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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended DECEMBER 31, 2013

Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from TO

Commission File Number: 0-16159

AXOGEN, INC.

(Exact name of registrant as specified in its charter)

MINNESOTA	**41-1301878**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
13631 Progress Blvd., Suite 400 Alachua, FL	**32615**
(Address of principal executive offices)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:	**Common Stock, par value $0.01 per share** (Title of class)
Securities registered pursuant to Section 12(g) of the Act:	**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted in its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 28, 2013, the value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $25,236,771 based upon the last reported sale price of the Common Stock at that date by the Over-the-Counter Bulletin Board.

The number of shares outstanding of the registrant's Common Stock as of March 4, 2014 was 17,373,620 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2014 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days after the fiscal year ended December 31, 2013.

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FORWARD-LOOKING STATEMENTS

From time to time, in reports filed with the Securities and Exchange Commission (including this Form 10-K), in press releases, and in other communications to shareholders or the investment community, the Company may provide forward-looking statements concerning possible or anticipated 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 or operating performance. 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 Form 10-K 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" included in Item 1A of this Form 10-K. 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, whether as a result of new information, future events or otherwise.

PART I

ITEM 1. BUSINESS

General

We are a leading medical technology company dedicated to advancing the science and commercialization of peripheral nerve repair solutions. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body and their damage can result in the loss of muscle function and/or feeling.

Nerves can be damaged in a number of ways. When a nerve is cut due to a traumatic injury or surgery, functionality of the nerve may be compromised, causing the nerve to no longer carry the signals to and from the brain to the muscles and skin. This type of injury generally requires a surgical repair. The traditional gold standard has been to either suture the nerve ends together directly without tension or to bridge the gap between the nerve ends with a less important nerve surgically removed from elsewhere in the patient's own body referred to as nerve autograft. In addition, pressure on a nerve or blunt force trauma can cause nerve injuries that may require surgical intervention.

In order to improve the options available for the surgical repair and regeneration of peripheral nerves, AxoGen has developed and licensed patented and patent pending regenerative medicine technologies. AxoGen's innovative approach to regenerative medicine has resulted in first-in-class products that it believes are redefining the peripheral nerve repair market. AxoGen's products offer a full suite of surgical nerve repair solutions including Avance® Nerve Graft, the only off-the-shelf commercially available processed nerve allograft, human nerve tissue obtained from a donor, for bridging severed nerves without the comorbidities of a nerve autograft second surgical site, such as loss of feeling where the nerve was removed and potential pain at the donor site. The Company's AxoGuard® line of products are a natural scaffold ExtraCellular Matrix, or ECM, derived from pig tissue. AxoGuard® Nerve Connector is used as a coaptation aid to facilitate the tensionless repair of severed nerves, and AxoGuard® Nerve Protector is used to wrap and protect injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments.

AxoGen's products are used by surgeons during surgical interventions to repair a wide variety of nerve injuries throughout the body. These injuries range from a simple laceration of a finger to a complex brachial plexus injury (an injury to the network of nerves that originate in the neck) as well as nerve injuries caused by dental and other surgical procedures. Avance® Nerve Graft provides surgeons bridging material with the micro-architecture of a human nerve. This structure is essential and allows for bridging nerve gaps or discontinuities up to 70mm in length. Additionally, Avance® Nerve Graft has product and sales synergies with AxoGuard® Nerve Protector and AxoGuard® Nerve Connector. AxoGuard® products provide 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 form a tissue similar to the outermost layer of the nerve (nerve epineurium).

Regenerative Medical Products Industry

Regenerative medical products enable the repair, restoration, replacement or regeneration of tissue or organ systems of the body. Regenerative medical products are becoming common in various medical arenas because they have been shown to be effective repairing injured or defective tissues, such as bone, tendons, dermis and other tissues of the body. Surgeons utilize regenerative medical products because they can provide the complex structure required for implant integration and regeneration in the body.

