Soft Tissue Matrix[™] and optimism of continued growth within the nerve protection category following the full launch; optimism regarding strong interest and adoption of the Resensation[®] neurotization techniques for autologous and implant-based breast reconstructions, as well as statements under the subheading “2024 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, 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.

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,713	\$ 31,024
Restricted cash	6,000	6,002
Investments	1,921	—
Accounts receivable, net of allowance for doubtful accounts of \$603 and \$337, respectively	24,212	25,147
Inventory	27,636	23,020
Prepaid expenses and other	3,181	2,811
Total current assets	<u>78,663</u>	<u>88,004</u>
Property and equipment, net	87,838	88,730
Operating lease right-of-use assets	15,247	15,562
Intangible assets, net	4,768	4,531
Total assets	<u><u>\$ 186,516</u></u>	<u><u>\$ 196,827</u></u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 21,288	\$ 28,883
Current maturities of long-term lease obligations	1,644	1,547
Total current liabilities	<u>22,932</u>	<u>30,430</u>
Long-term debt, net of debt discount and financing fees	46,825	46,603
Long-term lease obligations	20,681	21,142
Debt derivative liabilities	2,922	2,987
Total liabilities	<u>93,360</u>	<u>101,162</u>
Commitments and contingencies - see Note 12		
Shareholders' equity:		
Common stock, \$0.01 par value per share; 100,000,000 shares authorized; 43,687,729 and 43,124,496 shares issued and outstanding	437	431
Additional paid-in capital	380,650	376,530
Accumulated deficit	(287,931)	(281,296)
Total shareholders' equity	<u>93,156</u>	<u>95,665</u>
Total liabilities and shareholders' equity	<u><u>\$ 186,516</u></u>	<u><u>196,827</u></u>

AXOGEN, INC.
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands, Except share and per share amounts)

	Three Months Ended	
	March 31, 2024	March 31, 2023
Revenues	\$ 41,378	\$ 36,664
Cost of goods sold	8,758	8,172
Gross profit	32,620	28,492
Costs and expenses:		
Sales and marketing	19,815	19,446
Research and development	7,409	6,326
General and administrative	9,956	10,061
Total costs and expenses	37,180	35,833
Loss from operations	(4,560)	(7,341)
Other (expense) income:		
Investment income	293	549
Interest expense	(2,326)	(16)
Change in fair value of derivatives	65	(185)
Other expense	(107)	(81)
Total other (expense) income, net	(2,075)	267
Net loss	\$ (6,635)	\$ (7,074)
Weighted average common shares outstanding — basic and diluted	43,233,149	42,571,021
Loss per common share — basic and diluted	\$ (0.15)	\$ (0.17)

AXOGEN INC.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
(unaudited)
(In thousands, except per share amounts)

	Three Months Ended	
	March 31, 2024	March 31, 2023
Net loss	\$ (6,635)	\$ (7,074)
Depreciation and amortization expense	1,582	780
Investment income	(293)	(549)
Income tax expense	103	83
Interest expense	2,326	16
EBITDA - non GAAP	<u>\$ (2,917)</u>	<u>\$ (6,744)</u>
Non cash stock-based compensation expense	3,919	2,954
Adjusted EBITDA - non GAAP	<u>\$ 1,002</u>	<u>\$ (3,790)</u>
Net loss	\$ (6,635)	\$ (7,074)
Non cash stock-based compensation expense	3,919	2,954
Adjusted net loss - non GAAP	<u>\$ (2,716)</u>	<u>\$ (4,120)</u>
Weighted average common shares outstanding basic and diluted	<u>43,233,149</u>	<u>42,571,021</u>
Loss per common share — basic and diluted	\$ (0.15)	\$ (0.17)
Non cash stock-based compensation expense	\$ 0.09	\$ 0.07
Adjusted net loss per common share - basis and diluted - non GAAP	<u>\$ (0.06)</u>	<u>\$ (0.10)</u>

AXOGEN, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(unaudited)
(In thousands, except per share)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
Three Months Ended March 31, 2024					
Balance, December 31, 2023	43,124,496	\$ 431	\$ 376,530	\$ (281,296)	97,152
Stock-based compensation	—	—	3,919	—	3,919
Issuance of restricted and performance stock units	539,233	5	(5)	—	—
Exercise of stock options and employee stock purchase plan	24,000	1	206	—	207
Net loss	—	—	—	(6,635)	(6,635)
Balance at March 31, 2024	<u>43,687,729</u>	<u>\$ 437</u>	<u>\$ 380,650</u>	<u>\$ (287,931)</u>	<u>93,156</u>
Three Months Ended March 31, 2023					
Balance, December 31, 2022	42,445,517	\$ 424	\$ 360,155	\$ (259,580)	100,999
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
Net loss	—	—	—	(7,074)	(7,074)
Balance at March 31, 2023	<u>42,809,994</u>	<u>428</u>	<u>363,739</u>	<u>(266,654)</u>	<u>97,513</u>

