
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 8-K

Current Report

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **February 4, 2015**

AXOGEN, INC.

(Exact name of registrant as specified in its charter)

Minnesota
(State or other jurisdiction of
incorporation)

001-36046
(Commission File Number)

41-1301878
(IRS Employer Identification No.)

**13631 Progress Boulevard, Suite 400,
Alachua, Florida**

(Address of Principal Executive Offices)

32615
(Zip Code)

Registrant's telephone number, including area code **(386) 462-6800**

(Former name or former address if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01 Other Events.

Preliminary Unaudited Financial Results

On February 4, 2015, AxoGen, Inc. (the "Company" or "AxoGen") issued a press release announcing its preliminary unaudited revenue and certain other financial information for the fourth quarter and full year ended December 31, 2014.

The Company expects fourth quarter revenue of approximately \$4.79 million, a 61% increase compared to revenue of approximately \$2.98 million in the fourth quarter of 2013. For the full year ended December 31, 2014, revenue is expected to be approximately \$16.8 million, representing a 54% increase compared to revenue of approximately \$10.9 million for the full year ended December 31, 2013.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K (the "Report").

In addition to these announced results, as of December 31, 2014, the Company had cash and cash equivalents of approximately \$8.2 million, which reflects the impact of approximately \$0.9 million of financing expenses paid for a refinancing completed in November 2014, under which (i) the Company borrowed \$25 million under a term loan agreement (the "Three Peaks Term Loan Agreement") dated November 12, 2014, by and among the Company, as borrower, its wholly owned subsidiary AxoGen Corporation, as guarantor, the lenders party thereto and Three Peaks Capital S.a.r.l., an indirect wholly-owned subsidiary of Oberland Capital Healthcare Master Fund LP, as administrative and collateral agent for the lenders, and (ii) the Company terminated the Revenue Interests Purchase Agreement by and between us and PDL BioPharma, Inc. dated October 5, 2012. The Three Peaks Term Loan Agreement is secured by substantially all of the Company's tangible and intangible assets (including, without limitation, the Company's intellectual property).

As of January 2, 2015, the Company had outstanding 19,488,814 shares of common stock, and common stock and common stock equivalents totaled 22,419,312 shares.

These preliminary results are based on currently available financial and operating information and management's preliminary analysis of the unaudited financial results for the quarter and year ended December 31, 2014 and are subject to finalization in connection with the preparation of the Company's audited financial statements for the year ended December 31, 2014. The Company has not completed the preparation of our financial statements for the year ended December 31, 2014 and additional details with respect to its 2014 results of operations are not yet available. The Company currently intends to report its complete financial results for the full year ended December 31, 2014 in early March 2015.

Expansion of AxoGen Sales Team

The Company provides full sales and distribution services through both a direct sales force and a team of independent distributors. As of December 31, 2014, the Company had 29 direct sales professionals and 23 independent distributors. The Company provides support and resources for independent distributors both within and outside the United States and are increasing its direct sales force in selected United States territories.

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Peripheral Nerve Regeneration Market Overview

Peripheral nerve injury ("PNI") is a major source of disability impairing the ability to move muscles or to feel normal sensations. Failure to treat nerve damage can, in severe cases, lead to full loss of sensation and/or function, pain and, sometimes, amputation. Many peripheral nerve injury patients who receive treatment do not optimally recover. Patients may suffer from both reduced, or no, muscle strength, and reduced, or no, sensitivity and pain.

Every day patients suffer traumatic wounds to peripheral nerves severe enough to require surgical treatment, including injuries from motor vehicle accidents, collisions, gun wounds, dislocations, fractures, lacerations, or other forms of penetrating trauma. The peripheral nerves commonly injured from these traumas include the digital, median, ulnar, radial, facial, spinal accessory and brachial plexus nerves. Traumatic PNI described herein, and excluding Oral and Carpal Tunnel defined below, is referred to by us as occurring in the "Extremity" PNI market.

Based upon epidemiological studies regarding the number of trauma patients and incidence of peripheral nerve injury in the population, the Company believes that each year in the U.S. more than 1.4 million people suffer traumatic injuries to peripheral nerves. The Company estimates that that traumatic and non-traumatic injuries to peripheral nerves result in over 700,000 extremity nerve repair procedures in the U.S. annually. ("Health", United States, 2011, Publication of U.S. Department of Health & Human Services; Noble, et al. J of Trauma Injury Infection and Critical Care 1998).