We believe the primary driver of sustained growth in the regenerative medical product market is continued favorable efficacy as compared to autograft tissue and synthetic medical products, and a wider understanding of this advantage by practitioners. Repair with nerve autograft requires a secondary recovery procedure to remove tissue from another location of the patient's body to repair the injured area and can result in loss of function at the site of donation. Further, nerve autograft may also be costly and time consuming and may result in complications such as infection. In addition to processed nerve allograft (Avance® Nerve Graft), alternatives to nerve autograft include hollow-tube synthetic or collagen-based medical products that are designed to provide some restoration of function but may be limited by biocompatibility with the body or manufacturing technologies and capabilities. Regenerative medical products often provide more desirable conditions for reconstruction and regeneration of tissue, creating a superior solution for patients and physicians. AxoGen follows this trend, providing regenerative medical products for peripheral nerve repair.

Regenerative medicine products typically consist of and rely on:

i. A scaffold or ECM to support the cells and/or provide the architecture of the tissue: and/or
ii. Cells to regenerate or recellularize the scaffold.

AxoGen's products are scaffolds, and the patients' own body provides the cells to regenerate or recellularize these scaffolds.

Peripheral Nerves and Their Regeneration

The peripheral nervous system, or PNS, consists of nerves that either extend outside of, or reside outside of, the central nervous system (the brain and spinal cord). Peripheral nerves provide the pathway for signals between the central nervous system and target organs,

regulating movement (motor nerves) and touch (sensory nerves). Therefore, if a peripheral nerve is crushed, severed, or otherwise damaged, its ability to deliver signals to the target organs is eliminated, or significantly reduced, and could result in a loss of sensation and/or functionality. The axon portion of the nerve cell, consisting of cell cytoplasm and resembling a hair-like fiber, carries signals from the cell body to the target organ. Axons can be quite long, even exceeding one meter, but are only a few micrometers in diameter. A typical nerve consists of hundreds of axons that lie within long, thin tubes (basal lamina tubes). Analogous to a fiber-optic cable, these basal lamina tubes are bundled together in groups called fascicles, and each nerve may contain numerous fascicles. This sheath structure provides protection for the axons and support for regeneration in the event of injury. Nerve injury occurs when a sufficient number of axons have been crushed or transected (severed), thereby disrupting signals to the target motor or sensory organ.

Given the right conditions, peripheral nerves have the ability to regenerate. Regenerating axons require the proper environmental conditions including; structure and guidance of axons in a tension and compression free environment. In an untreated severe crush injury or transected nerve, errant axons that are not guided by the nerve sheath structure, or other mechanism, can form painful and ineffective nerve proliferation (neuromas). This can then require revision surgery to relieve pain or bring back sensory and/or motor functionality. Therefore, the surgical treatment of nerve injuries is typically focused on restoring nerve functionality by providing structural guidance to regenerating axons while protecting the nerve to alleviate compression and tension.

Peripheral Nerve Regeneration Market Overview

Everyday 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. Specifically, military service men and women may suffer severe wounds from explosions and other military-related injuries. The peripheral nerves commonly injured from these traumas include the digital, median, ulnar, radial, facial, spinal accessory and brachial plexus nerves. Based upon epidemiological studies regarding the number of trauma patients and incidence of peripheral nerve injury in the population, each year in the U.S. more than 1.4 million people suffer traumatic injuries to peripheral nerves resulting in at least 700,000 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 occur after certain dental and oral surgery procedures such as third molar extractions and placement of dental implants during which an injury may be caused to the trigeminal nerve. This can result in numbness in certain areas of the face and mouth. 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. Finally, nerves are also damaged or compromised due to repetitive stress or 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.

Peripheral nerve injury 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 function and sometimes amputation. Many peripheral nerve injury patients who receive treatment do not optimally recover. They may suffer from both reduced, or no, muscle strength and reduced, or no, sensitivity.

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. Because a tension-free repair is important, when the gap is more than a few millimeters in length, the surgeon typically needs to bridge the gap between the nerve ends. Historically,

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to repair a severed nerve gap, surgeons have relied on an autotransplantation (autologous grafting or autograft). In nerve autograft procedures, surgeons remove nerve from another part of the patient’s body, frequently from the back of the lower leg, to repair the damaged 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. 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 autograft also increases operating time, and thus medical expenses, and increases the risk of surgical 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 repair. Further, nerve autograft tissue may not provide an appropriate diameter match with the diameter of the injured nerve stump.

