January 7, 2019

AxoGen, Inc. Pre-Announces Financial and Operational Results

Q4 Revenue of at least $23.4 million, a 38% YoY increase

FY 2018 Revenue of at least $83.9 million, a 39% YoY increase

Company reaffirms 2019 financial guidance and provides business update

Appoints Chris Crisman to Vice President, U.S. Sales

ALACHUA, Fla., Jan. 07, 2019 (GLOBE NEWSWIRE) -- AxoGen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today provided a business update, including preliminary unaudited fourth quarter and full year 2018 results and selected business highlights for the quarter and year ended December 31, 2018.

Preliminary Fourth Quarter and Year-End Performance Highlights

- Fourth quarter revenue is expected to be at least $23.4 million, up 38% compared to fourth quarter 2017 revenue of $17.0 million
- Full year 2018 revenue is expected to be at least $83.9 million, up 39% compared to 2017 revenue of $60.4 million
- Ended the fourth quarter with 85 direct sales representatives, an increase of nine representatives in the quarter and 25 year-over-year, as well as 17 independent sales agencies
- Increased active accounts by 33 in the fourth quarter to 712, up 20% from 591 a year ago
- Enrolled 168 of 170 target subjects in the RECON study in support of the Company's BLA application for Avance® Nerve Graft
- Completed 18 national education programs in 2018 and expect to conduct 25 programs in 2019

"The strong growth we delivered in 2018 reflects the progress we are seeing in our core trauma, oral and maxillofacial and breast reconstruction neurotization markets," said Karen Zaderej, chairman, CEO, and president of AxoGen. "In 2018, we invested for growth across the organization by expanding our commercial team and surgeon education programs, building our body of clinical evidence, and adding critical capabilities and leadership across the organization. In 2019, we will continue to take steps to drive sharper and more consistent commercial execution and build our platform of nerve repair."

The Company has separately announced the appointment of Chris Crisman to Vice

President, U.S. Sales, succeeding Shawn McCarrey, effective today.

Updates to 2018 Financial Guidance
Management updates its 2018 revenue guidance and now expects 2018 revenue will be at least $83.9 million. Management reiterates that its full year 2018 gross margin is expected to remain above 80%.

Reaffirms 2019 Financial Guidance
Management reiterates that 2019 annual revenue is expected to grow by at least 35% over 2018 revenue and that its gross margin is expected to remain above 80%.

The results disclosed in this press release are preliminary and unaudited. The Company will report full, audited results for the fourth quarter and year ended December 31, 2018 on February 26, 2019.

AxoGen 2018 Overview

Market Opportunity and Revenue Diversification

Updated estimated value of market opportunity in existing applications to $2.7 billion
As announced at the Company's Annual Analyst and Investor Day in November 2018, AxoGen believes the total addressable U.S. market (TAM) to be $2.7 billion, a $500 million increase from the Company's previous estimate. The revision was primarily driven by updated assumptions for net procedure values, and increased prevalence of Connector Assisted Repair[SM] in trauma cases. The $2.7 billion market estimate includes more than 900,000 procedures, with the majority (approximately 700,000) of those procedures in extremity trauma. The Company's extremity trauma market procedure estimate is derived in part from the 2015 National Hospital Ambulatory Medical Care Survey and uses multiple pieces of published literature to determine an appropriate prevalence assumption of nerve repair from annual injury-related emergency room visits.

Increased number of active accounts, further diversifying revenue base
The Company has a clear methodology for calculating its number of active accounts, defined as an account which has typically gone through the committee approval process, has at least one surgeon who has converted a portion of his or her treatment algorithms of peripheral nerve repair to the AxoGen portfolio and has ordered AxoGen products at least six times in the last 12 months. The Company ended the 2018 fiscal year with 712 active accounts, an increase of 121 active accounts over the previous year (20% growth). The top 10% of active accounts represented approximately 35% of revenue in the fourth quarter, which has remained fairly consistent over the past several quarters and we believe demonstrates the continued potential for expansion of our revenue base. Expected full year 2018 revenue of at least $83.9 million reflects this large, diverse customer base, supported by an expanding team of direct sales representatives.

