

Axogen, Inc. Reports 2021 First Quarter Financial Results

ALACHUA, Fla. and TAMPA, Fla., May 05, 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 first quarter ended March 31, 2021.

First Quarter 2021 Financial Results and Business Highlights

- Net revenue was \$31.0 million during the quarter, a 28% increase compared to first guarter 2020 revenue of \$24.3 million.
- Gross margin was 83.3% for the quarter, compared to 80.1% in the first quarter of 2020.
- Net loss for the quarter was \$6.7 million, or \$0.16 per share, compared to a net loss of \$8.2 million, or \$0.21 per share, in the first quarter of 2020.
- Adjusted net loss was \$3.1 million for the quarter, or \$0.08 per share, compared with adjusted net loss of \$7.6 million, or \$0.19 per share, in the first quarter of 2020.
- Adjusted EBITDA loss was \$1.9 million for the quarter, compared to an adjusted EBITDA loss of \$7.6 million in the first quarter of 2020.
- The balance of cash, cash equivalents, and investments on March 31, 2021 was \$97.2 million, compared to a balance of \$110.8 million on December 31, 2020.

"I am pleased with our first quarter performance," commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. "Surgeon demand for our products remains strong, supported by our substantial investment in clinical studies over the past decade. These studies continue to generate meaningful evidence, driving further surgeon adoption and reinforcing our confidence in the long-term growth potential of our business."

Additional Operational and Business Highlights

- Active accounts in the first quarter were 919, an 11% increase compared to 825 in the
 first quarter a year ago, and revenue from the top 10% of our active accounts
 continued to represent approximately 35% of total revenue in the quarter.
- Ended the quarter with 106 direct sales representatives, compared to 108 currently, 111 at year end, and 109 one year ago.
- Ended the quarter with 157 peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio.
- Reinitiated clinical study activities for the Rethink Pain[™] and Sensation-NOW[®]
 registries and are actively engaged in six sponsored studies currently enrolling across
 our four primary market applications.

2021 Financial Guidance

Management is reinitiating financial guidance and believes that full-year 2021 revenue will be in the range of \$133 million to \$136 million. Additionally, full-year 2021 gross margin is expected 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 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, Germany, 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. 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, 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.

Contact: Axogen, Inc.

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AXOGEN, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

(In Thousands, Except Share Amounts)

	March 31, 2021		Dec	cember 31, 2020	
Assets					
Current assets:					
Cash and cash equivalents	\$	39,843	\$	48,767	
Restricted cash		6,333		6,842	
Investments		51,062		55,199	
Accounts receivable, net		19,825		17,618	
Inventory		13,388		12,529	
Prepaid expenses and other		4,694		4,296	
Total current assets		135,145		145,251	
Property and equipment, net		44,395		38,398	
Operating lease right-of-use assets		15,442		15,614	
Finance lease right-of-use assets		59		64	
Intangible assets		2,328		2,054	
Total assets	\$	197,369	\$	201,381	
Liabilities and Shareholders' Equity					
Current liabilities:					
Accounts payable and accrued expenses	\$	20,831	\$	21,968	
Current maturities of long-term lease obligations	1,442			863	
Total current liabilities		22,273		22,831	
Long-term debt, net of financing fees		32,140		32,027	
Debt derivative liability		2,519		2,497	
Long-term lease obligations		20,731		20,874	
Other long-term liabilities		2		3	
Total liabilities		77,665		78,232	
Shareholders' equity:					
Common stock, \$.01 par value per share; 100,000,000 shares authorized; 40,842,717 and 40,618,766 shares issued and outstanding		408		406	
Additional paid-in capital		329,603		326,390	
Accumulated deficit		(210,307)		(203,647)	
Total shareholders' equity		119,704		123,149	
Total liabilities and shareholders' equity	\$	197,369	\$	201,381	

AXOGEN, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS Three Months ended March 31, 2021 and 2020 (In Thousands) (unaudited)

		Three Months Ended				
		Mar 31, 2021	Mar 31, 2020			
Revenues	\$	31,037	\$	24,261		
Cost of goods sold		5,172		4,816		
Gross profit		25,865		19,445		
Costs and expenses:						
Sales and marketing		17,973		17,838		

Research and development	5,748	4,614
General and administrative	8,364	5,502
Total costs and expenses	32,085	 27,954
Loss from operations	(6,220)	 (8,509)
Other income (expense):		
Interest income	34	311
Interest expense	(444)	(31)
Other income (expense)	(30)	37
Total other income (expense)	(440)	 317
Net loss	\$ (6,660)	\$ (8,192)
Weighted average common shares outstanding – basic and diluted	40,706	39,698
Loss per common share – basic and diluted	\$ (0.16)	\$ (0.21)
Adjusted net loss - non GAAP Adjusted net loss per common share - basic and	(3,129)	(7,636)
diluted	\$ (80.0)	\$ (0.19)