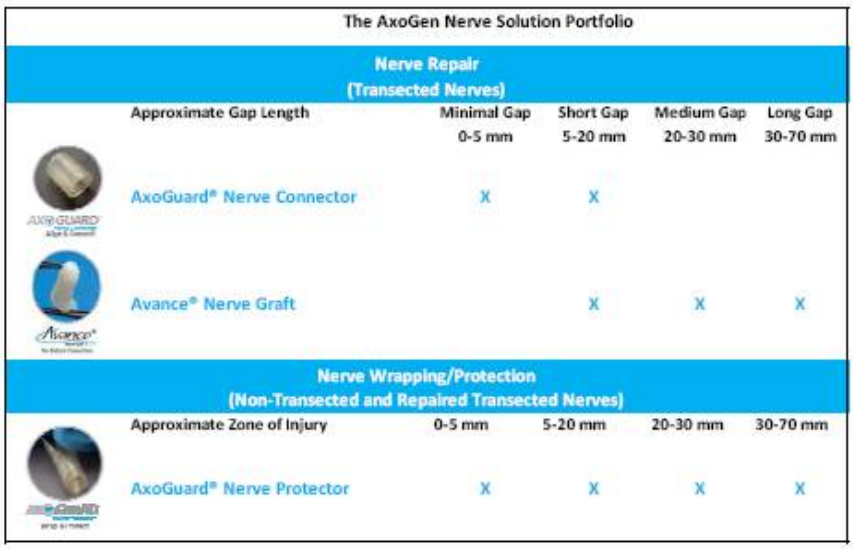
Drawbacks of repair with autograft eventually led to the development of hollow-tube conduits, or hollow-tube nerve cuffs for peripheral nerve repair made of, for instance, bovine collagen or polyglycolic acid. The nerve cuff is typically an absorbable hollow tube that, unlike natural nerve, does not have internal microarchitecture and basal lamina tubes to support regenerating axons; as a result, it is deficient in the qualities that natural nerve possesses to support nerve regeneration. 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 conduits are most effective only when used in very short gaps and the reliability of successful nerve recovery diminishes as gap length increases.

The shortcomings of hollow-tube conduits limit where they may be used effectively. Thus, 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 a second surgical site of an autograft. AxoGen believes its product portfolio meets this market need.

AxoGen’s Product Portfolio

Overview of AxoGen's Products

AxoGen's proprietary products and technologies are designed to overcome fundamental challenges in nerve repair. AxoGen's Avance® Nerve Graft is the alternative to autografts and other off-the-shelf nerve repair products for nerve gaps up to 70mm in length. AxoGuard® Nerve Connector is a coaptation aid for transected nerve injuries. AxoGuard® Nerve Protector completes the product portfolio and is a protective wrap for nerves damaged by compression, or where the surgeon wants to protect and isolate the nerve during the healing process after surgery. The AxoGen product portfolio, depicted below, provides surgeons off-the-shelf solutions for a wide variety of peripheral nerve injuries.



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Avance® Nerve Graft

Avance® Nerve Graft is intended for the surgical repair of peripheral nerve discontinuities to support regeneration across the defect (a gap created when the nerve is severed). It is intended to act as a bridge in order to guide and structurally support axonal regeneration across a nerve gap caused by traumatic injury or surgical intervention. Avance® Nerve Graft is decellularized and sterile extracellular matrix (ECM) processed from human peripheral nerve tissue. AxoGen developed the Avance® Nerve Graft by following the guiding principle that the human body created the optimal nerve structure. AxoGen, through its licensing efforts and research, developed the Avance® process, a proprietary method for processing recovered human peripheral nerve tissue in a manner that preserves the essential structure of the ECM while cleansing away cellular and noncellular debris. Avance® Nerve Graft provides the natural nerve structure of an autograft and the ease and availability of an off-the-shelf product. AxoGen believes that Avance® Nerve Graft is the first and only off-the-shelf commercially available allograft nerve for bridging nerve discontinuities. The Avance® Nerve Graft is comprised of bundles of small diameter endoneurial tubes that are held together by an outer sheath called the epineurium. Avance® Nerve Graft has been processed to remove cellular and noncellular factors such as cells, fat, blood, axonal debris and chondroitin sulfate proteoglycans, ("CSPG"), while preserving the three-dimensional laminin lined tubular bioscaffold (i.e. microarchitecture), epineurium and microvasculature of the peripheral nerve. After processing, Avance® Nerve Graft is flexible and pliable, and its epineurium can be sutured in place allowing for tension-free approximation of the proximal and distal peripheral nerve stumps. The design results in a product that has clean and clear pathways for the regenerating axons to grow through. During the healing process, the body revascularizes and gradually remodels the graft into the patient's own tissue while allowing the processed nerve allograft to physically support axonal regeneration across the nerve discontinuity.