Beyond traumatic injury to nerves, nerve damage also occurs due to surgical intervention and represents an opportunity for surgical repair. Some of these nerve cases PNIs can also occur during certain dental and oral surgery procedures such as third molar extractions, and placement of dental implants and removal of tumors during which an injury may be caused to one or more sections of the trigeminal nerve ("Oral"). This can result in numbness in certain areas of the face and mouth. Finally, nerves are also damaged or compromised due to compression injuries. For instance, severe and recurrent carpal tunnel cases may result in complications and damage to the nerve that requires further surgical intervention and protection of the nerve. The Company refers to PNI caused by carpal tunnel syndrome as "Carpal Tunnel". In addition, nerves can be severed during the removal of cancerous tissues. For example, nerves that support erectile function may be injured or removed following a surgical prostatectomy to remove prostate cancer resulting in impotence and incontinence. Further, breast cancer patients may have reduced sensation in the tissue used to reconstruct the breast after mastectomy.

In the cases where a nerve is severed, if the gap between the two ends of the nerve is extremely small, the surgeon may be able to reconnect the nerve without tension through direct suturing or for gaps up to a few millimeters in length, using a coaptation aid ("Primary Repair"). When the gap in the nerve tissue is more than a few millimeters in length, the surgeon typically needs to bridge the gap between the nerve ends to ensure a tension-free repair ("Gap Repair"). Historically, to repair a gap in a severed nerve, surgeons have relied on a nerve autotransplantation (autologous nerve grafting or nerve autograft). In nerve autograft procedures, surgeons remove nerve from another part of the patient's body, frequently the sural nerve from the back of the lower leg, to repair the damaged nerve. Nerve autografting is often effective in repairing a damaged peripheral nerve, but it presents a tradeoff — the surgeon can attempt to fix the damaged nerve but must create an additional nerve deficit at another location in the body. For example, a patient may opt to get movement and feeling back in their finger while losing some sensation in their foot. Additionally, the secondary surgery to obtain the needed nerve autograft also increases operating time, and thus medical expenses, and increases the risk of surgical site infection and other complications. In the case of extreme trauma where multiple nerves need to be repaired, it may not be possible to recover enough nerve from the patient to complete the Gap Repair. Further, nerve autograft tissue may not provide an appropriate diameter match with the diameter of the injured nerve stump, an important factor in a successful repair outcome.

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Drawbacks of repair with autograft nerve eventually led to the development of hollow-tubes conduits, or hollow-tube nerve cuffs for peripheral nerve Primary and Gap Repair made of, for instance, bovine collagen or polyglycolic acid. The nerve cuff is typically an absorbable hollow tube that, unlike natural peripheral nerve, does not have internal microarchitecture and endoneurial tubes to support

regenerating axons; as a result, it is deficient in the qualities that natural nerve possesses to support nerve regeneration across a gap. Hollow-tube conduits may also lack pliability and structural integrity needed when used around joints and may be difficult to use in a confined space. Clinical data has demonstrated that hollow-tube conduits are most effective only when used in very short gaps, what the Company defines as Primary Repair, and the reliability of successful nerve recovery diminishes as gap length increases.

The shortcomings of hollow-tube conduits for nerve repair limit where they may be used effectively. Thus, the Company believes the nerve repair market needs an alternative off-the-shelf product that provides the natural ECM scaffold and three-dimensional structure of a typical nerve for bridging nerve discontinuities without the comorbidities of an additional second surgical site required for harvest of autograft nerve tissue. The Company believes its Avance® Nerve Graft and AxoGuard® Nerve Connector products meet this market need.

Compression on a nerve or blunt force trauma can also cause nerve injuries that may require surgical intervention. In these cases, the nerve is not severed and thus does not create the need for a Primary or Gap Repair. However, the surgeon may want to protect and isolate the nerve during the healing process. In these situations nerve protection is provided by wrapping the nerve with a particular material (“Nerve Protection”).

AxoGuard® Nerve Protector is a porcine submucosa extracellular matrix used for Nerve Protection. Other Nerve Protection products are usually made from bovine collagen or polyglycolic acid and are typically absorbable. AxoGuard® Protector provides the unique features of pliability, suturability, and translucence for visualization of the underlying nerve, while also allowing the patient’s own cells to incorporate into the extracellular matrix to remodel and separate the nerve from the surrounding tissue layers. One of the advantages of AxoGuard® Nerve Connector is that it reduces the number of required sutures (versus direct repair), and the Company believes AxoGuard® Nerve Connector can also reduce surgery time by up to 40%. (Boechstyns, Jhand Surg. 2013;38:2405-2411).

