November 7, 2023

# Axogen, Inc. Reports 2023 Third Quarter Financial Results

ALACHUA, Fla. and TAMPA, Fla., Nov. 07, 2023 (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, 2023.

**Third Quarter Financial Results**

- Revenue was $41.3 million during the third quarter, an increase of approximately 12% over the third quarter of 2022.
- The Company estimates that revenues from emergent trauma procedures represented approximately half of total revenues during the third quarter and grew in the mid-single digit range versus the third quarter of 2022.
- The Company estimates that revenues from scheduled non-trauma procedures represented approximately half of total revenues during the third quarter and grew approximately 20% from the third quarter of 2022.
- Gross margin was 80.5% for the quarter, compared to 83.3% in the third quarter of 2022.
- Net loss of $4.1 million, or $0.10 per share, compared to net loss of $4.3 million, or $0.10 per share in the third quarter of 2022.
- Adjusted net income of $0.7 million or $0.01 per share, compared to adjusted net loss of $0.4 million, or $0.01 per share, in the third quarter of 2022.
- Adjusted EBITDA of $2.4 million, compared to adjusted EBITDA of $0.4 million in the third quarter of 2022.
- The balance of all cash and cash equivalents and investments on September 30, 2023, was $38.6 million, compared to $40.8 million on June 30, 2023. The net change of $2.2 million includes interest and other charges capitalized into the Company's new processing facility.

“We are pleased with our performance in the quarter, which includes improvement in our emergent trauma category as well as continued strength in scheduled procedures. This performance was driven by stabilization in the hospital operating environment, and improved commercial execution,” stated Karen Zaderej, Axogen's Chairman, CEO, and President. “We remain focused on executing our strategic initiatives anchored in the strength of our clinical

data, innovation, market development, and commercial execution to continue to drive surgeon adoption and growth."

**Operational and Business Highlights**

- In August, the Company began processing tissue in the new, state-of-the-art APC facility, which provides for up to 3 times current capacity and was designed for long-term growth and expansion.
- The Company is continuing to expand its offering in the nerve protection market with the national launch of Axoguard HA+ Nerve Protector™ in August, and expects to launch Avive+ Soft Tissue Matrix™ in Q1 2024.
- The Company continues to anticipate a Pre-BLA meeting with the FDA in early first quarter 2024 where it will request utilization of a rolling submission process for the Biologics License Application (BLA) for Avance® nerve graft which would begin later in the first quarter. The Company anticipates completing the submission in the second quarter of 2024 and believes this process will support BLA approval in the first half of 2025.
- The Company has exceeded its initial goal of training 20 additional surgical teams on techniques in implant-based Resensation® and now expects to have more than 30 teams trained by the end of this year.
- Core Accounts totaled 372, an increase of 12% over prior-year level of 331, and an increase of 7% sequentially. Revenue from Core Accounts now represent approximately 65% of revenue, up from approximately 60% in prior quarters.
- Active Accounts totaled 1016, an increase of 7% over prior-year level of 952, and an increase of 4% sequentially.
- Ended the quarter with over 200 peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio.
- Ended the quarter with 116 direct sales representatives compared to 115 on June 30, 2023, and 111 a year ago.

**2023 Financial Guidance**

Management is maintaining full-year 2023 revenue guidance in the range of $154 million to $159 million, which represents annual growth of 11% - 15%. The Company anticipates that gross margin will be reduced with the continued transition to the new processing facility in the fourth quarter and continues to expect that gross margin for the full year 2023 will be approximately 80%.

**Axoguard HA+ Nerve Protector Launch**

In August 2023, the Company completed the full market release of Axoguard HA+ Nerve Protector™, an extension of its nerve protection platform. 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 patients' and surgeons' 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 (877) 407-0993 or using 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 Avance Nerve Graft**

Avance nerve graft is a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site. Avance provides structural guidance for regenerating axons, and revascularizes and remodels into the patient's own tissue. It is available in a variety of lengths and diameters.

A 2010 written agreement between the FDA and Axogen allows the company to continue marketing Avance as a section 361 Human Cells, Tissues and Cellular and Tissue Based Product (HCT/P) while taking the necessary steps to file a Biologics License Application (BLA) under section 351.

In 2018 the FDA granted a Regenerative Medicine Advance Therapy (RMAT) designation for Avance nerve graft. A regenerative medicine therapy is eligible for the designation if it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such a disease or condition. The RMAT designation provides access to a streamlined approval process for regenerative medicine technologies and ensures continued informal meetings with the FDA in support of the BLA for Avance nerve graft.

**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 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 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.