With lengths up to 70 mm and diameters up to 5 mm, the Avance® Nerve Graft allows surgeons to choose the correct length for the relevant nerve gap for repairs up to 70 mm, as well as to match the diameter to the proximal and distal end of the severed nerve. The Avance® Nerve Graft is stored frozen and utilizes packaging that maintains the graft in a sterile condition. The packaging is typical for medical products so the surgical staff is familiar with opening the package for transfer of the Avance® Nerve Graft into the sterile surgical field. Such packaging also provides protection during shipment and storage and a reservoir for the addition of sterile fluid to aid in thawing the product. The Avance® Nerve Graft thaws in less than 10 minutes, and once thawed, it is ready for implantation.

The Avance® Nerve Graft provides the following key advantages:

- Provides a three-dimensional bioscaffold for bridging a nerve gap;
- No patient donor-nerve surgery, therefore no comorbidities associated with a secondary surgical site;
- Available in a variety of diametersup to 5mm to meet a range of anatomical needs
- Available in a variety of lengths up to 70mm, to meet a range of gap lengths,
- Decellularized and cleansed extracellular matrix that remodels into patient's own tissue;
- Structurally supports the body's own regeneration process;
- Handles similar to an autograft, and is flexible and pliable;
- Alleviates tension at the repair site;

- Three year shelf life; and
- Supplied sterile.

AxoGuard® Nerve Connector

AxoGuard® Nerve Connector is an ECM for tensionless repair of severed nerves. AxoGuard® Nerve Connector is a tubular, multilaminar extracellular matrix with an open lumen where the severed nerve ends are placed. The AxoGuard® Nerve Connector is a coaptation aid used to align and connect nerves. It is typically used with less than a 5mm gap between the severed nerve ends. The AxoGuard® Nerve Connector material allows the body's natural healing process to repair the nerve by isolating and protecting it during the healing process. The patient's own cells incorporate into the extracellular matrix product to remodel and form a tissue similar to the outermost layer of the nerve (nerve epineurium). AxoGuard® Nerve Connector is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs.

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AxoGuard® Nerve Connector can be used to:

- Relieve tension at the coaptation site of severed nerves;
- Aid coaptation in direct repair, grafting, or cable grafting repairs; and
- Reinforce the coaptation site.

AxoGuard® Nerve Connector has the following advantages:

- Only porcine submucosa extra-cellular matrix product used to repair severed nerve tissue;;
- Alleviates tension at the repair site and allows vascular channels to remain open;
- Does not degrade and becomes incorporated into the patient's own tissue
- Reduces the number of required sutures (versus direct repair);
- Moves location of sutures away from the coaptation face;
- Reduces potential for fascicular mismatch;
- Allows visualization of underlying nerve tissue;
- Conforms to the nerve;
- Strong and flexible, easy to suture; and
- Stored at room temperature with an 18 month shelf life.

AxoGuard® Nerve Protector

The AxoGuard® Nerve Protector is a product used to wrap and protect injured peripheral nerves and reinforce reconstructed nerve gaps while preventing soft tissue attachments. It is designed to protect and isolate the nerve during the healing process after surgery. AxoGuard® Nerve Protector is a multilaminar extracellular matrix that separates and protects the nerve from the surrounding tissues. The patient's own cells incorporate into the extracellular matrix to remodel and form a tissue similar to the nerve epineurium. AxoGuard® Nerve Protector is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs. AxoGuard® Nerve Protector competes against off-the-shelf biomaterials such as reconstituted collagen as well as the use of the patients own tissue such as vein and hypothenar fat pad wrapping.

