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Axogen Reports Preliminary Unaudited Revenue for Fourth Quarter and Full-Year 2021

ALACHUA, Fla. and TAMPA, Fla., Jan. 10, 2022 (GLOBE NEWSWIRE) -- Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today announced preliminary unaudited fourth quarter and full-year 2021 revenue.

Preliminary Unaudited Fourth Quarter and Year-End Performance Highlights

- Fourth quarter revenue is expected to be approximately \$31.5 million, a 3% decrease compared to fourth-quarter 2020 revenue of \$32.5 million.
- Full-year 2021 revenue is expected to be approximately \$127.3 million, a 13% increase compared to 2020 revenue of \$112.3 million.
- Fourth quarter revenue includes \$0.5 million from the reversal of a sales return reserve recorded in the second quarter of 2021 for Avive[®] Soft Tissue Membrane, for which the company voluntarily suspended market availability on June 1, 2021. Avive revenue in the fourth quarter 2020 was approximately \$1.6 million; and totaled approximately \$4.1 million and \$5.5 million for the years ended, 2021 and 2020, respectively.
- Ended the fourth quarter with 115 direct sales representatives compared to 109 at the end of the third quarter and 111 as of December 31, 2020.
- Increased Core Accounts in the fourth quarter to 294, a 9% increase compared to 269 in the fourth quarter a year ago. Revenue from Core Accounts continued to represent approximately 60% of total revenue.
- Increased Active Accounts in the fourth quarter to 951, a 6% increase from 893 in the fourth quarter a year ago. Revenue from the top 10% of our Active Accounts continued to represent approximately 35% of total revenue.

“Our commercial team continued to navigate variability in surgical procedure volumes and hospital staffing challenges, which negatively impacted revenue, particularly in the final weeks of the quarter due to a surge in COVID-19 cases,” commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “We drove solid growth in 2021 based on the continued adoption of our nerve repair solutions despite ongoing market challenges. As we enter 2022, we look forward to the release of topline results of our RECON[™] study in the second quarter, and we remain focused on our mission of restoring nerve function and quality of life to patients with peripheral nerve injuries.”

Updated 2021 Financial Guidance

Management now expects 2021 revenue to be approximately \$127.3 million and continues

to expect full-year 2021 gross margin above 80%. Management will address the Company's full-year 2022 outlook on its fourth quarter 2021 earnings call on February 21, 2022.

Investor meetings scheduled this week

Members of the Axogen senior management team will participate in the Solebury Trout Virtual Management Access Event January 10-13, 2022. These annual meetings provide an opportunity for management to meet individually with investors to discuss Axogen's differentiated platform for nerve repair in an expanding set of applications.

The results disclosed in this press release are preliminary and unaudited. The Company expects to report full, audited results for the fourth quarter and year ended December 31, 2021 on February 21, 2022 after the close of market. The company's updated corporate presentation is available through the investors page on www.axogeninc.com.

About the RECON Clinical Study

RECON is a multicenter, prospective, randomized, subject, and evaluator blinded comparative clinical study of nerve cuffs (manufactured conduits) and Avance[®] Nerve Graft evaluating recovery outcomes for the repair of nerve discontinuities. The phase 3 pivotal study is designed to test for non-inferiority between the static two-point discrimination outcomes for Avance Nerve Graft and manufactured conduit. The study design also allows for a sequential test for superiority of Avance Nerve Graft, following the non-inferiority analysis.

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; and 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. 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, our 2021 financial guidance, product development, product potential, regulatory process and approvals, APC renovation timing and expense, 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.

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