

AxoGen, Inc. Reports 2016 Fourth Quarter and Full Year Financial Results

Record Q4 Revenue of \$11.4 million, representing 46% growth over prior year Record Full year 2016 Revenue of \$41.1 million, representing 50% growth over prior year

ALACHUA, Fla., Feb. 22, 2017 (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 fourth quarter and full year ended December 31, 2016.

Fourth Quarter 2016 Financial Results and Recent Business Highlights

- Revenue of \$11.4 million, up 46% compared to \$7.8 million in the fourth quarter of 2015
- Gross margin of 84.0% compared to 81.9% in the fourth guarter of 2015
- EBITDA loss of \$2.6 million compared to EBITDA loss of \$2.6 million in Q4 2015
- Appointed renowned nerve surgeon Ivan Ducic M.D., Ph.D. as Medical Director
- Launched Avive™ Soft Tissue Membrane in November
- Raised \$18.6 million in net proceeds through a public offering of common stock on October 13th
- Refinanced \$25.0 million debt facility on October 25th, which will reduce annual interest costs by at least \$1.5 million
- Adjusted net loss for the fourth quarter of 2016 was \$3.2 million, or \$0.10 per share, compared with a net loss of \$3.6 million, or \$0.12 per share, in the fourth quarter of 2015

"We are pleased to complete another successful quarter, with record revenues of \$11.4 million and growth of 46 percent," stated Karen Zaderej, President and Chief Executive Officer. "We also made several important strategic advancements in the quarter, including the launch of Avive™ Soft Tissue Membrane, continued expansion of our sales team, the launch of new market development activities in breast reconstruction neurotization and the repair of lower limb iatrogenic nerve injuries, as well as our continued efforts in surgeon education. We believe these efforts, combined with our recent equity raise and debt refinancing, demonstrate our ability to successfully execute our strategy and have positioned us to continue to drive awareness and growth in the emerging peripheral nerve repair market in 2017."

Additional Fourth Quarter Operational Highlights

Increased active accounts in the fourth quarter to 452, up 41% from 320 a year ago

- Ended the guarter with 51 direct sales representatives and 20 independent distributors
- Conducted four national education courses in the fourth guarter
- Increased the number of peer reviewed clinical publications for our surgical portfolio by five to a total of 44
- Conducted a breast reconstruction neurotization meeting with eight key opinion leading surgeons to review mastectomy patient challenges and concerns as well as surgical techniques that may allow for the return of breast sensation for women who choose autologous reconstruction following a mastectomy
- Reported positive clinical data from our MATCH study, a subset of the RANGER® registry, finding Avance® Nerve Graft, with a meaningful recovery rate of 85%, provided a statistically significant difference with regard to return of meaningful sensory function as compared to manufactured conduits, which only provided a meaningful recovery level of 51%
- Expanded the clinical data set in Oral and Maxillofacial surgery to include nerve reconstruction following the removal of benign facial tumors, with two separate investigator initiated studies finding promising results for large gap defects of up to 70 mm and results that are consistent with our previously reported RANGER® registry
- Ended the quarter with \$30 million in cash compared to \$16 million at the end of the Q3. The \$14 million net increase in cash was the result of the company's \$18.6 million equity raise in October, partially offset by debt refinancing fees paid of \$2.9 million and net operating use of cash in Q4 of \$1.7 million
- Ended the quarter with \$25 million of total bank debt, compared to \$25 million at the end of Q3

Full Year 2016 Summary Financial Results and Recent Business Highlights

- 2016 Revenue of \$41.1 million, an increase of 50% compared to \$27.3 million for the prior year
- Gross margin of 84.3% compared to 82.3% in 2015
- Improved EBITDA loss to \$7.7 million compared to EBITDA loss of \$9.0 million in 2015
- Completed 13 national education courses in 2016 and expect to conduct 15 courses in 2017
- Launched two new innovative products including Avive™ Soft Tissue Membrane and AcroVal™ Neurosensory & Motor Testing System
- Appointed former Covidien senior executive Amy Wendell to the Board of Directors
- Expanded leadership team with the appointment of Peter Mariani as Chief Financial Officer, Kevin Leach as Vice President of Marketing, and Ivica "Ivan" Ducic MD, PhD as Medical Director

"We strengthened our strategic capabilities during 2016, which resulted in improved clinical and commercial execution," continued Zaderej. "We believe our record revenue of \$41.1 million and 50 percent growth demonstrate our ability to continue to lead this developing nerve repair market."

2017 Financial Guidance

Management reiterates 2017 annual revenue will grow at least 40% over 2016 revenue and gross margins will remain above 80%.