AXOGEN, INC.
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Three Months Ended	
	March 31, 2024	March 31, 2023
Cash flows from operating activities:		
Net loss	\$ (6,635)	\$ (7,074)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,520	709
Amortization of right-of-use assets	315	464
Amortization of intangible assets	62	71
Amortization of debt discount and deferred financing fees	222	219
Provision for (recovery) bad debt	255	(267)
Provision for inventory write-down	367	581
Investment (gains) losses	(10)	(426)
Change in fair value of derivatives	(65)	185
Share-based compensation	3,919	2,954
Change in operating assets and liabilities:		
Accounts receivable	681	175
Inventory	(4,983)	(1,525)
Prepaid expenses and other	(262)	(509)
Accounts payable and accrued expenses	(7,291)	(2,442)
Operating lease obligations	(360)	(537)
Cash paid for interest portion of finance leases	(1)	(1)
Net cash used in operating activities	\$ (12,266)	\$ (7,423)
Cash flows from investing activities:		
Purchase of property and equipment	(924)	(4,304)
Purchase of investments	(1,910)	(10,203)
Proceeds from sale of investments	—	13,974
Cash payments for intangible assets	(417)	(253)
Net cash used in investing activities	\$ (3,251)	\$ (786)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt		
Cash paid for debt portion of finance leases	(3)	(1)
Proceeds from exercise of stock options and ESPP stock purchases	207	634
Net cash provided by financing activities	\$ 204	\$ 633
Net decrease in cash, cash equivalents, and restricted cash	(15,313)	(7,576)
Cash, cash equivalents, and restricted cash, beginning of period	37,026	21,535
Cash, cash equivalents, and restricted cash, end of period	\$ 21,713	\$ 13,959

AXOGEN, INC.
Reclassification Financial Tables
(in thousands)

	Year Ended December 31, 2022			Year Ended December 31, 2023		
	As Previously Reported	As Currently Reported	Adjustments	As Previously Reported	As Currently Reported	Adjustments
Revenues	\$ 138,584	\$ 138,584	\$ -	\$ 159,012	\$ 159,012	\$ -
Cost of goods sold	24,147	29,775	5,628	31,138	37,143	6,006
Gross profit	114,437	108,809	(5,628)	127,874	121,869	(6,006)
Gross Profit %	82.6%	78.5%	-4.1%	80.4%	76.6%	-3.8%
Costs and expenses:						
Sales and marketing	80,228	71,983	(8,245)	86,060	77,580	(8,481)
Research and development	27,158	25,627	(1,531)	28,333	27,339	(995)
General and administrative	36,758	40,906	4,148	34,943	38,412	3,470
Total costs and expenses	144,144	138,516	(5,628)	149,336	143,331	(6,006)
Loss from operations	(29,707)	(29,707)	-	(21,462)	(21,462)	-
Total other income (expense), net	759	759	-	(255)	(255)	-
Net loss	\$ (28,948)	\$ (28,948)	\$ -	\$ (21,717)	\$ (21,717)	\$ -

	Quarter ended March 31, 2023			Quarter Ended June 30, 2023		
	As Previously Reported	As Adjusted	Adjustments	As Previously Reported	As Currently Reported	Adjustments
Revenues	\$ 36,664	\$ 36,664	\$ -	\$ 38,154.86	\$ 38,154.86	\$ -
Cost of goods sold	6,709	8,172	1,463	7,228	8,503	1,275
Gross profit	29,955	28,492	28,492	30,927	29,652	(1,275)
Gross Profit %	81.7%	77.7%	-4.0%	81.1%	77.7%	-3.3%
Costs and expenses:						
Sales and marketing	21,618	19,446	(2,172)	20,838	18,861	(1,978)
Research and development	6,679	6,326	(353)	7,363	7,144	(219)
General and administrative	8,999	10,061	1,062	9,628	10,550	922
Total costs and expenses	37,297	35,834	(1,463)	37,830	36,555	(1,275)
Loss from operations	(7,342)	(7,342)	-	(6,903)	(6,903)	-
Total other income (expense), net	267	267	-	242	242	-
Net loss	\$ (7,074)	\$ (7,074)	\$ -	\$ (6,661)	\$ (6,661)	\$ -

	Quarter Ended September 30, 2023			Quarter Ended December 31, 2023		
	As Previously Reported	As Currently Reported	Adjustments	As Previously Reported	As Currently Reported	Adjustments
Revenues	\$ 41,271	\$ 41,271	\$ -	\$ 42,922	\$ 42,922	\$ -
Cost of goods sold	8,043	9,567	1,524	9,158	10,902	1,744
Gross profit	33,228	31,704	(1,524)	33,764	32,020	(1,744)
Gross Profit %	80.5%	76.8%	-3.7%	78.7%	74.6%	-4.1%
Costs and expenses:						
Sales and marketing	21,429	19,166	(2,264)	22,174	20,106	(2,068)
Research and development	6,989	6,694	(295)	7,302	7,174	(127)
General and administrative	8,835	9,870	1,035	7,480	7,931	451
Total costs and expenses	37,254	35,730	(1,524)	36,956	35,212	(1,744)
Loss from operations	(4,025)	(4,025)	-	(3,192)	(3,192)	-
Total other income (expense), net	(65)	(65)	-	(699)	(699)	-
Net loss	\$ (4,090)	\$ (4,090)	\$ -	\$ (3,891)	\$ (3,891)	\$ -



Source: Axogen, Inc.