AxoGuard® Nerve Protector can be used to:

- Wrap injured nerves, either alone or in conjunction with a nerve repair;
- Minimize risk of entrapment in compressed nerves;
- Protect partially severed nerves;
- Protect nerves in a traumatized wound bed; and
- Reinforce a coaptation site.

AxoGuard® Nerve Protector has the following advantages:

- Only porcine submucosa bioscaffold used to reinforce a coaptation site, wrap a partially severed nerve or protect nerve tissue;
- Isolates and protects the nerve in a traumatized wound bed;
- Does not degrade and provides an environment for supporting natural tissue repair;
- Easily conforms and wraps the injured nerve;
- Minimizes the potential for soft tissue attachments and nerve entrapment by physically isolating the nerve during the healing process;
- Allows nerve gliding;
- Strong and flexible, plus easy to suture;
- Stored at room temperature with an 18 month shelf life.

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Tissue Recovery and Processing for Avance® Nerve Graft

Avance® Nerve Graft Processing Overview

Over several years, AxoGen has developed the Avance® Process, an advanced and proprietary technique to process the Avance® Nerve Graft from donated peripheral nerve tissue. The Avance® Process requires special training over several months for each manufacturing associate who processes Avance® Nerve Grafts. The processing and manufacturing system for Avance® Nerve Graft has required significant capital investment, and AxoGen plans to make additional investments to continually improve its manufacturing and quality assurance processes and systems.

AxoGen's Avance® Process, depicted below, consists of several steps, including peripheral nerve tissue recovery and testing, donor medical review and release, processing, packaging, and sterilization to meet or exceed all applicable FDA, state, and international regulations and American Association of Tissue Banks ("AATB") standards. As an FDA registered tissue establishment, AxoGen utilizes both its own personnel and a variety of subcontractors for recovery, storage, testing, processing and sterilization of the donated peripheral nerve tissue. Additionally, independent certified laboratories have been contracted by AxoGen and its subcontractors to perform testing. The safety of Avance® Nerve Graft is supported by donor screening, process validation, process controls, and validated terminal sterilization methods. The AxoGen Quality System has built in redundancies so that each Avance® Nerve Graft released for implantation meets AxoGen's stringent quality control and product requirements.

Avance® Nerve Graft Tissue Recovery and Processing

AxoGen partners with FDA registered tissue establishments and AATB accredited recovery agencies or recovery agencies in compliance with AATB standards to recover human peripheral nerve tissue for Avance® Nerve Graft processing. After consent for donation is obtained, donations are screened and tested in detail for safety in compliance with the federal regulations and AATB standards on communicable disease transmission. AxoGen processes and packages Avance® Nerve Graft using its employees and equipment located at LifeNet Health, Virginia Beach, Virginia, an FDA registered tissue establishment, from the donated nerve tissue. Under the agreement with LifeNet Health, AxoGen pays LifeNet Health a facility fee. Either party may terminate the agreement with six months' written notice. The LifeNet Health facility provides a cost effective, quality controlled and licensed facility, however, AxoGen could reproduce a manufacturing space that would meet its needs if it no longer continued its relationship with LifeNet. AxoGen's processing methods and process controls have been developed and validated to ensure product uniformity and quality.

Avance® Nerve Graft Packaging

After processing, each Avance® Nerve Graft is visually inspected and organized by size (length and diameter) into finished product codes. It is then packaged in individual medical grade clamshells and primary packaging. The outer pouch is the primary sterility and moisture barrier. The packaging operation is performed in a controlled environment at LifeNet Health.

Avance® Nerve Graft Sterilization and Labeling

After being processed and packaged, Avance® Nerve Graft is then irradiated and currently returned to AxoGen's headquarters in Alachua, Florida. There, the product receives its final labels and is released following a final stringent technical and quality review. Orders for Avance® Nerve Graft are placed with AxoGen's customer care team and product is currently shipped from the Alachua facility. In October 2013, AxoGen established a distribution facility in Burleson, Texas and once all regulatory clearances have been obtained, processed and packaged product will be shipped to, and distributed from, the Burleson distribution facility.

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Avance® Nerve Graft Product Release

The AxoGen Quality System meets the requirements set forth under 21 CFR § 1271 for Human Cells, Tissues and Cellular and Tissue-Based Products, including Good Tissue Practices ("GTP") and is compliant with the 21 CFR § 820 Quality System Regulations ("QSR").

