August 7, 2023

Axogen, Inc. Reports 2023 Second Quarter Financial Results

ALACHUA, Fla. and TAMPA, Fla., Aug. 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 second quarter ended June 30, 2023.

Second Quarter Financial Results and Business Highlights

- Revenue was $38.2 million during the second quarter, an increase of approximately 11% over the second quarter of 2022.
- The Company estimates that revenues from scheduled non-trauma procedures represented approximately half of total revenues during the second quarter and grew over 20% from the second quarter of 2022.
- The Company estimates that revenues from emergent trauma procedures represented approximately half of total revenues during the second quarter and grew in the low single digit range versus the second quarter of 2022.
- Gross margin was 81.1% for the quarter, compared to 81.8% in the second quarter of 2022.
- Net loss of $6.7 million, or $0.16 per share, compared to net loss of $7.7 million, or $0.18 per share in the second quarter of 2022.
- Adjusted net loss of $1.3 million, or $0.03 per share, compared to adjusted net loss of $2.6 million, or $0.05 per share, in the second quarter of 2022.
- Adjusted EBITDA loss of $0.2 million, compared to an adjusted EBITDA loss of $1.6 million in the second quarter of 2022.
- The balance of all cash and cash equivalents and investments on June 30, 2023, was $40.8 million, as compared to $44.1 million on March 31, 2023. The net change includes capital expenditures of $3.6 million related to the construction of the Company's new processing facility in Dayton, OH, partially offset by $0.3 million of net positive other operating cash flow in the quarter.
- The Company successfully initiated the pilot launch of the Axoguard HA+ Nerve Protector™ in the second quarter and will fully launch this extension of its nerve protection platform later this month.
- On August 2nd the Phase 3 RECON study was published online in*The Journal of*

Hand Surgery. The Company had previously announced in May of 2022 that RECON had met its primary endpoint. The publication includes the authors analysis of the results, which found that Avance returned a greater degree of functional recovery than conduits and superiority was demonstrated as gap lengths increased.

"We are encouraged by the continued momentum of our overall business, which was led by over 20% growth of scheduled procedures," stated Karen Zaderej, AxoGen's Chairman, CEO, and President. "The strength of our scheduled procedures category is delivering on the Company's underlying goal of gaining deeper surgeon adoption and expanded use cases of our products across our core and active accounts."

"Emergent trauma procedures continue to experience headwinds as hospitals prioritize resources and address operating challenges particularly with routine trauma procedures. We believe that these challenges are transient and that recent clinical publications, demonstrating the clinical effectiveness, cost, and surgical time efficiencies of allograft nerve repairs, will support continued surgeon adoption and expansion of the trauma category," continued Zaderej.

- Core Accounts totaled 347, an increase of 16% over an adjusted* prior-year level of 299, and a decrease of 1% sequentially. Revenue from Core Accounts continued to represent approximately 60% of total revenue.
- Active Accounts totaled 974, an increase of 4% over an adjusted* prior-year level of 941, and a decrease of 1% sequentially. Revenue from the top 10% of Active Accounts represents approximately 35% of total revenue.
- Ended the quarter with over 200 peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio.
- We ended the quarter with 115 direct sales representatives compared to 116 on March 31, 2023 and a year ago.

Update on Axogen Processing Center (APC) and BLA Submission

The Company completed construction of the APC and in the second quarter placed into service the warehouse and office spaces, and now expects to begin processing tissue in the new facility later this month. The Company will include tissue processing information from the APC in its submission of the BLA for Avance Nerve Graft. Additionally, the Company will be requesting to utilize a rolling submission process with the FDA at a pre-BLA meeting that is expected to occur early first quarter of 2024. If the FDA agrees, the Company expects to begin the submission in the first quarter of 2024 and complete the submission in the second quarter of 2024. The company believes this process will support BLA approval in the first half 2025.

Axoguard HA+ Nerve Protector Launch

The Company successfully initiated the pilot launch of the Axoguard HA+ Nerve Protector™ in the second quarter and will fully launch this extension of its nerve protection platform later this month. 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.

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 transition to the new processing facility in the third and fourth quarters and that gross margins for the full year 2023 will be approximately 80%.

*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.

