

Axogen, Inc Reports 2022 Third Quarter Financial Results

ALACHUA, Fla. and TAMPA, Fla., Nov. 08, 2022 (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, 2022.

Third Quarter Financial Results 2022 and Business Highlights

- Net revenue was \$37.0 million during the third quarter, an increase of 18% over the third quarter of 2021.*
- Gross margin was 83.3% for the quarter compared to 83.2% in the third quarter of 2021.
- Net loss for the quarter was \$4.3 million, or \$0.10 per share, compared to net loss of \$7.1 million, or \$0.17 per share in the third quarter of 2021.
- Adjusted net loss for the quarter was \$0.4 million, or \$0.01 per share, compared to adjusted net loss of \$3.6 million, or \$0.08 per share, in the third quarter of 2021.
- Adjusted EBITDA was \$0.4 million for the quarter, compared to an adjusted EBITDA loss of \$2.5 million in the third quarter of 2021.
- The balance of all cash and cash equivalents and investments on September 30, 2022 was \$59.4 million, as compared to a balance of \$64.3 million on June 30, 2022. The net change includes capital expenditures of \$3.9 million related to the construction of the company's new processing facility in Dayton, OH, and approximately \$1.0 million net operating cash burn.
- Appointed William Burke to the Axogen Board of Directors, and Chair of the Audit Committee.
- As previously announced, Adrian Tyndall, M.D., MPH, FACEP will join the Axogen Board of Directors effective December 13, 2022, filling a vacancy with the simultaneous retirement of founding director, Mark Gold, M.D.

"We are pleased with our performance this quarter, as solid execution drove revenue growth in each of our products and across our applications," commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. "We are encouraged with our year-to-date progress including surgeons reception of our RECON study results, and are confident in our ability to achieve sustainable long-term growth as we continue our mission to restore nerve function and quality of life to patients with peripheral nerve injuries."

Additional Operational and Business Highlights

• Core Accounts totaled 331, an increase of 11% sequentially, and 17% over an

- adjusted* prior year level of 283. Revenue from Core Accounts continued to represent approximately 60% of total revenue.
- Active Accounts totaled 952, up 1% sequentially, and 2% over an adjusted* prior year level of 930. Revenue from the top 10% of Active Accounts represents approximately 35% of total revenue.
- Ended the quarter with a total of 207 new peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio, up from 196 the previous quarter.
- Ended the quarter with 111 direct sales representatives, compared to 116 at the end of the second quarter of 2022, and compared to 109 one year ago.
- Axogen's peripheral nerve repair portfolio was featured throughout the clinical and scientific sessions of the 77th Annual Meeting of the American Society for Surgery of the Hand (ASSH).

Updating 2022 Financial Guidance

Management is narrowing the range of our annual revenue guidance and expects full-year 2022 revenue to be in the range of \$137.5 million to \$140.0 million versus the prior range of \$135.0 million to \$142.0 million. Full-year 2022 gross margin is expected to be above 80%.

*The Company voluntarily suspended market availability of Avive[®] Soft Tissue Membrane on June 1, 2021, and therefore no Avive revenue was recorded in either the third quarter of 2021 or 2022.

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, 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; 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. 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 impact of COVID-19 on our business, including but not limited to global supply chain issues, hospital staffing challenges and its impact on our business, statements regarding our growth, our financial guidance and performance, product development, product potential, regulatory process and approvals, APC renovation timing and expense, sales growth, product adoption, market awareness of our products, anticipated capital requirements, including the potential of future financings, data validation, expected clinical study enrollment, timing and outcomes, our visibility at and sponsorship of conferences and our educational events, regulatory process and approvals and other factors, including legislative, regulatory, political, geopolitical, and economic developments, including global business disruption caused by Russia's invasion of Ukraine and related sanctions, not within our control. The forward-looking statements are and will be subject to risks and uncertainties, which may cause actual results to differ materially from those expressed or implied in such forward-looking statements. Forward-looking statements contained in this press release should be evaluated together with the many risks and uncertainties that affect our business and our market, particularly 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, as well as other risks and cautionary statements set forth in our filings with the U.S. Securities and Exchange Commission. 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, whether as a result of new information, future events, changed circumstances, or otherwise.

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 Axogen's GAAP financial measures to the corresponding non-GAAP measures 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.

