

Axogen, Inc. Reports Third Quarter 2020 Financial Results

ALACHUA, Fla., Oct. 29, 2020 (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, 2020.

Third Quarter 2020 Financial Results and Recent Business Highlights

- Net revenue was \$33.4 million during the quarter, an increase of 17% compared to third guarter 2019 revenue of \$28.6 million.
- Gross margin was 83.0% for the quarter, compared to 84.2% in the third quarter of 2019.
- Net loss was \$1.5 million for the quarter, or \$0.04 per share, compared to a net loss of \$5.6 million, or \$0.14 per share, in the third quarter of 2019.
- Adjusted net income was \$1.5 million for the quarter, or \$0.04 per share, compared with adjusted net loss of \$2.6 million, or \$0.07 per share, in the third quarter of 2019.
- Adjusted EBITDA was \$2.3 million for the quarter, compared to an adjusted EBITDA loss of \$3.0 million in the third quarter of 2019.
- The balance of cash, cash equivalents, and investments on September 30, 2020 was \$106.7 million, compared to a balance of \$109.9 million on June 30, 2020. The net change includes capital expenditures of \$5.2 million related to our new facilities in Tampa and Dayton, partially offset by positive operating cash flow of \$2.0 million in the third quarter.
- Appointed Paul G. Thomas to the Axogen, Inc. Board of Directors. Thomas has more than 30 years of experience in the medtech industry, currently serves on the board of directors of Abiomed (NASDAQ: ABMD) and Surgalign Spine Technologies (NASDAQ: SRGA) and is the CEO and Co-Founder of Prominex, Inc. He also previously served as Chairman and CEO of LifeCell Corporation.

"I am very pleased with our third quarter performance and return to growth despite the ongoing COVID-19 pandemic," commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. "We believe the strength of our performance reflects our team's improved commercial execution, the priority that surgeons and hospitals have placed on the timely repair of nerve injuries, and the clinical and economic benefits of Axogen technologies for patients, surgeons, and healthcare facilities. We remain focused on our commercial strategy of driving deeper adoption of our technologies in our largest market opportunity, extremity trauma, and achieving long term, sustainable growth."

Additional Recent Operational and Business Highlights

- Ended the third quarter with 110 direct sales representatives, a decrease of two from last quarter, and up from 105 at the end of Q3 2019.
- Active accounts in the third quarter were 875, an increase of 11% compared to 791 in the third quarter a year ago.
- Ended the quarter with 138 peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio.
- Axogen's peripheral nerve repair portfolio was featured at the clinical and scientific sessions of the 75th Annual Meeting of the American Society for Surgery of the Hand (ASSH) held virtually from October 1-3, 2020, including key presentations highlighting the clinical and economic value of Avance[®] Nerve Graft as compared to traditional nerve autograft.

MATCHSM Conduit Cohort of RANGER® Registry Published

On October 1, 2020, clinical data from the MATCH conduit cohort of the RANGER registry comparing Avance Nerve Graft repairs to manufactured conduits was published in the *Journal of Hand Surgery*. The scientific article, titled *A Multicenter Matched Cohort Study of Processed Nerve Allograft and Conduit in Digital Nerve Reconstruction*, included 162 nerve repairs with gaps up to 25mm and found that Avance Nerve Graft outcomes were significantly better than conduits with a meaningful recovery rate of 88% vs. 61% for conduits (p=0.001) and improved average static two-point discrimination of 9.7mm vs. 12.2mm for conduits (p=0.018). More specifically, the study stratified injuries into gap length groups of those less than 15mm, and those between 15mm and 25mm. Avance outcomes exceeded those of conduit with meaningful recovery rates of 92% versus 67% in the less than 15mm group (p=0.008) and 85% versus 45% in the 15mm to 25mm group (p=0.001). This study is the largest nerve repair study to date comparing Avance Nerve Graft and conduits.

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.

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 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; 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; and Avive[®] Soft Tissue Membrane, a processed human umbilical cord intended for surgical use as a resorbable soft tissue barrier. 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, product development, product potential, 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, as amended on Form 10-K/A, for the fiscal year ended December 31, 2019, 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 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.