**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, our ability to submit the BLA on a rolling basis, timing of the submission and approval of the BLA, development and market launch timetable for Avive+, 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 transition 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 and

Part II, Item 1A., “Risk Factors,” for our Quarterly Report on Form 10-Q for the most recently ended fiscal quarter. 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:
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**Axogen, Inc.**
**Condensed Consolidated Balance Sheets**
**(unaudited)**
**(In thousands, except share and per share amounts)**

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 31,094 | $ 15,284 |
| Restricted cash | 6,002 | 6,251 |
| Investments | 1,494 | 33,505 |
| Accounts receivable, net of allowance for doubtful accounts of $319 and $650, respectively | 23,263 | 22,186 |
| Inventory | 23,019 | 18,905 |
| Prepaid expenses and other | 2,567 | 1,944 |
| **Total current assets** | 87,439 | 98,075 |
| Property and equipment, net | 89,030 | 79,294 |
| Operating lease right-of-use assets | 13,873 | 14,369 |
| Intangible assets, net | 4,288 | 3,649 |
| **Total assets** | $ 194,630 | $ 195,387 |
| **Liabilities and shareholders' equity** | | |
| **Current liabilities:** | | |
| Accounts payable and accrued expenses | $ 25,550 | $ 22,443 |
| Current maturities of long-term lease obligations | 1,096 | 1,310 |
| **Total current liabilities** | 26,646 | 23,753 |
| Long-term debt, net of debt discount and financing fees | 46,378 | 45,712 |
| Long-term lease obligations | 19,927 | 20,405 |
| Debt derivative liabilities | 3,869 | 4,518 |
| **Total liabilities** | 96,820 | 94,388 |
| **Commitments and contingencies - see Note 12** | | |
| **Shareholders' equity:** | | |
| Common stock, $0.01 par value per share; 100,000,000 shares authorized; 43,039,399 and 42,445,517 shares issued and outstanding | 430 | 424 |
| Additional paid-in capital | 374,783 | 360,155 |
| Accumulated deficit | (277,403) | (259,580) |
| **Total shareholders' equity** | 97,810 | 100,999 |
| **Total liabilities and shareholders' equity** | $ 194,630 | $ 195,387 |

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

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | **September 30, 2023** | **September 30, 2022** | **September 30, 2023** | **September 30, 2022** |
| **Revenues** | $ 41,271 | $ 36,959 | $ 116,090 | $ 102,420 |
| **Cost of goods sold** | 8,043 | 6,176 | 21,980 | 18,006 |
| **Gross profit** | 33,228 | 30,783 | 94,110 | 84,414 |
| **Costs and expenses:** | | | | |
| Sales and marketing | 21,429 | 19,792 | 63,885 | 60,349 |
| Research and development | 6,989 | 7,050 | 21,032 | 20,347 |
| General and administrative | 8,835 | 8,796 | 27,461 | 27,817 |
| **Total costs and expenses** | 37,253 | 35,638 | 112,378 | 108,513 |
| **Loss from operations** | (4,025) | (4,855) | $ (18,268) | (24,099) |
| **Other income (expense):** | | | | |
| Investment income (loss) | 367 | 186 | 1,151 | 172 |
| Interest expense | (827) | (61) | (992) | (664) |
| Change in fair value of derivatives | 402 | 469 | 649 | 1,155 |
| Other expense | (6) | (57) | (363) | (97) |
| **Total other (expense) income, net** | (64) | 537 | 445 | 566 |
| **Net loss** | $ (4,089) | $ (4,318) | $ (17,823) | $ (23,533) |
| Weighted average common shares outstanding — basic and diluted | 43,022,328 | 42,220,519 | 42,821,284 | 42,008,013 |
| Loss per common share — basic and diluted | $ (0.10) | $ (0.10) | $ (0.42) | $ (0.56) |

**Axogen, Inc.**
**RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES**
**(unaudited)**
**(In thousands, except share and per share amounts)**

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | **September 30, 2023** | **September 30, 2022** | **September 30, 2023** | **September 30, 2022** |
| **Net loss** | $ (4,089) | $ (4,318) | $ (17,823) | $ (23,533) |
| Depreciation and amortization expense | 1,224 | 830 | 2,874 | 2,380 |
| Investment income | (367) | (186) | (1,151) | (172) |
| Income tax expense | 12 | 31 | 331 | 64 |
| Interest expense | 827 | 61 | 992 | 664 |
| **EBITDA - non GAAP** | $ (2,393) | $ (3,582) | $ (14,777) | $ (20,597) |
| Non cash stock-based compensation expense | $ 4,747 | $ 3,849 | $ 13,091 | $ 11,437 |
| Litigation and related costs | — | 101 | — | 584 |
| **Adjusted EBITDA (loss) - non GAAP** | $ 2,354 | $ 368 | $ (1,686) | $ (8,576) |
| **Net loss** | $ (4,089) | $ (4,318) | $ (17,823) | $ (23,533) |
| Non cash stock-based compensation expense | 4,747 | 3,849 | 13,091 | 11,437 |
| Litigation and related costs | — | 101 | — | 584 |
| **Adjusted net income (loss) - non GAAP** | $ 658 | $ (368) | $ (4,732) | $ (11,512) |
| **Weighted average common shares outstanding — basic and diluted** | 43,022,328 | 42,220,519 | 42,821,284 | 42,008,013 |
| **Loss per common share — basic and diluted** | $ (0.10) | $ (0.10) | $ (0.42) | $ (0.56) |
| Non cash stock-based compensation expense | $ 0.11 | $ 0.09 | $ 0.31 | $ 0.27 |
| Litigation and related costs | $ — | $ — | $ — | $ 0.01 |
| **Adjusted net income (loss) per common share — basic and diluted - non GAAP** | $ 0.01 | $ (0.01) | $ (0.11) | $ (0.28) |

