

# AxoGen, Inc. Reports 2018 Third Quarter Financial Results

Q3 Revenue of \$22.7 million, representing 41% growth over prior year; Management reiterates full year 2018 guidance and introduces 2019 guidance

ALACHUA, Fla., Oct. 29, 2018 (GLOBE NEWSWIRE) -- AxoGen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for damage or discontinuity to peripheral nerves, today reported financial results and business highlights for the third quarter ended September 30, 2018.

#### Third Quarter 2018 Financial Results and Recent Business Highlights

- Revenue of \$22.7 million, up 41% compared to \$16.0 million in the third quarter of 2017
- Gross margin of 84.7% compared to 84.4% in the third quarter of 2017
- Net loss for the quarter was \$4.1 million, or \$0.11 per share, compared to net loss of \$2.1 million, or \$0.06 per share, in the third quarter of 2017
- Adjusted net loss for the quarter was \$1.9 million, or \$0.05 per share, compared to adjusted net loss of \$1.2 million, or \$0.04 per share, in the third quarter of 2017
- Adjusted EBITDA loss of \$2.4 million compared to adjusted EBITDA loss of \$433,000 in Q3 2017
- As separately announced today, on September 26th the U.S. Food and Drug Administration (FDA) granted the Regenerative Medicine Advanced Therapy (RMAT) designation to Avance® Nerve Graft. The RMAT designation provides a streamlined approval pathway for regenerative medicine technologies that aim to treat, modify, reverse or cure a serious or life-threatening disease or condition, with preliminary clinical evidence indicating the potential to address unmet medical needs for such disease or condition.

"We are pleased to report another strong quarter of growth for AxoGen," said Karen Zaderej, chairman, CEO, and president of AxoGen. "Our third quarter performance was driven by continued improvements in the productivity of our direct sales force and reflects growing surgeon acceptance of Avance® Nerve Graft, a biologically active nerve therapy with more than ten years of comprehensive clinical evidence. We continue to advance our differentiated platform for nerve repair with demonstrated clinical consistency and meaningful

recovery outcomes."

#### **Additional Third Quarter and Recent Operational Highlights**

- Increased active accounts by 45 in the third quarter to 679, up 21% from 563 a year ago
- Ended the quarter with 76 direct sales representatives, an increase of four representatives in the quarter and 23 representatives in the last 12 months, and 20 independent sales agencies
- Conducted four national education programs in the third quarter and 14 programs yearto-date, including four Fellows programs
- Increased the number of clinical presentations related to our surgical portfolio by three, for a total of 25 for the year
- Added three peer reviewed clinical publications to our surgical portfolio for a total of 65
- Entered into an agreement to lease 75,000 square feet of office space in a building to be completed in Q1 of 2020 in Tampa, FL; and, extended the office lease for the Company's Alachua facility through at least Q2 of 2021
- On October 26, the Company entered into a lease for approximately 15,000 square feet of space in Tampa, FL to be utilized as temporary office space until the permanent facility is completed
- Ended the quarter with \$126.4 million in cash, cash equivalents, and investments compared to \$133.6 million at the end of Q2 2018. Cash burn in the quarter includes \$4.9 million related to completing the purchase of the AxoGen Processing Center in Dayton, OH

"We are seeing growing surgeon awareness of our clinical data that we believe will continue to drive adoption in our core trauma market," noted Zaderej. "In addition, we are pleased with the surgeon response to our OMF application, as well as our early market development efforts in breast reconstruction neurotization. We will continue to evolve our market development and application expansion strategy and look forward to providing more detail on these initiatives at our November 19 Analyst and Investor Day in New York."

#### 2018 Financial Guidance

Management reiterates 2018 revenue will grow at least 40% over 2017 revenue and gross margins will remain above 80%. Additionally, management continues to expect to have at least 80 direct sales representatives by year end.

#### **Introducing 2019 Financial Guidance**

Management expects full year 2019 revenue will grow at least 35% over 2018 revenue and gross margins will remain above 80%.

#### **AxoGen Analyst & Investor Day**

AxoGen will host its Third Annual Analyst and Investor Day in New York City on November

19, 2018. AxoGen executives and surgeon thought leaders will discuss the company's comprehensive platform for nerve repair and the emerging nerve repair market. Those interested in attending the event can RSVP at axogenevents@troutgroup.com.

