

November 7, 2024



Axogen, Inc Reports Third Quarter 2024 Financial Results and Provides BLA Update

ALACHUA, Fla. and TAMPA, Fla., Nov. 07, 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 third quarter ended September 30, 2024.

Third Quarter Financial Results

- Third quarter revenue was \$48.6 million, a 17.9% increase compared to the third quarter of 2023.
- In the third quarter of 2024, gross margin decreased to 74.9%, down from 76.8% in the third quarter of 2023.
- Net loss for the quarter was \$1.9 million, or \$0.04 per share, compared to net loss of \$4.1 million, or \$0.10 per share in the third quarter of 2023.
- Adjusted net income for the quarter was \$3.1 million, or \$0.07 per share, compared to adjusted net loss of \$0.7 million, or \$0.01 per share, in the third quarter of 2023.
- Adjusted EBITDA was \$6.5 million for the quarter, compared to an adjusted EBITDA of \$2.4 million in the third quarter of 2023.
- The balance of all cash, cash equivalents, and investments on September 30, 2024, was \$30.5 million, as compared to a balance of \$27.1 million on June 30, 2024

“We are pleased with the third quarter’s topline revenue and EBITDA growth. Notably, our revenue performance in the quarter was broad based across our entire portfolio of nerve repair and protection applications, reflecting improved sales productivity and commercial execution,” commented Michael Dale, CEO and Director of Axogen, Inc. “Since joining the Axogen team, everything I’ve observed and experienced reaffirms my estimation that we have significant undeveloped potential to make nerve repair an expected standard of care around the world.”

Summary of Business Highlights

- On November 1st, the U.S. Food and Drug Administration (FDA) notified the company that they accepted the filing of its Biologics License Application (BLA) for Avance Nerve Graft[®] under a standard review and assigned a Prescription Drug User Fee Act

(PDUFA) goal date of September 5th, 2025. The FDA further indicated that it does not currently plan to hold an advisory committee for the application.

- During the quarter, at the American Society for Surgery of the Hand (ASSH), we presented novel data highlighting the extent of nerve damage that occurs in common injuries, the importance of protection of the nerve coaptation site and the growing role of Avance Nerve Graft in sensory, mixed and motor nerve repair.
- Recently, we executed on a National Resensation Breast program as well as numerous regional surgeon education programs in Extremities and Head & Neck.

2024 Financial Guidance

We are maintaining our full year revenue guidance in the range of \$182 million to \$186 million, and now expect to be at the high end of our 74-76% full year gross margin range. Additionally, we reiterate that we expect to be net cash flow positive cumulatively for the period from April 1st through year end.

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, without limitation, the estimation of significant undeveloped potential to make nerve repair an expected standard of care around the world, the Company's expectations regarding the potential for approval of the BLA in September 2025, 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 and in our subsequent Quarterly Reports on Form 10Q. 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 condensed 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.
InvestorRelations@axogeninc.com

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

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,662	\$ 31,024
Restricted cash	6,000	6,002
Investments	5,868	—
Accounts receivable, net of allowance for doubtful accounts of \$888 and \$337, respectively	24,629	25,147
Inventory, net	29,363	23,020
Prepaid expenses and other	1,730	2,811
Total current assets	86,252	88,004
Property and equipment, net	85,632	88,730
Operating lease right-of-use assets	14,886	15,562
Intangible assets, net	5,215	4,531
Total assets	\$ 191,985	\$ 196,827
 Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 21,177	\$ 28,883
Current maturities of long-term lease obligations	1,856	1,547
Total current liabilities	23,033	30,430
Long-term debt, net of debt discount and financing fees	47,272	46,603
Long-term lease obligations	19,734	21,142
Debt derivative liabilities	2,445	2,987
Other long-term liabilities	94	—
Total liabilities	92,578	101,162
 Commitments and contingencies - see Note 12		
 Shareholders' equity:		
Common stock, \$0.01 par value per share; 100,000,000 shares authorized; 44,002,323 and 43,124,496 shares issued and outstanding	440	431
Additional paid-in capital	390,677	376,530
Accumulated deficit	(291,710)	(281,296)
Total shareholders' equity	99,407	95,665
Total liabilities and shareholders' equity	\$ 191,985	\$ 196,827