Based on estimates prepared by the Company, it believes the annual U.S. PNI market for its current product portfolio for Extremity, Oral and Carpal Tunnel is approximately \$1.6 billion (the “Market”). The Company estimates that the Extremity portion of the Market is approximately \$1.3 billion. The estimated size of the Extremity portion of the Market is based upon epidemiological studies regarding the general number of trauma patients, physician interviews and incidence of PNI in the population. The Company believes that, each year in the U.S., more than 1.4 million people suffer traumatic injuries to peripheral nerves. The Company estimates that traumatic and non-traumatic injuries to peripheral nerves result in over 700,000 Extremity nerve repair procedures. (“Health”, United States, 2011, Publication of U.S. Department of Health & Human Services; Noble, et al. J of Trauma Injury Infection and Critical Care 1998; Kurt Brattain, MD, Magellan Medical Technology Consultants, Inc., Minneapolis, Minnesota 2013). The Company further estimated the portion of extremity nerve repair procedures that would be addressed by our Gap Repair, Primary Repair and Nerve Protection products then applied the average sales price of the AxoGen product that applies to the procedure (Avance® Nerve Graft, AxoGuard® Nerve Connector and AxoGuard® Nerve Protector, respectively). As a result, the Company estimates that the market sizes, within the Extremity portion of the Market, for its Avance® Nerve Graft, AxoGuard® Nerve Connector and AxoGuard® Nerve Protector products are approximately \$668 million, \$161 million and \$483 million, respectively.

The Company estimates that the Oral portion of the Market is approximately \$129 million, based upon research that has indicated approximately 68,000 PNI occur in the U.S. each year that are related to third molar extractions, anesthetic injections and dental implants. (The Prophylactic Extraction of Third Molars: A Public Health Hazard: Jay W. Friedman, DDS, Health Policy and Ethics; Peer Reviewed; Friedman American Journal of Public Health; September 2007, Vol 97, No. 9, pp 1554 — 1559 — Journal of Oral Implantology, Vol. XXXVI/No. Five/2010; “Inferior Alveolar Nerve Injury in Implant Dentistry: Diagnosis, Causes, Prevention, and Management”; Ahmed Ali Alhassani, BDS - “Nerve Injuries after Dental Injection: A Review of the Literature”; Clinical Practice, July/August 2006, Vol. 72, No. 6, Miller H. Smith, BMedSc, DDS; Kevin E. Lung, BSc, DDS, MSc, FRCD(C)). The Company has applied the average sales price of the Avance® Nerve Graft and AxoGuard® Nerve Protector that address Oral PNI in order to derive the Oral portion of the Market.

The Company estimates that the Carpal Tunnel portion of the Market is approximately \$160 million. According to literature, there are approximately 500,000 carpal tunnel relief surgeries performed annually in the U.S., and, the Company assumes that 20% of such surgeries require revision procedures to address the recurrence of symptoms. (“Vein-Graft Wrapping for the Treatment of Recurrent Compression of the Median Nerve”, Microsurgery 16:752-756 1995, Dean G. Sotereanos, M.D.). As a result, the Company estimates that approximately 100,000 carpal tunnel revision surgeries are performed each year in the U.S. to address the recurrence of symptoms. These revision surgeries are required due to compression of the nerve due to soft tissue attachments from the surrounding tissue or tissue infiltration entrapping the nerve. To prevent additional recurrences, surgeons will opt to use a Nerve Protection product, such as the AxoGuard® Nerve Protector. In order to derive the Carpal Tunnel portion of the Market, the Company multiplied the average sales price of its AxoGuard® Nerve Protector by the number of estimated carpal tunnel revisions.

The Company continues to look at expansion markets beyond those that it has defined as Extremity, Oral and Carpal Tunnel. In addition to these areas, the Company believes a market exists to treat nerves that are severed during the removal of both benign and cancerous tumors. For example, nerves that support erectile function may be injured or removed following a surgical prostatectomy to remove prostate cancer, resulting in impotence and incontinence. Further, a patient who receives repair of peripheral nerves in the breast following a mastectomy and reconstruction may avoid the reduced sensation typically experienced by many breast cancer patients. The Company believes that it will continue to identify market expansion opportunities for its current product portfolio.

