

Axogen, Inc. Reports 2021 Third Quarter Financial Results

ALACHUA, Fla. and TAMPA, Fla., Nov. 03, 2021 (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, 2021.

Third Quarter 2021 Financial Results and Recent Business Highlights

- Net revenue was \$31.2 million during the quarter, a 7% decrease compared to third quarter 2020 revenue of \$33.4 million. Prior-year revenue included approximately \$3.3 million from procedures deferred from the first half of 2020 as a result of the initial impact of the COVID-19 pandemic, and approximately \$1.5 million from the sale of Avive[®] Soft Tissue Membrane, for which the company voluntarily suspended market availability on June 1, 2021.
- Gross margin was 83.2% for the quarter, compared to 83.0% one year ago.
- Net loss for the quarter was \$7.1 million, or \$0.17 per share, compared to a net loss of \$1.5 million, or \$0.04 per share, in the third quarter of 2020.
- Adjusted net loss was \$3.6 million for the quarter, or \$0.09 per share, compared with adjusted net income of \$1.5 million, or \$0.04 per share, in the third quarter of 2020.
- Adjusted EBITDA loss was \$2.5 million for the quarter, compared to an adjusted EBITDA of \$2.3 million in the third quarter of 2020.
- The balance of cash, cash equivalents, and investments on September 30, 2021 was \$98.1 million, compared to a balance of \$106.2 million on June 30, 2021. The net change includes capital expenditures of \$8.0 million related to construction of our new processing facility in Dayton and \$0.2 million of operating cash burn in the guarter.
- RANGER[®] neuroma publication noted that 80% of subjects who had their neuromas resected and the resulting gap reconstructed with Avance[®] Nerve Graft reported an improvement in their pain, and 88% of subjects reported meaningful return of sensory function.¹

"Our third quarter results were negatively impacted by lower-than-expected procedure volumes as hospitals addressed an increase in COVID cases and staffing challenges," commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. "We view these lower procedure volumes in the third quarter as transitory in nature, and we are confident in the underlying strength of our business as well as our ability to support our customers as surgical schedules and staffing challenges improve."

Additional Operational and Business Highlights

- Core accounts in the third quarter were 292, an 18% increase compared to 248 in the third quarter of 2020 and continue to represent approximately 60% of total revenue.
- Active accounts were 954, a 9% increase compared to 875 in the third quarter a year ago. Revenue from the top 10% of our active accounts continued to represent approximately 35% of total revenue in the quarter.
- Ended the quarter with 109 direct sales representatives, consistent with prior quarter and compared to 110 one year ago.
- Ended the quarter with 169 peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio.
- Axogen's peripheral nerve repair portfolio was featured throughout the clinical and scientific sessions of the 76th Annual Meeting of the American Society for Surgery of the Hand (ASSH) held in-person and online from September 30 to October 2, 2021.
 - Specific data read out from the RANGER registry on over 600 upper extremity nerve repairs demonstrated meaningful recovery in 82% of sensory and mixed/motor repairs.²

Updating 2021 Financial Guidance

Management is revising financial guidance, expecting full-year 2021 revenue will be in the range of \$127.0 million to \$129.0 million versus the prior range of \$134.5 million to \$137.5 million. Additionally, management continues to expect full-year 2021 gross margin to remain above 80%.

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 by phone are invited to call toll free at 1-877-407-0993 or use the direct dial-in number 1-201-689-8795. Those interested in listening to the conference call live via the Internet can do so by visiting the Investors page of the Company's website at www.axogeninc.com and clicking on the webcast link on the Investors home page.

Following the conference call, a replay will be available on the Company's website at www.axogeninc.com under Investors.

About the RANGER Registry

The RANGER Registry, a multicenter Registry of Avance Nerve Graft's Utilization and Recovery Outcomes Post Peripheral Nerve Reconstruction, is an active multicenter clinical registry designed to continuously monitor and collect injury, repair, safety, and outcomes data for peripheral nerve injuries repaired with processed nerve allograft (Avance Nerve Graft), nerve autograft, and manufactured conduits. The study, launched in 2008, includes more than 30 centers. RANGER is an Axogen sponsored ongoing open label registry study. Each patient outcome is dependent upon the nature and extent of nerve loss or damage, timing between nerve loss and repair, and the natural course of the patient's recovery.

