

November 3, 2021



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 quarter.
- 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. Forward-looking 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.

¹*Clinical 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.*

²*Axogen Data on file.*

Contact:

Axogen, Inc.

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AXOGEN, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(In Thousands, Except Share and Per Share Amounts)

	September 30, 2021	December 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	<u>134,968</u>	<u>145,251</u>
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	<u>\$ 209,971</u>	<u>\$ 201,381</u>
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	<u>23,359</u>	<u>22,831</u>
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	<u>94,690</u>	<u>78,232</u>
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	<u>115,281</u>	<u>123,149</u>
Total liabilities and shareholders' equity	<u>\$ 209,971</u>	<u>\$ 201,381</u>

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Three and Nine Months Ended September 30, 2021 and 2020
(In Thousands, Except Per Share Amounts)

	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Revenues	\$ 31,204	\$ 33,428	\$ 95,821	\$ 79,805
Cost of goods sold	5,239	5,697	17,503	16,118
Gross profit	<u>25,965</u>	<u>27,731</u>	<u>78,318</u>	<u>63,687</u>
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	<u>32,654</u>	<u>28,776</u>	<u>98,381</u>	<u>81,495</u>
Loss from operations	<u>(6,689)</u>	<u>(1,045)</u>	<u>(20,063)</u>	<u>(17,808)</u>
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>(452)</u>	<u>(434)</u>	<u>(1,636)</u>	<u>32</u>
Net loss	<u>\$ (7,141)</u>	<u>\$ (1,479)</u>	<u>\$ (21,699)</u>	<u>\$ (17,776)</u>
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	September 30, 2020	September 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		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
Shares	Amount			

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	-		-		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	<u>41,558,929</u>	<u>\$</u>	<u>415</u>	<u>\$</u>	<u>340,212</u>	<u>\$</u>	<u>(225,346)</u>	<u>\$</u>	<u>115,281</u>

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	<u>41,558,929</u>	<u>\$</u>	<u>415</u>	<u>\$</u>	<u>340,212</u>	<u>\$</u>	<u>(225,346)</u>	<u>\$</u>	<u>115,281</u>

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	-		-		-		(1,479)		(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	<u>40,123,841</u>	<u>\$</u>	<u>401</u>	<u>\$</u>	<u>318,949</u>	<u>\$</u>	<u>(197,637)</u>	<u>\$</u>	<u>121,713</u>

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	<u>40,123,841</u>	<u>\$</u>	<u>401</u>	<u>\$</u>	<u>318,949</u>	<u>\$</u>	<u>(197,637)</u>	<u>\$</u>	<u>121,713</u>

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

	Nine Months Ended	
	September 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		
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	\$ -



Source: Axogen, Inc.