#### **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 (877) 407-0993 or use the direct dial-in number at (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 <a href="https://www.axogeninc.com">www.axogeninc.com</a> 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 <a href="https://www.axogeninc.com">www.axogeninc.com</a> 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. We are passionate about helping to restore peripheral nerve function and quality of life to patients with physical damage or discontinuity 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, an 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 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 AcroVal® Neurosensory & Motor Testing System and AxoTouch® Two-Point Discriminator. 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 peripheral 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, our growth, our 2018 and 2019 guidance, product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, 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. 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. Forwardlooking 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.

#### **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. We also use the non-GAAP financial measures of Adjusted Net Loss and Adjusted Net Loss Per Common Share - basic and diluted which excludes non-cash stock compensation expense and loss on extinguishment of debt 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 liquidity 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.

#### **Contacts:**

AxoGen, Inc.

Kaila Krum, VP, Investor Relations and Corporate Development

#### kkrum@AxoGenInc.com

The Trout Group – Investor Relations Brian Korb 646.378.2923 bkorb@troutgroup.com

### AXOGEN, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

	\$ September 30, 2018	December 31, 2017		
Assets				
Current assets:				
Cash and cash equivalents	\$ 25,629,057	\$	36,506,624	
Investments	100,740,344		-	
Accounts receivable, net	13,990,477		11,064,720	
Inventory	10,949,045		7,315,942	
Prepaid expenses and other	 1,477,419		853,381	
Total current assets	152,786,342		55,740,667	
Property and equipment, net	7,673,263		2,197,039	
Intangible assets	 1,198,131		936,992	
Total assets	\$ 161,657,736	\$	58,874,698	
Liabilities and Shareholders' Equity				
Current liabilities:				
Borrowings under revolving loan agreement	\$ -	\$	4,000,000	
Accounts payable and accrued expenses	11,956,797		8,952,061	
Current maturities of long term obligations	35,962		735,017	
Contract liabilities, current	 22,540		31,668	
Total current liabilities	12,015,299		13,718,746	
Long Term Obligations, net of current maturities and deferred financing				
fees	38,314		19,809,772	
Other long-term liabilities	76,002		95,514	
Contract liabilities	 48,694		68,631	
Total liabilities	 12,178,309		33,692,663	
Shareholders' equity (deficit):				
Common stock, \$.01 par value; 100,000,000 shares authorized; 38,672,216 and	000 700		0.40 500	
34,350,329 shares issued and outstanding	386,722		343,503	
Additional paid-in capital	294,589,477		153,167,817	
Accumulated deficit	 (145,496,772 )		(128,329,285 )	
Total shareholders' equity	 149,479,427		25,182,035	
Total liabilities and shareholders' equity	\$ 161,657,736	\$	58,874,698	

## AXOGEN, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS Three and Nine Months ended September 30, 2018 and 2017 (unaudited)

	Three Months Ended			Nine Months Ended				
	September 30,		September 30,		September 30,		September 30,	
		2018		2017		2018		2017
Revenues	\$	22,660,139	\$	16,046,253	\$	60,504,496	\$	43,455,390
Cost of goods sold		3,464,010		2,504,278		9,282,605		6,697,127
Gross profit		19,196,129		13,541,975		51,221,891		36,758,263
Costs and expenses:								
Sales and marketing		14,653,307		9,466,496		41,148,567		27,515,266
Research and development		3,306,856		1,795,292		7,966,535		4,727,551
General and administrative		6,070,547		3,778,612		16,751,038		10,659,756
Total costs and expenses		24,030,710		15,040,400		65,866,140		42,902,573
Loss from operations		(4,834,581 )		(1,498,425 )		(14,644,249 )		(6,144,310 )
Other income (expense):								
Investment income		727,115		-		883,665		-
Interest expense		5,964		(577,941)		(1,123,861)		(1,639,874)
Interest expense – deferred financing costs		-		(46,110)		(81,329)		(136,711)
Loss on extinguishment of debt		-		-		(2,186,114)		-
Other expense		(126 )		(1,603)		(15,598)		(25,388)
Total other income (expense)		732,953		(625,654)		(2,523,237)		(1,801,973 )
Net loss	\$	(4,101,628 )	\$	(2,124,079 )	\$	(17,167,486 )	\$	(7,946,283)
Weighted Average Common Shares outstanding  – basic and diluted		38,504,810		33,286,211	_	36,582,261		33,146,546
	_		_		_		=	
Loss Per Common share – basic and diluted	\$	(0.11)	\$	(0.06)	\$	(0.47)	\$	(0.24)
Adjusted Net Loss - non GAAP	\$	(1,890,155 )	\$	(1,205,053 )	\$	(9,000,143 )	\$	(5,454,291)
Adjusted Net Loss Per Common Share - basic and diluted	\$	(0.05)	\$	(0.04)	\$	(0.25)	\$	(0.16)