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, the United Kingdom, South Korea, and several other European and international 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. The forward-looking statements may include, without limitation, statements related to the expected impact of COVID-19 on our business, statements regarding our growth, our 2021 financial guidance, product development, product potential, regulatory process and approvals, APC renovation timing and expense, financial performance, sales growth, product adoption, market awareness of our products, data validation, our assessment of our internal controls over financial reporting, our visibility at and sponsorship of conferences and educational events. 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. Forwardlooking statements contained in this press release should be evaluated together with the many uncertainties that affect our business and our market, particularly those discussed under Part I, Item 1A., "Risk Factors," of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, 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.

¹Clinical Outcomes of Symptomatic Neuroma Resection and Reconstruction with Processed Nerve Allograft. Plast Reconstr Surg Glob Open. 2021 Oct 4;9(10):e3832. Jain SA, Nydick J, Leversedge F, Power D, Styron J, Safa B, Buncke G.

²Axogen Data on file.

Contact:

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AXOGEN, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

(In Thousands, Except Share and Per Share Amounts)

	September 2021		Dec	ember 31, 2020
Assets				
Current assets:				
Cash and cash equivalents	\$	46,730	\$	48,767
Restricted cash		6,333		6,842
Investments		44,989		55,199
Accounts receivable, net		18,567		17,618
Inventory		15,453		12,529
Prepaid expenses and other		2,896		4,296
Total current assets	·	134,968		145,251
Property and equipment, net		56,328		38,398
Operating lease right-of-use assets		15,588		15,614
Finance lease right-of-use assets		47		64
Intangible assets		2,701		2,054
Other long-term assets		339		_
Total assets	\$	209,971	\$	201,381
Liabilities and Shareholders' Equity				
Current liabilities:				
Accounts payable and accrued expenses	\$	21,685	\$	21,968
Current maturities of long-term lease obligations		1,674		863
Total current liabilities	·	23,359		22,831
Long-term debt, net of financing fees		46,238		32,027
Debt derivative liabilities		3,822		2,497
Long-term lease obligations		21,271		20,874
Other long-term liabilities		_		3
Total liabilities		94,690		78,232
Shareholders' equity:	·			
Common stock, \$.01 par value per share; 100,000,000 shares authorized		415		406
Additional paid-in capital		340,212		326,390
Accumulated deficit		(225,346)		(203,647)
Total shareholders' equity	·	115,281		123,149
Total liabilities and shareholders' equity	\$	209,971	\$	201,381

AXOGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

Three and Nine Months Ended September 30, 2021 and 2020 (unaudited)

(In Thousands, Except Per Share Amounts)

	Three Months Ended				Nine Months Ended				
	Sep	tember 30,	Sep	tember 30,	Se	ptember 30,	September 30,		
		2021		2020	2021		2020		
Revenues	\$	31,204	\$	33,428	\$	95,821	\$	79,805	
Cost of goods sold		5,239		5,697		17,503		16,118	
Gross profit		25,965	-	27,731		78,318		63,687	
Costs and expenses:									
Sales and marketing		18,370		17,726		55,594		49,854	
Research and development		6,404		4,230		17,875		12,915	
General and administrative		7,880		6,820		24,912		18,726	
Total costs and expenses		32,654		28,776		98,381		81,495	
Loss from operations	· <u> </u>	(6,689)		(1,045)		(20,063)	<u> </u>	(17,808)	
Other (expense) income:			-						
Investment income		17		28		80		576	
Interest expense		(417)		(397)		(1,427)		(459)	
Change in fair value of derivatives		(46)		(71)		(152)		(71)	
Other expense		(6)		6		(137)		(14)	
Total other (expense) income, net	· <u> </u>	(452)		(434)		(1,636)	<u> </u>	32	
Net loss	\$	(7,141)	\$	(1,479)	\$	(21,699)	\$	(17,776)	
Weighted average common shares outstanding – basic and diluted		41,468		40,094		41,088		39,873	
Loss per common share – basic and diluted	\$	(0.17)	\$	(0.04)	\$	(0.53)	\$	(0.45)	
Adjusted net income (loss) - non GAAP	\$	(3,602)	\$	1,468	\$	(10,425)	\$	(12,016)	
Adjusted net income (loss) per common share – basic and diluted	\$	(0.09)	\$	0.04	\$	(0.25)	\$	(0.30)	

AXOGEN, INC.

RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES

Three and Nine Months Ended September 30, 2021 and 2020 (unaudited)

(In Thousands, Except Per Share Amounts)

	Three Months Ended					Nine Months Ended				
	September 30, 2021		Sep	tember 30, 2020	Sep	tember 30, 2021	September 30, 2020			
Gross profit	\$	25,965	\$	27,731	\$	78,318	\$	63,687		
Avive inventory write-down and production costs		-		-		1,429		-		
Adjusted gross profit	\$	25,965	\$	27,731	\$	79,747	\$	63,687		
Net loss	\$	(7,141)	\$	(1,479)	\$	(21,699)	\$	(17,776)		
Depreciation and amortization expense		706		439		2,207		1,104		
Investment income		(17)		(28)		(80)		(576)		
Income tax expense		_		_		67		_		
Interest expense		417		397		1,427		459		
EBITDA - non GAAP	\$	(6,035)	\$	(671)	\$	(18,078)	\$	(16,789)		
Non cash stock compensation expense		2,911		2,947		9,410		5,725		
Litigation and related costs		628		_		1,864		35		
Adjusted EBITDA - non GAAP	\$	(2,496)	\$	2,276	\$	(6,804)	\$	(11,029)		
Net loss	\$	(7,141)	\$	(1,479)	\$	(21,699)	\$	(17,776)		
Non cash stock compensation expense		2,911		2,947		9,410		5,725		
Litigation and related costs		628		_		1,864		35		
Adjusted Net Income (Loss) - non GAAP	\$	(3,602)	\$	1,468	\$	(10,425)	\$	(12,016)		
Weighted average common shares outstanding – basic and diluted		41,468		40,094		41,088		39,873		
Adjusted net income (loss) per common share – basic and diluted	\$	(0.09)	\$	0.04	\$	(0.25)	\$	(0.30)		

AXOGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

Three and Nine Months Ended September 30, 2021 and 2020 (unaudited)

(In Thousands, Except Share Amounts)

	Common Stock Shares Amount		Additional		I		Total		
			mount	Paid-in Capital			cumulated Deficit	Shareholders' Equity	
For the Three Months Ended September 30, 2021:				_					
Balance at June 30, 2021	41,337,108	\$	413	\$	336,495	\$	(218,205)	\$	118,703
Net loss	-		-		-		(7,141)		(7,141)
Stock-based compensation	- 07.040		-		2,911		-		2,911
Issuance of restricted and performance stock units Exercise of stock options and employee stock purchase	67,249		1		(1)		-		-
plan	154,572		1		807		-		808
Balance at September 30, 2021	41,558,929	\$	415	\$	340,212	\$	(225,346)	\$	115,281
For the Nine Months Ended September 30, 2021:									
Balance at December 31, 2020	40,618,766	\$	406	\$	326,390	\$	(203,647)	\$	123,149
Net loss	-		-		-		(21,699)		(21,699)
Stock-based compensation	-		-		9,410		-		9,410
Issuance of restricted and performance stock units	206,193		2		(2)		-		-
Exercise of stock options and employee stock purchase plan	733,970		7		4,414		-		4,421
Balance at September 30, 2021	41,558,929	\$	415	\$	340,212	\$	(225,346)	\$	115,281
For the Three Months Ended September 30, 2020: Balance at June 30, 2020	40,022,499	\$	400	\$	315.518	\$	(196,158)	\$	119,760
Net loss	40,022,499	φ	400	φ	313,316	Φ	(1,479)	Φ	(1,479)
Stock-based compensation	_		_		2,947		-		2,947
Issuance of restricted and performance stock units	22,529		-		-		-		-
Shares surrendered by employees to pay tax withholdings	(1,230)		-		(8)		-		(8)
Exercise of stock options and employee stock purchase plan	80,043		1		492		-		493
Balance at September 30, 2020	40,123,841	\$	401	\$	318,949	\$	(197,637)	\$	121,713
For the Nine Months Ended September 30, 2020:									
Balance at December 31, 2019	39,589,755	\$	396	\$	311,618	\$	(179,861)	\$	132,153
Net loss	-		-		-		(17,776)		(17,776)
Stock-based compensation	-		-		5,725		-		5,725
Issuance of restricted and performance stock units	168,311		2		(2)		-		-
Shares surrendered by employees to pay tax withholdings	(38,086)		(1)		(664)		-		(665)
Exercise of stock options and employee stock purchase plan	403,861		4	_	2,272	_			2,276
Balance at September 30, 2020	40,123,841	\$	401	\$	318,949	\$	(197,637)	\$	121,713