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

	Three Months Ended		Nine Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Revenues	\$ 48,644	\$ 41,271	\$ 137,933	\$ 116,090
Cost of goods sold	12,206	9,567	33,531	26,242
Gross profit	<u>36,438</u>	<u>31,704</u>	<u>104,402</u>	<u>89,848</u>
Costs and expenses:				
Sales and marketing	18,924	19,165	58,437	57,471
Research and development	6,996	6,694	21,063	20,164
General and administrative	10,834	9,870	30,206	30,481
Total costs and expenses	<u>36,754</u>	<u>35,729</u>	<u>109,706</u>	<u>108,116</u>
Loss from operations	<u>(316)</u>	<u>(4,025)</u>	<u>(5,304)</u>	<u>(18,268)</u>
Other income (expense):				
Investment income	296	367	816	1,151
Rental income	90	—	90	—
Interest expense	(1,893)	(827)	(6,405)	(992)
Change in fair value of derivatives	13	402	542	649
Other expense	(48)	(6)	(153)	(363)
Total other (expense) income, net	<u>(1,542)</u>	<u>(64)</u>	<u>(5,110)</u>	<u>445</u>
Net loss	<u>\$ (1,858)</u>	<u>\$ (4,089)</u>	<u>\$ (10,414)</u>	<u>\$ (17,823)</u>
Weighted average common shares outstanding — basic and diluted	<u>43,882,110</u>	<u>43,022,328</u>	<u>43,610,481</u>	<u>42,821,284</u>
Loss per common share — basic and diluted	<u>\$ (0.04)</u>	<u>\$ (0.10)</u>	<u>\$ (0.24)</u>	<u>\$ (0.42)</u>

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

	Three Months Ended		Nine Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Net loss	\$ (1,858)	\$ (4,089)	\$ (10,414)	\$ (17,823)
Depreciation and amortization expense	1,719	1,224	5,034	2,874
Investment income	(296)	(367)	(816)	(1,151)
Income tax expense	26	12	76	331
Interest expense	1,893	827	6,405	992
EBITDA - non GAAP	\$ 1,484	\$ (2,393)	\$ 285	\$ (14,777)
Non cash stock-based compensation expense	\$ 5,004	\$ 4,747	\$ 12,830	\$ 13,091
Adjusted EBITDA - non GAAP	\$ 6,488	\$ 2,354	\$ 13,115	\$ (1,686)
Net loss	\$ (1,858)	\$ (4,089)	\$ (10,414)	\$ (17,823)
Non cash stock-based compensation expense	5,004	4,747	12,830	13,091
Adjusted net income (loss) - non GAAP	\$ 3,146	\$ 658	\$ 2,416	\$ (4,732)
Weighted average common shares outstanding basic and diluted	43,882,110	43,022,328	43,610,481	42,821,284
Loss per common share — basic and diluted	\$ (0.04)	\$ (0.10)	\$ (0.24)	\$ (0.42)
Non cash stock-based compensation expense	0.11	0.11	0.29	0.31
Adjusted net income (loss) per common share - basis and diluted - non GAAP	\$ 0.07	\$ 0.01	\$ 0.05	\$ (0.11)