AxoGen has established quality procedures for review of tissue recovery, relevant donor medical record review and release to processing that meet or exceed FDA requirements as defined in 21 CFR §1271, state regulations, international regulations and AATB standards. Furthermore, AxoGen utilizes validated processes for the handling of raw material components, environmental control, processing, packaging and terminal sterilization. In addition to ongoing monitoring activities for product conformity to specifications and sterility, product biocompatibility, shipping methods and shelf life have been validated in accordance with applicable industry standards.

Manufacturing for the AxoGuard® Product Line

AxoGuard® is manufactured by Cook Biotech Incorporated, West Lafayette, Indiana ("Cook Biotech"), which was established in 1995 to develop and manufacture tissue grafts utilizing porcine extracellular matrix technology. AxoGen decided to expand its portfolio of products and felt that the unique ECM material offered by Cook Biotech provided the combination of properties needed in nerve reconstruction. Cook Biotech's ECM material is pliable, capable of being sutured, translucent and allows the patient's own cells to incorporate into the extracellular matrix to remodel and form a tissue similar to the nerve's epineurium. In August 2008, Cook Biotech entered into an agreement, amended in March 2012, with AxoGen to distribute its product worldwide in the field of the peripheral and central nervous system, but excluding use of the AxoGuard® product in the oral cavity for endodontic and periodontal applications and oral and maxillofacial surgery solely as they relate to dental, soft or hard tissue repair or reconstruction. The exclusion results in certain areas of AxoGen's market expansion into the oral surgery market being limited to the Avance® Nerve Graft.

The agreement has an initial seven-year term from the date of the original agreement and following such initial term, the agreement automatically renews for an additional seven (7) year period provided that the parties agree to meet at least ninety (90) days before the end of such initial term to review whether the purchase price of the products obtained from Cook Biotech need to be adjusted and reasonably agree to such adjustment in writing, where such agreement shall not be unreasonably withheld. The Cook Biotech agreement also requires certain minimum purchases, although through mutual agreement the parties have not established such minimums and to date have not enforced such provision, and establishes a formula for the transfer cost of the AxoGuard® products. Under the agreement, AxoGen provides purchase orders to Cook Biotech, and Cook Biotech fulfills the purchase orders.

Sales and Marketing

Overview

The AxoGen portfolio of nerve repair solutions offers a full range of products for all surgical peripheral nerve repair needs. AxoGen is focused on the developing market of peripheral nerve repair and regeneration and is committed to improving awareness of new surgical peripheral nerve repair options, as well as building additional scientific and clinical data to assist surgeons and patients in making informed choices. AxoGen believes that there is an opportunity to rethink current approaches to nerve repair and that its approach will solidify its position as a leader in the field of products for peripheral nerve injuries. The following provides the key elements of AxoGen's sales and marketing strategy.

Increase Awareness of AxoGen's Products

Prior to the introduction of AxoGen's portfolio of products, surgeons had a limited number of options available for the surgical repair of nerve injuries. AxoGen entered the market to improve the standard of care for patients. It has brought the science of nerve repair to life by developing repair options based on extracellular matrix tissue. Unlike other off-the-shelf nerve repair options, an extracellular matrix remodels into the patient's own tissue and provides physical support for the body's natural healing process.

AxoGen intends to increase market share by improving awareness of nerve repair techniques and AxoGen's products through the continued use of educational conferences and presentations, surgical resident and fellow training, scientific publications, and a knowledgeable and professional sales team. AxoGen expects to increase usage with existing customers as well as expand the overall customer base. AxoGen is focused on plastic reconstructive surgeons and orthopedic and plastic surgeons who perform surgeries on patients suffering traumatic nerve injuries and who perform hand reconstructive surgeries and certain oral surgeons who repair oral nerve injuries.