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AXOGEN, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

	September 3 2020	80, De	December 31, 2019		
Assets					
Current assets:					
Cash and cash equivalents	\$ 60,002	2 \$	35,724		
Restricted Cash	7,607	7	6,000		
Short-term investments	39,126	;	60,786		
Accounts receivable, net	18,758	3	16,944		
Inventory	11,929)	13,861		

Total current assets 139,973		135,021
Property and equipment, net 36,110		14,887
Operating lease right-of-use assets 15,987		3,133
Finance lease right-of-use assets 70		87
Intangible assets 1,797		1,515
Total assets \$ 193,937	\$	154,643
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Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses \$ 16,279	\$	19,130
Current maturities of long term obligations 2,499		1,736
Contract liabilities, current 14		14
Total current liabilities 18,792		20,880
Long-term debt, net of financing fees 31,817		_
Debt derivative liability 2,450		_
Common stock derivative option liability 183		
Long-term lease obligations 18,976		1,595
Other long-term liabilities 6		15
Total liabilities 72,224		22,490
Shareholders' equity:		
Common stock, \$.01 par value; 100,000,000		
shares authorized; 40,123,841 and 39,589,775		
shares issued and outstanding 401		396
Additional paid-in capital 318,949		311,618
Accumulated deficit (197,637)		(179,861)
Total shareholders' equity 121,713		132,153
Total liabilities and shareholders' equity \$ 193,937	\$	154,643

Prepaid expenses and other

AXOGEN, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS Three and Nine Months ended September 30, 2020 and 2019 (unaudited)

2,551

1,706

	Three Months Ended			Nine Months Ended				
	:	Sept 30, 2020	;	Sept 30, 2019		Sept 30, 2020		Sept 30, 2019
Revenues	\$	33,428	\$	28,564	\$	79,805	\$	78,550
Cost of goods sold		5,697		4,510		16,118		12,468
Gross profit		27,731		24,054		63,687		66,082
Costs and expenses:								
Sales and marketing		17,726		18,245		49,854		53,146
Research and development		4,230		4,181		12,915		12,602
General and administrative		6,820		7,740		18,726		24,321
Total costs and expenses		28,776		30,166		81,495		90,069
Loss from operations		(1,045)		(6,112)		(17,808)		(23,987)
Other income (expense):						<u> </u>		
Interest income		28		555		576		1,925
Interest expense		(397)		(7)		(459)		(32)
Change in fair value of derivative liabilities		(71)		_		(71)		_
Other expense		6		(7)		(14)		(3)
Total other income (expense)		(434)		541		32		1,890
Net loss	\$	(1,479)	\$	(5,571)	\$	(17,776)	\$	(22,097)
Weighted average common shares outstanding – basic and diluted		40,094		39,340		39,873		39,151
Loss per common share – basic and diluted	\$	(0.04)	\$	(0.14)	\$	(0.45)	\$	(0.56)
Adjusted net income (loss) - non GAAP		1,468		(2,644)		(12,016)		(12,386)
Adjusted net income (loss) per common share - basic and diluted	\$	0.04	\$	(0.07)	\$	(0.30)	\$	(0.32)

AXOGEN, INC. RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES Three and Nine Months ended September 30, 2020 and 2019 (unaudited)

	Three Months Ended			Nine Months Ended				
	•	Sept 30, 2020	Sept 30, 2019		Sept 30, 2020		Sept 30, 2019	
Net loss	\$	(1,479)	\$	(5,571)	\$	(17,776)	\$	(22,097)
Depreciation and amortization expense		439		244		1,104		757
Investment income		(28)		(555)		(576)		(1,925)
Income tax		_		(3)		_		(15)
Interest expense		397		7		459		32
EBITDA - non GAAP	\$	(671)	\$	(5,878)	\$	(16,789)	\$	(23,248)
Non cash stock compensation expense		2,947		2,395		5,725		7,384
Litigation and related costs		_		532		35		2,327
Adjusted EBITDA - non GAAP	\$	2,276	\$	(2,951)	\$	(11,029)	\$	(13,537)
Net loss	\$	(1,479)	\$	(5,571)	\$	(17,776)	\$	(22,097)
Non cash stock compensation expense		2,947		2,395		5,725		7,384
Litigation and related costs				532		35		2,327
Adjusted Net Income (Loss) - non GAAP	\$	1,468	\$	(2,644)	\$	(12,016)	\$	(12,386)
Weighted average common shares outstanding – basic and diluted		40,094		39,340		39,873		39,151
Adjusted net income (loss) per common share - basic and diluted	\$	0.04	\$	(0.07)	\$	(0.30)	\$	(0.32)

AXOGEN, INC. CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY Three and Nine Months Ended September 30, 2020 and 2019 (unaudited)