#### AXOGEN, INC.

## RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES Three and Nine Months ended September 30, 2018 and 2017 (unaudited)

	Three Months Ended			Nine Months Ended				
	September 30,		September 30,		September 30,		September 30,	
	2018		2017		2018		2017	
Net loss	\$	(4,101,628 )	\$	(2,124,079 )	\$	(17,167,486 )	\$	(7,946,283)
Depreciation and amortization expense		199,730		128,963		574,684		346,839
Amortization expense of intangible assets		18,835		18,753		58,550		60,459
Income Taxes		-		-		12,656		23,974
Investment income		(727,115)		-		(883,665)		-
Interest expense		(5,964)		577,941		2,637,204		1,639,874
Interest expense - deferred financing costs		-		46,110		754,100		136,711
EBITDA - non GAAP	\$	(4,616,142 )	\$	(1,352,312 )	\$	(14,013,957)	\$	(5,738,426 )
Non Cash Stock Compensation Expense		2,211,473		919,026		5,981,229		2,491,992
·	•	(2,404,669)	\$	(433,286 )	\$	(8,032,728 )	\$	(3,246,434 )
Adjusted EBITDA - non GAAP	Ψ	(2,404,009 )	Ψ	(433,200 )	Ψ	(0,032,720 )	Ψ	(3,240,434 )
Net loss	\$	(4,101,628)	\$	(2,124,079)	\$	(17,167,486)	\$	(7,946,283)
Loss on extinguishment of debt		-		-		2,186,114		-
Non cash stock compensation expense		2,211,473		919,026		5,981,229		2,491,992
Adjusted Net Loss - non GAAP	\$	(1,890,155 )	\$	(1,205,053 )	\$	(9,000,143 )	\$	(5,454,291 )
Weighted Average Common Shares outstanding – basic and diluted		38,504,810		33,286,211		36,582,261		33,146,546
Adjusted Net Loss Per Common Share - basic and diluted	\$	(0.05)	\$	(0.04)	\$	(0.25 )	\$	(0.16 )

#### AXOGEN, INC.

### CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS Nine Months ended September 30, 2018 and 2017 (unaudited)

**Nine Months Ended** September 30, September 30, 2018 2017 Cash flows from operating activities: \$ (17,167,486)\$ (7,946,283)Net loss Adjustments to reconcile net loss to net cash used in operating activities: 574.684 346.839 Depreciation 58,550 60,459 Amortization of intangible assets Amortization of deferred financing costs 81,329 136,711 1,361 Loss on disposal of equipment Loss on extinguishment of debt 2,186,114 Provision for bad debt 297,563 83,733 Provision for inventory write down 876,656 999,698 Changes in investment gains and losses (375,101)Share-based compensation 5,981,229 2.491.992 Change in assets and liabilities: Accounts receivable (2,232,090)(3,223,320)Inventory (4,509,760)(2,239,801)Prepaid expenses and other (624,038)(60,108)Accounts payable and accrued expenses 3,004,736 70,365 Contract and other liabilities (48,577)99,367 Net cash used in operating activities (12,886,060)(8,189,118) Cash flows from investing activities: Purchase of property and equipment (6,052,269)(616,432)Purchase of investments (103,865,243)Sale of investments 3,500,000 Acquisition of intangible assets (182,953)(319,689)Net cash used for investing activities (106,737,201)(799,385)Cash flows from financing activities: Proceeds from issuance of common stock 132,963,000 Cash paid for equity offering (256,770)Borrowing on revolving loan 26,253,043 41.553.210 (30,488,886)(41,578,233) Payments on revolving loan and prepayment penalties Repayments of long-term debt and prepayment penalties (22,502,114)(15,589)Debt issuance costs (29,472) Proceeds from exercise of stock options 2,777,421 1,085,279 Net cash provided by financing activities 108,745,694 1,015,195 Net increase (decrease) in cash and cash equivalents (10,877,567)(7,973,308)Cash and cash equivalents, beginning of year 36,506,624 30,014,405 25,629,057 22,041,097 Cash and cash equivalents, end of period Supplemental disclosures of cash flow activity:

\$

1,321,920

1,631,795



Cash paid for interest

Source: AxoGen, Inc.