Contact: Axogen, Inc. Ed Joyce, Director, Investor Relations ejoyce@axogeninc.com

Axogen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(In Thousands, Except Share and Per Share Amounts)

	Sep	otember 30, 2022	December 31, 2021		
Assets					
Current assets:					
Cash and cash equivalents	\$	14,318	\$	32,756	
Restricted cash		6,251		6,251	
Investments		38,792		51,330	
Accounts receivable, net of allowance for doubtful accounts of \$606 and \$276, respectively		21,363		18,158	
Inventory		19,116		16,693	
Prepaid expenses and other		2,614		1,861	
Total current assets		102,454		127,049	
Property and equipment, net		74,867		62,923	
Operating lease right-of-use assets		14,751		15,193	
Intangible assets, net		3,448		2,859	
Total assets	\$	195,520	\$	208,024	
Liabilities and shareholders' equity Current liabilities: Accounts payable and accrued expenses	\$	22,017	\$	22,459	
Current maturities of long-term lease obligations		1,530		1,834	
Total current liabilities		23,547		24,293	
Long-term debt, net of debt discount and financing fees		45,487		44,821	
Long-term lease obligations		20,634		20,798	
Debt derivative liabilities		4,407		5,562	
Total liabilities		94,075		95,474	
Commitments and contingencies - see Note 12					
Shareholders' equity:					
Common stock, \$0.01 par value per share; 100,000,000 shares authorized; 42,272,223 and 41,736,950 shares issued and outstanding		423		417	
Additional paid-in capital		355.187		342.765	
Accumulated deficit		(254,165)		(230,632)	
Total shareholders' equity		101,445	-	112,550	
Total liabilities and shareholders' equity	\$	195,520	\$	208,024	
Total habilities and shareholders equity	Ψ	100,020	Ψ	200,024	

Axogen, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(In Thousands, Except Per Share Amounts)

	Three Months Ended				Nine Months Ended				
	September 30, 2022		September 30, 2021		September 30, 2022		Se	eptember 30, 2021	
Revenues	\$	36,959	\$	31,204	\$	102,420	\$	95,821	
Cost of goods sold		6,176		5,239		18,006		17,503	
Gross profit		30,783		25,965		84,414		78,318	
Costs and expenses:									
Sales and marketing		19,792		18,370		60,349		55,594	
Research and development		7,050		6,404		20,347		17,875	
General and administrative		8,796		7,880		27,817		24,912	
Total costs and expenses		35,638		32,654		108,513		98,381	
Loss from operations		(4,855)		(6,689)		(24,099)		(20,063)	
Other (expense) income:									
Investment income		186		17		172		80	
Interest expense		(61)		(417)		(664)		(1,427)	
Change in fair value of derivatives		469		(46)		1,155		(152)	
Other expense		(57)		(6)		(97)		(137)	
Total other expense, net		537		(452)		566		(1,636)	
Net loss	\$	(4,318)	\$	(7,141)	\$	(23,533)	\$	(21,699)	
Weighted average common shares outstanding — basic and diluted		42,220,519	_	41,467,596		42,008,013		41,087,568	
Loss per common share — basic and diluted	\$	(0.10)	\$	(0.17)	\$	(0.56)	\$	(0.53)	

Axogen, Inc. RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES

Three and Nine Months ended September 30, 2022 and 2021 (unaudited)

(In Thousands, Except Per Share Amounts)

	Three Months Ended					Nine Months Ended			
	September 30, 2022		September 30, 2021		September 30, 2022		Se	eptember 30, 2021	
Net loss	\$	(4,318)	\$	(7,141)	\$	(23,533)	\$	(21,699)	
Depreciation and amortization expense		830		706		2,380		2,207	
Investment income		(186)		(17)		(172)		(80)	
Income tax expense		31		20		64		47	
Interest expense		61		417		664		1,009	
EBITDA - non GAAP	\$	(3,582)	\$	(6,015)	\$	(20,597)	\$	(18,516)	
Non cash stock-based compensation expense		3,849		2,911		11,437		9,410	
Litigation and related costs		101		628		584		1,236	
Adjusted EBITDA - non GAAP	\$	368	\$	(2,476)	\$	(8,576)	\$	(7,870)	
Net loss	\$	(4,318)	\$	(7,141)	\$	(23,533)	\$	(21,699)	
Non cash stock-based compensation expense		3,849		2,911		11,437		9,410	
Litigation and related costs		101		628		584		1,236	
Adjusted net loss - non GAAP	\$	(368)	\$	(3,602)	\$	(11,512)	\$	(11,053)	
Weighted average common shares outstanding basic and diluted		42,220,519		41,467,596		42,008,013		41,087,568	
Loss per common share — basic and diluted	\$	(0.10)	\$	(0.17)	\$	(0.56)	\$	(0.53)	
Non cash stock-based compensation expense	\$	0.09	\$	0.07	\$	0.27	\$	0.23	
Litigation and related costs	\$		\$	0.02	\$	0.01	\$	0.03	
Adjusted net loss per common share - basis and diluted - non GAAP	\$	(0.01)	\$	(0.08)	\$	(0.28)	\$	(0.27)	