Upcoming Investor Events

Members of the AxoGen senior management team will participate at the following upcoming

conferences:

- BTIG Annual Medical Technology, Diagnostics, and Healthcare IT Conference in Snowbird, Utah, March 1-2
- 29th Annual ROTH Conference in Dana Point, CA on March 13
- Canaccord Genuity Musculoskeletal Conference in San Diego, CA on March 14
- Oppenheimer 27th Annual Healthcare Conference in New York City, NY, March 21

Management's Assessment of Internal Controls

The Company's market capitalization has increased to a level such that its annual assessment of the effectiveness of its internal controls over financial reporting must now be audited, and the result of that audit will be included in its Form 10-K as of December 31, 2016 in compliance with the provisions of Sarbanes Oxley section 404. The Company expects to report material weaknesses in its internal control as of December 31, 2016 related to the design and operation of key controls around the calculations of significant judgment and estimates, as well as quarterly cycle count procedures associated with consigned inventories.

Management's assessment has not resulted in any changes of prior period financial results or statements.

The Company has reviewed and modified the design of internal controls over financial reporting and will continue to make additional modifications as necessary. The material weaknesses will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

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. Inc.

AxoGen (AXGN) is a global leader in innovative surgical solutions for peripheral nerve injuries. AxoGen's portfolio of products includes Avance[®] Nerve Graft, an off-the-shelf processed human nerve allograft for bridging severed 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 nerves, AxoGuard[®] Nerve Protector, a porcine submucosa ECM product used to wrap and protect injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments, and Avive[™] Soft Tissue Membrane, a minimally processed human umbilical cord membrane that may be used as a resorbable soft tissue covering to separate tissue layers and modulate inflammation in the surgical bed. Along with these core surgical

products, AxoGen also offers AxoTouch[™] Two-Point Discriminator and AcroVal[™] Neurosensory & Motor Testing System. These evaluation and measurement tools assist health care professionals in detecting changes in sensation, assessing return of sensory, grip, and pinch function, evaluating effective treatment interventions, and providing feedback to patients on nerve function. The AxoGen portfolio of products is available in the United States, Canada, the United Kingdom, 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," 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 regarding our assessment on our internal control over financial reporting, statements regarding our growth, our 2017 guidance, product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, and our visibility at and sponsorship of conferences and educational events. The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the statements. These risks include, but are not limited to, the potential that we or our independent auditors may identify additional control deficiencies in our internal control over financial reporting, including deficiencies that constitute material weaknesses within the meaning of the accounting requirements. Forward-looking statements in this release should be evaluated together with the many uncertainties that affect AxoGen's business and its market, particularly those discussed in the risk factors and cautionary statements in AxoGen's filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees 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 law, AxoGen assumes no responsibility to update any forward-looking statements whether as a result of new information, future events, or otherwise.

AXOGEN, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,014,405	\$ 25,909,500
Accounts receivable, net	8,052,203	4,782,989
Inventory	5,458,840	3,933,960
Prepaid expenses and other	511,804	424,925
Total current assets	44,037,252	35,051,374
Property and equipment, net	1.494.247	970.870
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Intangible assets		828,979		678,082
	\$	46,360,478	\$	36,700,326
Liabilities and Shareholders' Equity				
Current liabilities:				
Borrowings under revolving loan agreement	\$	4,025,023	\$	
Accounts payable and accrued expenses		7,002,165		3,695,127
Current maturities of long term obligations		20,899		
Deferred revenue, current		33,282		14,118
Total current liabilities		11,081,369		3,709,245
Note Payable - Revenue Interest Purchase				
Agreement, net				24,701,693
Long Term Obligations, net of current		00 005 745		
maturities and deferred financing fees		20,265,745		
Deferred revenue		92,215		93,797
Total liabilities		31,439,329	_	28,504,735
Shareholders' equity:				
Common stock, \$.01 par value; 50,000,000 shares authorized; 33,008,865 and 29,984,591				
shares issued and outstanding		330,088		299,846
Additional paid-in capital		132,474,884		111,368,424
Accumulated deficit				
	((117,883,823)		(103,472,679)
Total shareholders' equity		14,921,149		8,195,591
	\$	46,360,478	\$	36,700,326

AXOGEN, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS Three Months and Years ended December 31, 2016 and 2015