	Common Stock Additional Paid-in Capital		Accumulated Deficit		Total Shareholders' Equity		
For the Three Months Ended September 30, 2020:							
Balance at June 30, 2020	\$	400	\$ 315,518	\$	(196,158)	\$	119,760
Net loss		-	-		(1,479)		(1,479)
Stock-based compensation		-	2,947		-		2,947
Shares surrendered by employees to pay taxes Exercise of stock options and employee stock		-	(8)		-		(8)
purchase plan		1	492		-		493
Balance at September 30, 2020	\$	401	\$ 318,949	\$	(197,637)	\$	121,713
For the Nine Months Ended September 30, 2020:							
Balance at December 31, 2019	\$	396	\$ 311,618	\$	(179,861)	\$	132,153
Net loss		-	-		(17,776)		(17,776)
Stock-based compensation		_	5,725		-		5,725
Issuance of restricted /performance service awards		2	(2)		-		-
Shares surrendered by employees to pay taxes		(1)	(664)		-		(665)
Exercise of stock options and employee stock purchase plan		4	2,272		-		2,276
Balance at September 30, 2020	\$	401	\$ 318,949	\$	(197,637)	\$	121,713

For the Three Months Ended September 30, 2019: Balance at June 30, 2019

Net loss Stock-based compensation	\$ 393	\$ 304,820	\$ (167,252) (5,571)	\$ 137,960 (5,571)
Shares surrendered by employees to pay taxes Exercise of stock options and employee stock	-	2,397	-	2,397
purchase plan	2	623	-	625
Balance at September 30, 2019	\$ 395	\$ 307,839	\$ (172,823)	\$ 135,411
For the Nine Months Ended September 30, 2019:				
Balance at December 31, 2018	\$ 389	\$ 297,319	\$ (150,726)	\$ 146,982
Net loss	-	-	(22,097)	(22,097)
Stock-based compensation	-	7,384	-	7,384
Exercise of stock options and employee stock purchase plan	6	3,136	-	3,142
Balance at September 30, 2019	\$ 395	\$ 307,839	\$ (172,823)	\$ 135,411

Six Months Ended

AXOGEN, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS Nine Months Ended September 30, 2020 and 2019 (unaudited)

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	Sept 30, 2020	Sept 30, 2019			
Cash flows from operating activities:					
Net loss	\$ (17,776)	(22,097)			
Adjustments to reconcile net loss to net cash used in	, , , ,	(, ,			
operating activities:					
Depreciation	993	631			
Amortization of right-of-use assets	1,282	1,352			
Amortization of intangible assets	111	89			
Amortization of deferred financing fees	22	_			
Provision for bad debt	(115)	(150)			
Provision for inventory write down	2,108	(44)			
Change in fair value of derivatives	71	_			
Change in investment gains and losses	(29)	(957)			
Share-based compensation	5,725	7,384			
Change in assets and liabilities:					
Accounts receivable	(1,700)	20			
Inventory	(176)	(1,657)			
Prepaid expenses and other	(844)	(1,099)			
Accounts payable and accrued expenses	(911)	1,288			
Operating Lease Obligations	(1,213)	(1,276)			
Cash paid for interest portion of Finance Leases	(2)	(3)			
Contract and other liabilities	(9)	(23)			
Net cash used in operating activities	(12,463)	(16,542)			
Cash flows from investing activities:					
Purchase of property and equipment	(18,907)	(3,676)			
Purchase of short-term investments	(41,794)	(104,314)			
Sale/Maturities of short-term investments	63,483	122,071			
Cash payments for intangible assets	(393)	(396)			
Net cash provided by investing activities	2,389	13,685			
Net cash provided by investing activities	2,309	13,003			
Cash flows from financing activities:					
Proceeds from the issuance long term debt	35,000	_			
Proceeds from the paycheck protection plan	7,820	_			
Payment of paycheck protection plan	(7,820)	_			
Payments of debt issuance costs	(642)	_			
Payments for repurchase of common stock for	. ,				
employee tax withholding	(665)	_			

Cash paid for debt portion of finance leases	(10)	(24)
Proceeds from exercise of stock options and warrants	2,276	3,142
Net cash provided by financing activities	35,959	3,118
Net increase in cash, cash equivalents and restricted cash Cash, cash equivalents and restricted cash,	25,885	261
beginning of year	41,724	30,294
Cash, cash equivalents and restricted cash, end of period	\$ 67,609	\$ 30,555
Supplemental disclosures of cash flow activity: Cash paid for interest Supplemental disclosure of non-cash investing and financing activities	 379	 31
Acquisition of fixed assets in accounts payable and accrued expenses	1,271	684
Right-of-use asset and operating lease liability	14,119	 26
Embedded derivative associated with the long-term debt	2,562	



Source: Axogen, Inc.