Conference Call

The Company will host a conference call and webcast for the investment community today at 4:30 p.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 RECON

RECON is a multicenter, prospective, randomized, subject and evaluator blinded comparative clinical study of nerve cuffs (manufactured conduits) and Avance® Nerve Graft, evaluating recovery outcomes for the repair of nerve discontinuities. The phase 3 pivotal study is designed to provide clinical evidence for the Company’s BLA filing to transition the Company’s Avance Nerve Graft from a section 361 tissue product to a section 351 biologic product; and, as such was designed to test for non-inferiority between static two-point discrimination outcomes for Avance Nerve Graft and manufactured conduit. The study design also allows for a sequential test for superiority of Avance Nerve Graft, following the non-inferiority analysis.

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 statements about (i) fully launching Axoguard HA+ later this month, (ii) anticipated timetable for seeking approval of the rolling BLA submission in early first quarter of 2024, (iii) subject to approval of the rolling submission, anticipated timetable for the initial BLA submission in the first quarter of 2024 and completion in the second quarter of 2024, (iv) potential BLA approval in the first half of 2025, and (v) initial processing of tissue in the new facility later this month, 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:
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Axogen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share amounts)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 23,219	$ 15,284
Restricted cash	6,252	6,251
Investments	11,312	33,505
Accounts receivable, net of allowance for doubtful accounts of $595 and $650, respectively	21,573	22,186
Inventory	21,237	18,905
Prepaid expenses and other	2,583	1,944
Total current assets	86,176	98,075
Property and equipment, net	87,459	79,294
Operating lease right-of-use assets	13,958	14,369
Intangible assets, net	4,048	3,649
Total assets	$ 191,641	$ 195,387
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 22,893	$ 22,443
Current maturities of long-term lease obligations	1,040	1,310
Total current liabilities	23,933	23,753
Long-term debt, net of debt discount and financing fees	46,154	45,712
Long-term lease obligations	20,131	20,405
Debt derivative liabilities	4,271	4,518
Total liabilities	94,489	94,388
Commitments and contingencies - see Note 12		
Shareholders' equity:		
Common stock, $0.01 par value per share; 100,000,000 shares authorized; 42,979,541 and 42,445,517 shares issued and outstanding	430	424
Additional paid-in capital	370,036	360,155
Accumulated deficit	(273,314)	(259,580)
Total shareholders' equity	97,152	100,999
Total liabilities and shareholders' equity	$ 191,641	$ 195,387

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

	Three Months Ended		Six Months Ended	
	June 30, 2023	**June 30, 2022**	**June 30, 2023**	**June 30, 2022**
Revenues	$ 38,155	$ 34,454	$ 74,819	$ 65,461
Cost of goods sold	7,228	6,284	13,937	11,830
Gross profit	30,927	28,170	60,882	53,631
Costs and expenses:				
Sales and marketing	20,838	19,669	42,456	40,557
Research and development	7,363	7,022	14,043	13,296
General and administrative	9,628	9,403	18,627	19,021
Total costs and expenses	37,829	36,094	75,126	72,874
Loss from operations	(6,902)	(7,924)	(14,244)	(19,243)
Other income (expense):				
Investment income (loss)	235	32	784	(15)
Interest expense	(148)	(249)	(164)	(603)
Change in fair value of derivatives	432	434	247	686
Other expense	(277)	(33)	(357)	(40)
Total other income, net	242	184	510	28
Net loss	$ (6,660)	$ (7,740)	$ (13,734)	$ (19,215)
Weighted average common shares outstanding — basic and diluted	42,862,384	41,994,618	42,719,096	41,900,000
Loss per common share — basic and diluted	$ (0.16)	$ (0.18)	$ (0.32)	$ (0.46)

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		Six Months Ended	
	June 30, 2023	**June 30, 2022**	**June 30, 2023**	**June 30, 2022**
Net loss	$ (6,660)	$ (7,740)	$ (13,734)	$ (19,215)
Depreciation and amortization expense	871	777	1,650	1,550
Investment (income) loss	(235)	(32)	(784)	15
Income tax expense	240	33	318	33
Interest expense	148	249	164	603
EBITDA - non GAAP	$ (5,636)	$ (6,713)	$ (12,386)	$ (17,014)
Non cash stock-based compensation expense	5,390	4,910	8,344	7,588
Litigation and related costs	—	216	—	483
Adjusted EBITDA - non GAAP	$ (246)	$ (1,587)	$ (4,042)	$ (8,943)
Net loss	$ (6,660)	$ (7,740)	$ (13,734)	$ (19,215)
Non cash stock-based compensation expense	5,390	4,910	8,344	7,588
Litigation and related costs	—	216	—	483
Adjusted net loss - non GAAP	$ (1,270)	$ (2,614)	$ (5,390)	$ (11,144)
Weighted average common shares outstanding — basic and diluted	42,862,384	41,994,618	42,719,096	41,900,000
Loss per common share — basic and diluted	$ (0.16)	$ (0.18)	$ (0.32)	$ (0.46)
Non cash stock-based compensation expense	0.13	0.12	$ 0.20	$ 0.18
Litigation and related costs	—	0.01	$ —	$ 0.01
Adjusted net loss per common share — basic and diluted - non GAAP	$ (0.03)	$ (0.05)	$ (0.12)	$ (0.27)