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 September 30, 2024					
Balance at June 30, 2024	43,824,738	\$ 438	\$ 385,101	\$ (289,852)	\$ 95,687
Net loss	—	—	—	(1,858)	(1,858)
Stock-based compensation	—	—	5,004	—	5,004
Issuance of restricted and performance stock units	112,185	1	(1)	—	—
Exercise of stock options and employee stock purchase plan	65,400	1	573	—	574
Balance at September 30, 2024	<u>44,002,323</u>	<u>\$ 440</u>	<u>\$ 390,677</u>	<u>\$ (291,710)</u>	<u>\$ 99,407</u>
Nine Months Ended September 30, 2024					
Balance at December 31, 2023	43,124,496	\$ 431	\$ 376,530	\$ (281,296)	\$ 95,665,197
Net loss	—	—	—	(10,414)	(10,414)
Stock-based compensation	—	—	12,830	—	12,830
Issuance of restricted and performance stock units	695,571	7	(7)	—	—
Exercise of stock options and employee stock purchase plan	182,256	2	1,324	—	1,326
Balance at September 30, 2024	<u>44,002,323</u>	<u>\$ 440</u>	<u>\$ 390,677</u>	<u>\$ (291,710)</u>	<u>\$ 99,407</u>
Three Months Ended September 30, 2023					
Balance at June 30, 2023	42,979,541	\$ 430	\$ 370,036	\$ (273,314)	\$ 97,152
Net loss	—	—	—	(4,089)	(4,089)
Stock-based compensation	—	—	4,747	—	4,747
Issuance of restricted and performance stock units	59,858	—	—	—	—
Exercise of stock options and employee stock purchase plan	—	—	—	—	—
Balance at September 30, 2023	<u>43,039,399</u>	<u>\$ 430</u>	<u>\$ 374,783</u>	<u>\$ (277,403)</u>	<u>\$ 97,810</u>
Nine Months Ended September 30, 2023					
Balance at December 31, 2022	42,445,517	\$ 424	\$ 360,155	\$ (259,580)	\$ 100,999
Net loss	—	—	—	(17,823)	(17,823)
Stock-based compensation	—	—	13,091	—	13,091
Issuance of restricted and performance stock units	356,236	4	(4)	—	—
Exercise of stock options and employee stock purchase plan	237,646	2	1,541	—	1,543
Balance at September 30, 2023	<u>43,039,399</u>	<u>\$ 430</u>	<u>\$ 374,783</u>	<u>\$ (277,403)</u>	<u>\$ 97,810</u>

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

	Nine Months Ended	
	September 30, 2024	September 30, 2023
Cash flows from operating activities:		
Net loss	\$ (10,414)	\$ (17,823)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4,831	2,660
Amortization of right-of-use assets	889	826
Amortization of intangible assets	202	214
Amortization of debt discount and deferred financing fees	669	666
Provision for (recovery of) bad debt	604	(311)
Change in fair value of derivatives	(542)	(649)
Investment (gains) loss	(95)	(660)
Share-based compensation	12,830	13,091
Change in operating assets and liabilities:		
Accounts receivable	(85)	(766)
Inventory	(6,343)	(4,114)
Prepaid expenses and other	1,189	(623)
Accounts payable and accrued expenses	(7,125)	3,012
Operating lease obligations	(1,303)	(1,012)
Cash paid for interest portion of finance leases	(2)	(2)
Other liabilities	495	(14)
Net cash used in operating activities	\$ (4,200)	\$ (5,505)
Cash flows from investing activities:		
Purchase of property and equipment	\$ (2,431)	\$ (12,409)
Purchase of investments	(5,773)	(10,203)
Proceeds from sale of investments	—	42,874
Cash payments for intangible assets	(1,280)	(732)
Net cash (used in) provided by investing activities	\$ (9,484)	\$ 19,530
Cash flows from financing activities:		
Cash paid for debt portion of finance leases	\$ (6)	\$ (7)
Proceeds from exercise of stock options and ESPP stock purchases	1,326	1,543
Net cash provided by financing activities	\$ 1,320	\$ 1,536
Net (decrease) increase in cash, cash equivalents, and restricted cash	(12,364)	15,561
Cash, cash equivalents, and restricted cash, beginning of period	37,026	21,535
Cash, cash equivalents, and restricted cash, end of period	\$ 24,662	\$ 37,096



Source: Axogen, Inc.