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RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES Three Months ended March 31, 2021 and 2020 (In Thousands) (unaudited)

	Three Months Ended				
	Mar 31, 2021		N	Mar 31, 2020	
Net loss	\$	(6,660)	\$	(8,192)	
Depreciation and amortization expense		818		343	
Investment income		(34)		(311)	
Income tax		(5)		(10)	
Interest expense		444		31	
EBITDA - non GAAP	\$	(5,437)	\$	(8,139)	
Non cash stock compensation expense	\$	2,694	\$	556	
Litigation and related costs		837		_	
Adjusted EBITDA - non GAAP	\$	(1,906)	\$	(7,583)	
Net loss	\$	(6,660)	\$	(8,192)	
Non cash stock compensation expense		2,694		556	
Litigation and related costs		837			
Adjusted Net Loss - non GAAP	\$	(3,129)	\$	(7,636)	
Weighted average common shares outstanding -	_				
basic and diluted	\$	(0.16)	\$	(0.21)	
Non cash stock compensation expense		0.07		0.01	
Litigation and related costs		0.02			
Adjusted net loss per common share - basic and diluted	\$	(80.0)	\$	(0.19)	
Weighted average common shares outstanding – basic and diluted		40,706		39,698	

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(unaudited) (In Thousands, Except Share Amounts)

	Common Stock					Total		
For the Three Months Ended March 31, 2021:	Shares	A	mount	Additional Paid- in Capital	Ad	cumulated Deficit	Sha	areholders' Equity
Balance at December 31, 2020 Net Loss Issuance of restricted/performance service awards	40,618,766 - 94,533	\$	406 - 1	\$ 326,390 - (1)	\$	(203,647) (6,660)	\$	123,149 (6,660)
Stock-based compensation Exercise of stock options and employee stock purchase plan	- 129,418		- 1	2,694 520		-		2,694 521
Balance at March 31, 2021	40,842,717	\$	408	\$ 329,603	\$	(210,307)	\$	119,704
For the Three Months Ended March 31, 2020:								
Balance at December 31, 2019	39,589,755	\$	396	\$ 311,618	\$	(179,861)	\$	132,153
Net Loss	-		-	-		(8,192)		(8,192)
Issuance of restricted/performance service awards	137,634		1	(1)		-		-
Stock-based compensation	-		-	556		-		556
Shares surrendered by employees to pay taxes Exercise of stock options and employee stock	(36,963)		-	(639)		-		(639)
purchase plan	48,341		-	316				316
Balance at March 31, 2020	39,738,767	\$	397	\$ 311,850	\$	(188,053)	\$	124,194

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CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS Three Months ended March 31, 2021 and 2020 (In Thousands) (unaudited)

	Fiscal Year				
	Mar 31, 2021			Mar 31,	
				2020	
Cash flows from operating activities:					
Net loss	\$	(6,660)	\$	(8,192)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation		772		307	
Amortization of right-of-use assets		500		470	
Amortization of intangible assets		46		36	
Amortization of deferred financing costs		112		_	
Provision for bad debt		(26)		22	
Provision for inventory write down		783		924	
Change in fair value of derivatives		22		_	
Change in investment gains and losses		15		(49)	
Share-based compensation		2,694		556	
Change in assets and liabilities:					
Accounts receivable		(2,153)		3,902	
Inventory		(1,642)		(1,626)	
Prepaid expenses and other		(342)		(2,024)	
Accounts payable and accrued expenses		(4,896)		(1,903)	
Operating Lease Obligations		119		(472)	
Contract and other liabilities		(1)		(3)	
Net cash used in operating activities		(10,657)		(8,052)	

Cash flows from investing activities:			
Purchase of short-term investments		(15,278)	(11,760)
Purchase of property and equipment		(3,095)	(5,021)
Sale/Maturities of short-term investments		19,400	25,450
Cash payments for intangible assets		(321)	(119)
Net cash provided by investing activities		706	8,550
Cash flows from financing activities:			
Payments for repurchase of common stock for employee tax withholding		_	(639)
Cash paid for debt portion of finance leases		(4)	(5)
Proceeds from exercise of stock options and		(.)	(0)
warrants		521	316
Net cash provided by / (used in) financing			
activities		517	(328)
Net increase in cash, cash equivalents and restricted cash	t	(9,434)	170
Cash, cash equivalents and restricted cash,		(, ,	44.704
beginning of year	_	55,609	 41,724
Cash, cash equivalents and restricted cash, end of period	\$	46,175	\$ 41,894
Supplemental disclosures of cash flow activity:			
Cash paid for interest	\$	312	\$ 11
Supplemental disclosure of non-cash investing and financing activities			
Acquisition of fixed assets in accounts payable and			
accrued expenses	\$	4,836	\$ 3,674
Right-of-use asset and operating lease liability	\$	321	\$ 120
Acquisition of intangible assets in accounts payable			•
and accrued expenses	\$	166	\$ -



Source: Axogen, Inc.