	Three Mo	nths Ended	Years	Ended
	December 31,	December 31,	December 31,	December 31,
	2016	2015	2016	2015
Revenues	\$ 11,408,672	\$ 7,808,848	\$ 41,107,538	\$ 27,331,092
Cost of goods sold	1,829,804	1,415,258	6,467,250	4,848,396
Gross profit	9,578,868	6,393,590	34,640,288	22,482,696
Costs and expenses:				
Sales and marketing	8,349,206	5,831,972	28,425,503	20,089,369
Research and development	1,178,502	893,721	4,212,023	3,237,171
General and administrative	2,770,561	2,319,808	10,132,624	8,422,866
Total costs and expenses	12,298,269	9,045,501	42,770,150	31,749,406
Loss from operations	(2,719,401)	(2,651,911)	(8,129,862)	(9,266,710)
Other income (expense):				
Interest expense	(2,130,694)	(927,840)	(5,386,268)	(3,988,619)
Interest expense—deferred financing costs	(780,135)	(31,537)	(875,389)	(127,912)
Other income (expense)	3,246	(205)	(19,625)	26,816
Total other income (expense)	(2,907,583)	(959,582)	(6,281,282)	(4,089,715)
Net loss	\$ (5,626,984)	\$ (3,611,493)	\$ (14,411,144)	\$ (13,356,425)
Weighted Average Common Shares outstanding – basic and diluted	32,567,893	29,926,001	30,702,164	26,075,670
Loss Per Common share - basic and diluted	\$ (0.17)	\$ (0.12)	\$ (0.47)	\$ (0.51)
Adjusted net loss	\$ (3,176,379)	\$ (3,611,494)	\$ (11,960,539)	\$ (13,356,425)
Adjusted net loss per Common share	\$ (0.10)	\$ (0.12)	\$ (0.39)	\$ (0.51)

RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES Three Months and Years ended December 31, 2016 and 2015

	Three Months Ended			Years Ended				
	December 31, December 31, 2016 2015		,	December 31, 2016			December 31, 2015	
Net loss	\$	(5,626,984)	\$	(3,611,493)	\$	(14,411,144)	\$	(13,356,425)
Depreciation and amortization expense		98,484		61,102		361,617		203,140
Amortization expense of intangible assets		26,821		11,819		74,871		45,828
Interest expense		2,130,694		927,840		5,386,268		3,988,619
Interest expense - deferred financing costs		780,135		31,537		875,389		127,912
EBITDA - non GAAP	\$	(2,590,850)	\$	(2,579,195)	\$	(7,712,999)	\$	(8,990,926)

AXOGEN, INC. RECONCILIATION OF NET LOSS TO ADJUSTED NET LOSS Three Months and Years ended December 31, 2016 and 2015

	Three Months Ended				Years Ended				
	December 31, December 31, 2016 2015		Dec	cember 31, 2016	December 3 2015				
Net loss	\$	(5,626,984)	\$	\$ (3,611,493)		\$ (14,411,144)		\$ (13,356,425)	
Prepayment fees net of accrued interest		1,700,131			1	,700,131			
Write off of deferred financing fees		750,474				750,474			
Adjusted Net Loss	\$	(3,176,379)	\$	(3,611,493)	\$ (11	,960,539)	\$ (1	3,356,425)	
Adjusted net loss per Common share	\$	(0.10)	\$	(0.12)	\$	(0.39)	\$	(0.51)	

AXOGEN, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS Years ended December 31, 2016 and 2015

	2016		2015
Cash flows from operating activities: Net loss Adjustments to reconcile net loss to net cash used for operating activities:	\$ (14,411,144)	\$	(13,356,425)
Depreciation	361,617		203,140
Amortization of intangible assets	74,871		45,828
Amortization of deferred financing costs	124,915		127,913
Write off of deferred financing costs	750,474		
Provision for bad debts	79,593		125,371
Stock-based compensation	1,390,277		1,316,509
Interest added to note	1,924,279		461,643
Change in assets and liabilities:			
Accounts receivable	(3,348,807)		(2,036,052)
Inventory	(1,524,880)		(720,340)
Prepaid expenses and other	(86,879)		(315,556)
Accounts payable and accrued expenses	3,443,660		1,117,733
Deferred Revenue	17,582		(21,583)
Net cash used for operating activities	(11,204,442)		(13,051,819)
Cash flows from investing activities:			
Purchase of property and equipment	(963,787)		(408,782)
Acquisition of intangible assets	 (225,768)	_	(146,736)

Net cash used for investing activities		(1,189,555)	_	(555,518)
Cash flows from financing activities:			_	
Proceeds from issuance of common stock		18,668,092		30,968,386
Borrowing on revolving loan		6,684,894		
Payments on revolving loan		(6,684,894)		
Repayments of long term debt		(2,446,676)		
Debt issuance costs		(800,847)		(180,139)
Proceeds from exercise of stock options		1,078,333		512,799
Net cash provided by financing activities		16,498,902	_	31,301,046
Net increase in cash and cash equivalents		4,104,905	_	17,693,709
Cash and cash equivalents, beginning of year		25,909,500		8,215,791
Cash and cash equivalents, end of period	\$	30,014,405	;	\$ 25,909,500
Supplemental disclosures of cash flow activity:			=	
Cash paid for interest	\$	5,769,372	;	\$ 3,525,978
Supplemental disclosure of non-cash investing and financing activities:				
Payments of fixed assets in accounts payable Payments of long term debt with proceeds from term loan of \$21,000,000 and revolver loan of	\$	32,153	;	\$ 168,775
\$4,000,000		25,000,000		

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