Announced 2019 market development and clinical initiatives in the surgical treatment of chronic neuropathic pain
AxoGen believes that the surgical treatment of pain represents a market expansion opportunity as surgeons and patients seek a solution for chronic neuropathic pain. The Company estimates that the total addressable market could be more than $2 billion across many applications for the surgical treatment of pain. AxoGen will focus initially on orthopedic

and trauma procedures, which are estimated to be approximately $1 billion of the larger opportunity. AxoGen expects to begin several market development and clinical initiatives in 2019 to support a broader commercial launch.

Barriers to Entry

Avance® Nerve Graft Granted Regenerative Medicine Advance Therapy ("RMAT") designation by U.S. Food and Drug Administration (FDA)

In September 2018 the FDA granted a RMAT designation for Avance® Nerve Graft. A regenerative medicine therapy is eligible for the designation if it is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such a disease or condition. The RMAT designation provides access to a streamlined approval process for regenerative medicine technologies and ensures continued informal meetings with the FDA in support of the biologic license application ("BLA") for Avance® Nerve Graft.

The Company believes that any future, competitive peripheral nerve allograft would be required to follow the standard pathway for biologic licensing, which typically entails multiple clinical trials and takes many years. The FDA provided updated guidance in December 2017 which made clear that any processing that alters the biological characteristics of peripheral nerve tissue would be considered more than minimal manipulation, and therefore require a BLA prior to marketing.

The Company has maintained a collaborative dialogue with the FDA and will continue to work closely with the FDA as it progresses towards its BLA submission. Upon BLA approval, Avance® Nerve Graft will have 12 years of data exclusivity with regard to potential biosimilars.

Robust intellectual property portfolio

AxoGen's world-wide intellectual property ("IP") portfolio includes trademarks, trade secrets, and numerous patents and, if issued, patent applications, that provide both offensive and defensive protection. Our Avance® Nerve Graft is protected by several families of patents directed to the grafts and methods of preparation that extend beyond our commercial process. Some such patented methods expressly claim use of "anionic sulfonate detergents" or "anionic surface-active detergents", only one of which is Triton X-200. In 2018, AxoGen developed a replacement for Dow's now-discontinued Triton X-200 and validated the Avance® Nerve Graft processing using that replacement.

AxoGen also maintains as trade secret certain aspects of its process for preparing its Avance® Nerve Graft and continues to expand its trademarks across its product portfolio. In addition, the Company believes that its AxoGuard® line of products holds a competitive advantage in the marketplace that would be difficult, if not economically infeasible, for potential market entrants – or current market participants – to overcome.

Clinical Advances

Nearing completion of 170 subjects enrolled in RECON Study

AxoGen's RECON study in support of its BLA submission is progressing well, with 168

subjects enrolled. The Company anticipates enrollment of the remaining two target subjects shortly. The study requires a one year follow up period for all subjects. The statistical analysis plan of the study is designed with an interim analysis to provide a safeguard for the assumptions used in the design of the protocol. It is possible to adjust the study sample size to maintain the original power of the study in the event the pooled variance of the standard deviation, a key statistical assumption in the power analysis of the study, is not consistent with the original assumptions. This interim analysis is designed to protect the validity and integrity of the study and is expected to be completed and reviewed by the FDA in the first quarter.

Presented RANGER® registry data on more than 400 nerve repairs at 73rd Annual American Society of the Hand (ASSH) Meeting

The Company provided an update at the ASSH Meeting in October, which included the largest report to date on outcomes data for more than 400 nerve repairs with Avance® Nerve Graft, and highlighted outcomes on sensory, mixed, motor, and long gap nerve repairs. The RANGER® data showed 85% meaningful recovery in a substantial and expanding outcomes population, and further demonstrated that Avance® Nerve Graft outcomes consistently exceed those associated with synthetic conduits and are similar to nerve autografts without the associated donor site comorbidities.

Previously Scheduled Investor Meetings to be Held This Week

Members of the AxoGen senior management team will again participate in this year's Trout Group Annual 1-on-1 Management Access Event in San Francisco, January 7 – 9, 2019. These annual meetings provide an opportunity for management to meet individually with investors to address AxoGen's differentiated platform for nerve repair in an expanding set of applications.

The information discussed in these meetings is included on the corporate presentation which has been published to AxoGen's website.

About AxoGen

AxoGen, Inc. (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, 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 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 2018 and 2019 guidance, our assessment on our internal control over financial reporting, our growth, 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. 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.

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

Source: AxoGen, Inc.