**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 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** | 43,039,399 | $ 430 | $ 374,783 | $ (277,403) | 97,810 |
| **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** | 43,039,399 | $ 430 | 374,783 | $ (277,403) | $ 97,810 |
| **Three Months Ended September 30, 2022** | | | | | |
| **Balance at June 30, 2022** | 42,134,504 | $ 420 | $ 351,117 | $ (249,847) | 101,690 |
| Net loss | — | — | — | (4,318) | (4,318) |
| Stock-based compensation | — | — | 3,849 | — | 3,849 |
| Issuance of restricted and performance stock units | 55,934 | 1 | (1) | — | — |
| Exercise of stock options and employee stock purchase plan | 81,785 | 2 | 222 | — | 224 |
| **Balance at September 30, 2022** | 42,272,223 | $ 423 | $ 355,187 | $ (254,165) | $ 101,445 |
| **Nine Months Ended September 30, 2022** | | | | | |
| **Balance at December 31, 2021** | 41,736,950 | $ 417 | $ 342,765 | $ (230,632) | $ 112,550 |
| Net loss | — | — | — | (23,533) | (23,533) |
| Stock-based compensation | — | — | 11,437 | — | 11,437 |
| Issuance of restricted and performance stock units | 315,275 | 3 | (3) | — | — |
| Exercise of stock options and employee stock purchase plan | 219,998 | 3 | 988 | — | 991 |
| **Balance at September 30, 2022** | 42,272,223 | $ 423 | $ 355,187 | $ (254,165) | $ 101,445 |

**Axogen, Inc.**
**Condensed Consolidated Statements of Cash Flows**
**(unaudited)**
**(In thousands)**

| | Nine Months Ended | |
|---|---|---|
| | **September 30, 2023** | **September 30, 2022** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (17,823) | $ (23,533) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 2,660 | 2,182 |
| Amortization of right-of-use assets | 826 | 1,303 |
| Amortization of intangible assets | 214 | 198 |
| Amortization of debt discount and deferred financing fees | 666 | 667 |
| Provision for bad debt | (311) | 566 |
| Provision for inventory write-down | 1,841 | 1,381 |
| Change in fair value of derivatives | (649) | (1,155) |
| Change in investment gains or losses | (660) | 44 |
| Stock-based compensation | 13,091 | 11,437 |
| Change in operating assets and liabilities: | | |
| Accounts receivable | (766) | (3,695) |
| Inventory | (5,955) | (3,804) |
| Prepaid expenses and other | (623) | (828) |
| Accounts payable and accrued expenses | 3,012 | (870) |
| Operating lease obligations | (1,012) | (1,320) |
| Cash paid for interest portion of finance leases | (2) | (1) |
| Contract and other liabilities | (14) | — |
| **Net cash used in operating activities** | (5,505) | (17,428) |
| **Cash flows from investing activities:** | | |
| Purchase of property and equipment | (12,409) | (13,456) |
| Purchase of investments | (10,203) | (24,607) |
| Proceeds from sale of investments | 42,874 | 37,100 |
| Cash payments for intangible assets | (732) | (1,028) |
| **Net cash from (used in) investing activities** | 19,530 | (1,991) |
| **Cash flows from financing activities:** | | |
| Cash paid for debt portion of finance leases | (7) | (9) |
| Proceeds from exercise of stock options and ESPP stock purchases | 1,543 | 990 |
| **Net cash provided by financing activities** | 1,536 | 981 |
| **Net increase (decrease) in cash, cash equivalents, and restricted cash** | 15,561 | (18,438) |
| **Cash, cash equivalents, and restricted cash, beginning of period** | 21,535 | 39,007 |
| **Cash, cash equivalents, and restricted cash, end of period** | $ 37,096 | $ 20,569 |
| **Supplemental disclosures of cash flow activity:** | | |
| Cash paid for interest, net of capitalized interest | $ 325 | $ — |
| **Supplemental disclosure of non-cash investing and financing activities:** | | |
| Acquisition of fixed assets in accounts payable and accrued expenses | $ 853 | $ 2,090 |
| Obtaining of property and equipment in exchange for a lease liability | $ — | $ 22 |
| Obtaining a right-of-use asset in exchange for a lease liability | $ 366 | $ 920 |
| Acquisition of intangible assets in accounts payable and accrued expenses | $ 420 | $ 177 |

Source: Axogen, Inc.