AxoGen Clinical Trials

Generating clinical data is an important component of the Company’s marketing strategy. The Company is currently performing three clinical studies to gather data on the Avance® Nerve Graft. The studies are “A Multicenter Retrospective Study of Avance® Nerve Graft Utilization, Evaluations and Outcomes in Peripheral Nerve Injury Repair (“RANGER®)”, “A Multicenter, Prospective, Randomized, Comparative Study of Hollow Nerve Conduit and Avance® Nerve Graft Evaluation Recovery Outcomes of the Nerve Repair in the Hand

(“CHANGE”)” and a pilot study to evaluate the use of Avance® Nerve Graft in the reconstruction of nerves following prostatectomy.

The Company will continue to accept patients in the RANGER® clinical study, a utilization registry of Avance® Nerve Graft. Two publications and 35 scientific conference presentations have been generated to date from the registry. The RANGER® Study is an observational study in current enrollment. It is designed to allow enrollment of up to a total of 1,000 subjects over the next several years. The follow-up for the RANGER® Study is standard of care up to 36 months post nerve repair. At the time of the the Company’s Biologics License Application (“BLA”) submission for Avance® Nerve Graft, if 1,000

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subjects have not been enrolled and follow-up completed, the Company will submit an interim report in the BLA for the enrolled subjects.

The Company has worked with leading institutions, researchers and surgeons to support innovation in the field of surgical peripheral nerve repair. The Company believes to date, RANGER® is the largest multi-center observational clinical study conducted in peripheral nerve gap repair. The Company’s upcoming RECON study will also continue its clinical work, providing a new multi-center, prospective, randomized, clinical study on the Avance® Nerve Graft. The January 2012 edition of *Microsurgery* and November 2012 edition of *The Journal of Hand Surgery* each contain an article summarizing RANGER® study results. The article in the January 2012 edition of *Microsurgery* reported on 55 Avance® Nerve Graft nerve repairs and resulted in meaningful motor and sensory recovery in 87% of nerve discontinuities between 5 and 50 mm. Additionally, no implant related adverse events have been reported. (Brooks, et al. 2012). Processed nerve allografts for peripheral nerve reconstruction: A multicenter study of utilization and outcomes in sensory, mixed, and motor nerve reconstructions. *Microsurgery*, 32: 1—14. doi: 10.1002/micr.20975 and Cho, et al. 2012, *J Hand Surg Am* 37(11):2340-9). In Cho et al., RANGER® showed the Avance® Nerve Graft to provide 89% meaningful recovery for nerve injuries, and 78% meaningful recovery for mixed and motor nerve injuries. An expanded data milestone was presented at the 5th Vienna Symposium on Surgery of Peripheral Nerves in March 2014 and such expanded RANGER® data provides that of the injuries repaired with the Avance® Nerve Graft 90%, 80% and 87% achieved meaningful recovery for gap lengths of 5-14 mm, 15-29 mm and 30-65 mm, respectively.

The following describes available clinical outcomes data from published papers on the leading synthetic and collagen conduit. The Company has not performed a head-to-head clinical study comparing the Avance® Nerve Graft to the leading synthetic and collagen conduit. Published papers on the leading synthetic and collagen conduit by Weber, et al., 2000 and Wangenstein and Kalliainen, 2009, showed meaningful improvement: 74% in sensory nerves and 43% in sensory, mixed and motor nerves, respectively, of cases bridging a gap in the particular type of nerve. A paper published by Haug, et al., 2013 on the leading synthetic and collagen conduit showed meaningful improvement in 40% sensory nerves using the static 2-point discrimination test. Autograft studies by Weber, et al., 2000, Kim and Kline 2001-2006, Frykman and Gramyk, 1991, Frykman and Gramyk, 1991 and Kallio, 1993, as interpreted by Brooks et al. 2012, reported meaningful recovery: 86% in sensory nerves, 67-86% in sensory and mixed nerves, 80% in sensory nerves, 75-78% mixed nerves and 70% sensory nerves, respectively, of cases bridging a gap in the particular type of nerve. Published papers by Kim and Kline 2001-2006 and Frykman and Gramyk, 1991 reported successful recovery in 75% and 78% of mixed and motor nerves, respectively. A study by Kallio et al., 1993 showed recovery in 67% of mixed and motor nerves where recovery was defined as results indicating a classification of useful or better motor and sensory recovery.