Axogen, Inc.
Condensed Consolidated Statements of Changes in Shareholders' Equity
(unaudited)
(In Thousands, Except Share Amounts)

_	Common Stock			Additional Paid-in		A a a como collega d		Total Shareholders'	
	Shares	Amo	unt	Paid-in Capital		Accumulated Deficit		Sn	Equity
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
Three Months Ended September 30, 2021									
Balance at June 30, 2021	41,337,108	\$	413	\$	336,495	\$	(218,205)	\$	118,703
Net loss		*	_	*	—	Ψ.	(7,141)	Ψ.	(7,141)
Stock-based compensation	_		_	\$	2,911		—		2,911
Issuance of restricted and performance stock units	67,249		1	•	(1)				
Exercise of stock options and employee stock	, -				()				
purchase plan	154,572		1		807		_		808
Balance at September 30, 2021	41,558,929	\$	415	\$	340,212	\$	(225,346)	\$	115,281
Nine Months Ended Contember 20, 2004									
Nine Months Ended September 30, 2021	40 040 700	C	400	φ	226 200	ф	(202.047)	¢.	100 110
Balance at December 31, 2020 Net loss	40,618,766	\$	406	Ф	326,390	\$	(203,647)	\$	123,149
Stock-based compensation	_		_		9.410		(21,699)		(21,699) 9,410
Issuance of restricted and performance stock units	206,193		_		9,410		_		9,410
Exercise of stock options and employee stock	200, 193		2		(2)		_		_
purchase plan	733,970		7		4,414		_		4,421
Balance at September 30, 2021	41,558,929	\$	415	\$	340,212	\$	(225,346)	\$	115,281

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

		MILLE MOL	ilis Ellueu			
	Sep	otember 30, 2022	Sep	otember 30, 2021		
Cash flows from operating activities:						
Net loss	\$	(23,533)	\$	(21,699)		
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation		2,182		2,059		
Amortization of right-of-use assets		1,303		1,418		
Amortization of intangible assets		198		148		
Amortization of debt discount and deferred financing fees		667		384		
Provision for bad debt		566		(145)		
Provision for inventory write-down		1,381		2,850		
Change in fair value of derivatives		(1,155)		152		
Investment losses		44		49		
Stock-based compensation		11,437		9,410		
Change in operating assets and liabilities:						
Accounts receivable		(3,695)		(804)		
Inventory		(3,804)		(5,774)		
Prepaid expenses and other		(828)		1,146		
Accounts payable and accrued expenses		(870)		(927)		
Operating lease obligations		(1,320)		(154)		
Cash paid for interest portion of finance leases		(1)		(1)		
Contract and other liabilities				(3)		
Net cash used in operating activities		(17,428)		(11,891)		
Cash flows from investing activities:						
Purchase of property and equipment		(13,456)		(20,641)		
Economic development grant proceeds		_		950		
Purchase of investments		(24,607)		(39,139)		
Proceeds from sale of investments		37,100		49,300		
Cash payments for intangible assets		(1,028)		(534)		
Net cash used in investing activities		(1,991)		(10,064)		
Cash flows from financing activities:						
Payments for debt issuance costs		(9)		_		
Proceeds from the issuance of long-term debt		-		15,000		
Cash paid for debt portion of finance leases		_		(12)		
Proceeds from exercise of stock options and ESPP stock purchases		990		4,421		
Net cash provided by financing activities	-	981		19,409		
Net decrease in cash, cash equivalents, and restricted cash		(18,438)		(2,546)		
Cash, cash equivalents, and restricted cash, beginning of period		39,007		55,609		
	\$	20,569	\$	53,063		
Cash, cash equivalents, and restricted cash, end of period	Ψ	20,000	Ψ	30,000		
Supplemental disclosures of cash flow activity:						
Cash paid for interest, net of capitalized interest	\$	_	\$	646		
Supplemental disclosure of non-cash investing and financing activities:						
Acquisition of fixed assets in accounts payable and accrued expenses	\$	2,090	\$	1,460		
Obtaining a right-of-use asset in exchange for a lease liability	\$	920	\$	1,375		
Obtaining of property and equipment in exchange for a lease liability	\$	22	\$	_		
Embedded derivative associated with the long-term debt	\$	_	\$	1,173		
Acquisition of intangible assets in accounts payable and accrued expenses	\$	177	\$	261		

Nine Months Ended



Source: Axogen, Inc.