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
Nine Months Ended September 30, 2021 and 2020
(unaudited)
(In Thousands)

	Sej	otember 30,	September 30,			
		2021	2020			
Cash flows from operating activities:						
Net loss	\$	(21,699)	\$	(17,776)		
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation		2,059		993		
Amortization of right-of-use assets		1,418		1,282		
Amortization of intangible assets		148		111		
Amortization of deferred financing fees		384		22		
Provision for bad debt		(145)		(115)		
Provision for inventory write-down		2,850		2,108		
Change in fair value of derivatives		152		71		
Change in investment gains and losses		49		(29)		
Share-based compensation		9,410		5,725		
Change in operating assets and liabilities:						
Accounts receivable		(804)		(1,700)		
Inventory		(5,774)		(176)		
Prepaid expenses and other		1,146		(844)		
Accounts payable and accrued expenses		(927)		(911)		
Operating lease obligations		(154)		(1,213)		
Cash paid for interest portion of finance leases		(1)		(2)		
Contract and other liabilities		(3)		(9)		
Net cash used in operating activities		(11,891)		(12,463)		
Cash flows from investing activities:						
Purchase of property and equipment		(20,641)		(18,907)		
Economic development grant proceeds		950		_		
Purchase of investments		(39,139)		(41,794)		
Proceeds from sale of investments		49,300		63,483		
Cash payments for intangible assets		(534)		(393)		
Net cash (used in) provided by investing activities		(10,064)		2,389		
Cash flows from financing activities:						
Proceeds from the issuance of long-term debt		15,000		35,000		
Proceeds from the paycheck protection program				7,820		
Repayment of paycheck protection program		_		(7,820)		
Payments for debt issuance costs		_		(642)		
Payments of employee tax withholding in exchange of common stock awards		_		(665)		
Cash paid for debt portion of finance leases		(12)		(10)		
Proceeds from exercise of stock options		4,421		2,276		
Net cash provided by financing activities		19,409		35,959		
Net (decrease) increase in cash, cash equivalents and restricted cash		(2,546)		25,885		
Cash, cash equivalents and restricted cash, beginning of period		55,609		41,724		
Cash, cash equivalents and restricted cash, end of period	\$	53,063	\$	67,609		
Supplemental disclosures of cash flow activity:						
Cash paid for interest	\$	646	\$	379		
Supplemental disclosure of non-cash investing and financing activities	Ψ.	0.10	*	0.0		
Acquisition of fixed assets in accounts payable and accrued expenses	\$	1,460	\$	1,271		
Obtaining a right-of-use asset in exchange for a lease liability	\$	1,375	\$	14,119		
Embedded derivative associated with the long-term debt	\$	1,173	\$	2,562		
Acquisition of intangible assets in accounts payable and accrued expenses	\$	261	\$	2,002		
Acquisition of interngible according according payable and accided expenses	Ψ	201	Ψ	_		



Source: Axogen, Inc.