The Company conducted the CHANGE study as a pilot comparative study. It is a multicenter prospective randomized comparative pilot study of hollow tube conduits and Avance® Nerve Graft. Subject enrollment and follow-up have been completed and report development is in process. A pilot study on the repair of the cavernous nerves in prostate cancer patients at Vanderbilt has completed enrollment and a 24 month follow-up. The post nerve repair data analysis and report development are in process for this study and should be available the first half of 2015. A case series in digital nerve repair from the Mayo Clinic in Rochester MN has already been published. In addition, a number of investigator initiated studies and publications have been completed.

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U.S. Government Regulations Overview

As previously disclosed, the U.S. Food and Drug Administration (the “FDA”) issued a letter to the Company in November 2010 stating the agency’s intent to exercise enforcement discretion with respect to the introduction or delivery for introduction into interstate commerce of the Avance® Nerve Graft assuming that certain conditions are met relating to the transition of the Avance® Nerve Graft to regulation as a biological product under section 351 of the Public Health Service Act (the “PHS Act”). FDA is permitting the product to be distributed, subject to FDA enforcement discretion, provided that the Company: (1) transitions to compliance with section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, the current good manufacturing practice regulations in 21 CFR Parts 210 and 211 and the applicable regulations and standards in 21 CFR Parts 600-610 prior to initiation of a phase 3 clinical trial designed to demonstrate the safety, purity, and potency of the Avance® Nerve Graft; (2) conducts a phase 3 clinical trial to demonstrate safety, purity and potency of the Avance® Nerve Graft under a Special Protocol Assessment (“SPA”); (3) continues to comply with the regulations and standard at 21 CFR Part 1271; and (4) exercises due diligence in executing the transition plan.

With regard to the phase 3 clinical trial in the foregoing condition (2), the Company and the FDA agreed to the SPA in August 2011 and in accordance with FDA regulations, 21 CFR Part 312, the Company submitted an Investigational New Drug Application (“IND”) to the FDA in April 2013. The Company is currently responding to FDA comments regarding the IND, which is not yet effective. The Company expects enrollment of patients into the phase 3 clinical trial to begin in the later part of 2015. On June 7, 2013, the FDA placed the IND on Clinical Hold, pending the FDA’s receipt of additional information relating to the potency, mechanical characterization, and labeling of the product. The phase 3 clinical trial cannot begin until the FDA lifts the Clinical Hold. The Company is developing the data and information to respond to the FDA’s requests. Additionally, the Company was audited by the FDA in March 2013 and the quality system was found to

be in compliance with 21 CFR Part 1271. The Company is working to ensure compliance with the applicable regulations by having ongoing discussions on the transition of the quality system to 21 CFR Parts 210/211 and 600-610 regulations with the FDA and being audited by the FDA for compliance to 21 CFR Part 1271 of the regulations. Final determination of regulatory compliance will be made during FDA's pre-license inspection as part of the BLA review. If FDA is unable to agree with the Company, or if the Company is unable to meet the standards required of it by the FDA, regarding preclinical studies, clinical studies and Chemistry, Manufacturing, and Controls, the approval of the Company's BLA would become impossible or delayed.

The FDA will end the period of enforcement discretion upon a final determination of the Company's BLA submission or if the FDA finds that the Company does not meet the conditions for the transition plan, or are not exercising due diligence in executing the transition (e.g., not progressing toward the IND submission, study completion, or BLA submission in a timely or adequate fashion). If final action on the BLA is negative or the Company is found to not meet the conditions for the transition plan or its execution, the Company will not be able to continue to distribute the Avance® Nerve Graft, and the Company's business and financial condition will be materially adversely affected.

The Company continues to work diligently with the FDA and, in this context, continue to distribute the Avance® Nerve Graft products.

Cautionary Note Regarding Forward-Looking Statements

This Report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements may concern possible or anticipated

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future results of operations or business developments. 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", "may", "should", 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 product development, product potential, regulatory environment, sales and marketing strategies, capital resources, operating performance, the preliminary unaudited financial results for the fourth quarter of 2014 and the year ended December 31, 2014, or the estimated timing of final reports of financial results for the year ended December 31, 2014. 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 should be evaluated together with the many uncertainties that affect the Company's business and its market, particularly those discussed in the risk factors and cautionary statements in the Company's filings with the Securities and Exchange Commission, including as described in "Risk Factors" contained or incorporated by reference in this prospectus supplement and the accompanying prospectus, and in our most recent Annual Report on Form 10-K, as well as any amendments thereto reflected in subsequent filings with the SEC.