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 June 30, 2023					
Balance at March 31, 2023	42,809,994	$ 428	$ 363,739	$ (266,654)	$ 97,513
Net loss	—	—	—	(6,660)	(6,660)
Stock-based compensation	—	—	5,390	—	5,390
Issuance of restricted and performance stock units	57,659	1	(1)	—	—
Exercise of stock options and employee stock purchase plan	111,888	1	908	—	909
Balance at June 30, 2023	42,979,541	$ 430	$ 370,036	$ (273,314)	$ 97,152
Six Months Ended June 30, 2023					
Balance at December 31, 2022	42,445,517	$ 424	$ 360,155	$ (259,580)	$ 100,999
Net loss	—	—	—	(13,734)	(13,734)
Stock-based compensation	—	—	8,344	—	8,344
Issuance of restricted and performance stock units	296,378	4	(4)	—	—
Exercise of stock options and employee stock purchase plan	237,646	2	1,541	—	1,543
Balance at June 30, 2023	42,979,541	$ 430	$ 370,036	$ (273,314)	$ 97,152
Three Months Ended June 30, 2022					
Balance at March 31, 2022	41,972,987	$ 420	$ 345,538	$ (242,107)	$ 103,851
Net loss	—	—	—	(7,740)	(7,740)
Stock-based compensation		—	4,910	—	4,910
Issuance of restricted and performance stock units	44,054	—	—	—	—
Exercise of stock options and employee stock purchase plan	117,463	—	669	—	669
Balance at June 30, 2022	42,134,504	$ 420	$ 351,117	$ (249,847)	$ 101,690
Six Months Ended June 30, 2022					
Balance at December 31, 2021	41,736,950	$ 417	$ 342,765	$ (230,632)	$ 112,550
Net loss	—	—	—	(19,215)	(19,215)
Stock-based compensation	—	—	7,588	—	7,588
Issuance of restricted and performance stock units	259,341	2	(2)	—	—
Exercise of stock options and employee stock purchase plan	138,213	1	766	—	767
Balance at June 30, 2022	42,134,504	$ 420	$ 351,117	$ (249,847)	$ 101,690

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

	Six Months Ended	
	June 30, 2023	**June 30, 2022**
Cash flows from operating activities:		
	$ (13,734)	$ (19,215)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,506	1,418
Amortization of right-of-use assets	642	859
Amortization of intangible assets	144	132
Amortization of debt discount and deferred financing fees	442	442
Provision for bad debt	(37)	550
Provision for inventory write-down	1,052	928
Change in fair value of derivatives	(247)	(686)
Investment (income) loss	(578)	145
Stock-based compensation	8,344	7,588
Change in operating assets and liabilities:		
Accounts receivable	650	(2,719)
Inventory	(3,384)	(3,458)
Prepaid expenses and other	(639)	(1,081)
Accounts payable and accrued expenses	(529)	(786)
Operating lease obligations	(762)	(856)
Cash paid for interest portion of finance leases	(1)	—
Net cash used in operating activities	(7,131)	(16,739)
Cash flows from investing activities:		
Purchase of property and equipment	(8,719)	(9,086)
Purchase of investments	(10,203)	(6,024)
Proceeds from sale of investments	32,974	11,000
Cash payments for intangible assets	(516)	(852)
Net cash from (used in) investing activities	13,536	(4,962)
Cash flows from financing activities:		
Cash paid for debt portion of finance leases	(12)	(1)
Proceeds from exercise of stock options and ESPP stock purchases	1,543	767
Net cash provided by financing activities	1,531	766
Net increase (decrease) in cash, cash equivalents, and restricted cash	7,936	(20,935)
Cash, cash equivalents, and restricted cash, beginning of period	21,535	39,007
Cash, cash equivalents, and restricted cash, end of period	$ 29,471	$ 18,073
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	$ 1,818	$ 1,817
Obtaining a right-of-use asset in exchange for a lease liability	$ 268	$ 700
Acquisition of intangible assets in accounts payable and accrued expenses	$ 326	$ 186

Source: Axogen, Inc.