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 the Company assumes no responsibility to update any forward-looking statements except as required by law.

This Report also contains estimates, projections and other statistical data made by independent parties and by us relating to market size and growth, the incidence of certain medical conditions and other industry data. These data, to the extent they contain estimates or projections, involve a number of subjective assumptions and limitations, and you are cautioned not to give undue weight to such estimates or projections. Industry publications and other reports we have obtained from independent parties generally state that the data contained in these publications or other reports have been obtained in good faith or from sources considered to be reliable, but they do not guarantee the accuracy or completeness of such data. While we believe that the data from these industry publications and other reports are generally reliable, we have not independently verified the accuracy or completeness of such data. These and other factors could cause results to differ materially from those expressed in these publications and reports.

We have provided estimates of the potential United States market for our products. These estimates are based on a number of factors, including our expectation as to the number of patients with a certain medical condition that would potentially benefit from a particular product. While we have determined these estimates based on assumptions that we believe are reasonable, there are a number of factors that could cause our expectations to change or not be realized. Among these factors are the following: there is no assurance that doctors will adopt the use of our products as quickly or as broadly as we have assumed or that the number of peripheral nerve injuries that can be repaired with products is as large as we estimate. It is possible that the ultimate market for our products will differ significantly from our expectations due to these or other factors. As a result of these and other factors, investors should not place undue reliance on such estimates.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	AxoGen, Inc. press release, dated February 4, 2015

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AXOGEN, INC.

By: /s/ Gregory G. Freitag
Gregory G. Freitag
General Counsel

Date: February 4 2015

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	AxoGen, Inc. press release, dated February 4, 2015

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AxoGen, Inc. Announces Preliminary Fourth Quarter and Full Year Revenue

Nerve repair company expects to report 54% growth over previous year.

ALACHUA, FL — February 4, 2015 — AxoGen, Inc. (NASDAQ: AXGN), a leading medical technology company with a unique and innovative portfolio of products used to repair injured peripheral nerves, today announced preliminary unaudited revenue for the fourth quarter and full year ended December 31, 2014.

The Company expects fourth quarter revenue of \$4.79 million, a 61% increase compared to revenue of \$2.98 million in the fourth quarter of 2013. For the full year 2014, revenue is expected to be \$16.8 million, representing a 54% increase compared to revenue of \$10.9 million for the full year ended December 31, 2013.

These preliminary results are based on currently available financial and operating information and management's preliminary analysis of the unaudited financial results for the quarter and year ended December 31, 2014 and are subject to finalization in connection with the preparation of the Company's audited financial statements. The Company has not completed the preparation of its financial statements for 2014 and additional details with respect to the Company's 2014 results of operations are not yet available. The Company currently intends to report its complete financial results for the full year ended December 31, 2014 in early March.

About AxoGen, Inc.

AxoGen (NASDAQ: AXGN) is a leading medical technology company dedicated to peripheral nerve repair. AxoGen's portfolio of regenerative medicine products is available in the United States, Canada and several European countries and includes Avance® Nerve Graft, which AxoGen believes is the only off-the-shelf commercially available processed 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, and 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.

Avance® Nerve Graft is processed in the United States by AxoGen. AxoGuard® Nerve Connector and AxoGuard® Nerve Protector are manufactured in the United States by Cook Biotech Incorporated, and are distributed exclusively by AxoGen. AxoGen maintains its corporate offices in Alachua, Florida and is the parent of its wholly owned operating subsidiary, AxoGen Corporation.

To learn more about AxoGen, visit our website at www.AxoGenInc.com.

Cautionary Statement Concerning Forward-Looking Statements

This Press Release contains "forward-looking" statements as defined in the Private Securities Litigation Reform Act of 1995, including statements about our preliminary revenue for the fourth quarter. 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", 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 growth, our product development, product potential, the preliminary unaudited financial results for the fourth quarter and full year ended December 31, 2014, or the estimated timing of final reports of financial results for the full year ended December 31, 2014. 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.

Contact:

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