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Expand Clinical and Scientific Data Regarding the Performance of AxoGen Products

Data will be a mainstay of AxoGen's marketing strategy. AxoGen will continue to accept patients in its RANGER® clinical study (defined below in "Government Regulations"), a utilization registry of Avance® Nerve Graft. Two publications and 23 scientific conference presentations have been generated to date from the registry. A multicenter prospective randomized comparative pilot study of hollow tube conduits and Avance® Nerve Graft has completed subject enrollment and outcome follow-up. A case series in digital nerve repair from the Mayo Clinic in Rochester MN has already been published. A number of investigator initiated studies and publications have been completed. A pilot study on the repair of the cavernous nerves in prostate cancer patients has completed enrollment at Vanderbilt and is in follow-up. Case series in brachial plexus, military trauma, neurotization of breast reconstruction and compressive neuropathy are also being developed. AxoGen also supports outside research and will continue to work with investigators working on grants with a translational focus.

Expand the AxoGen Sales Team

AxoGen provides full sales and distribution services through both a direct sales force and a team of independent distributors. AxoGen provides support and resources for independent distributors both within and outside the United States and is increasing its direct sales force in selected United States territories. AxoGen provides products to hospitals, surgery centers and military hospitals, calling on plastic reconstructive surgeons and orthopedic and plastic hand surgeons to review the benefits of the AxoGen products. While surgeons make the

decision to implant the products in appropriate patients, hospitals make the decision to buy the products from AxoGen. In today's budget constrained environment, hospital committees review new technologies for cost effectiveness as well as quality. AxoGen believes that it has been successful in meeting the needs of these hospital committees by demonstrating the cost/benefit of its products and providing a fair value to the hospital.

AxoGen Strengths

AxoGen believes that it has the following strengths in the field of nerve repair and regeneration:

Established Surgical Nerve Repair and Regeneration Expertise

AxoGen has made a significant investment in understanding surgical nerve repair and regeneration through interaction with leading academic centers throughout the United States and by striving to build an outstanding internal team of technical and clinical experts.

Surgical Implant Commercialization Experience

The AxoGen commercialization team consists of sales, marketing, and customer service professionals with backgrounds in the medical device and biotechnology industries. The team has strong experience in the introduction of technologies and has been instrumental in beginning to establish the Avance® Nerve Graft and the AxoGuard® product line as a new standard of care for the surgical treatment of nerve injuries. AxoGen believes it can leverage these capabilities in expanding the commercial success of the current AxoGen products and future product opportunities.

Avance® Nerve Graft Performance

AxoGen has worked with leading institutions, researchers and surgeons to support innovation in the field of surgical peripheral nerve repair. To date, AxoGen's RANGER® study (defined below in "Government Regulations") is the largest multi-center clinical study conducted in peripheral nerve gap repair. AxoGen's RECON study will also continue AxoGen's 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 the RANGER® study results. The publication 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, D. N., Weber, R. V., Chao, J. D., Rinker, B. D., Zoldos, J., Robichaux, M. R., Ruggeri, S. B., Anderson, K. A., Bonatz, E. E., Wisotsky, S. M., Cho, M. S., Wilson, C., Cooper, E. O., Ingari, J. V., Safa, B., Parrett, B. M. and Buncke, G. M. (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). A meta-analysis of available clinical outcomes data from published papers on the leading synthetic collagen conduit showed meaningful improvement in only 53% of cases bridging a gap in the nerve. A similar meta-analysis for nerve autograft reported meaningful improvement in 60-88% of nerve repairs.

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International Opportunity for Product Sales

AxoGen currently focuses on the U.S. market, with additional limited foreign sales in Canada, Italy, Austria, United Kingdom, Netherlands, Israel and Switzerland. The need for the surgical repair of injured nerves is a global issue. Through its foreign sales, AxoGen has shown the capability to take its current product offering into new geographical markets. AxoGen does not currently have E.U.-wide approval for the Avance® Nerve Graft, but has its CE Mark for AxoGuard® products.

Research and Development

AxoGen believes it provides the most extensive product portfolio for peripheral nerve repair available. Our current development focus is to expand clinical data in both traumatic nerve repair and other surgical applications. Additional product line extensions of the Avance® and AxoGuard® products may be developed. In this regard, AxoGen introduced an AxoGuard® Connector line extension in February 2014 by providing a new longer 15mm product. AxoGen's current intention is to spend limited direct resources on extensive research into new unmet peripheral nerve needs. AxoGen does, however, work with academic intuitions in the expansion of treatments for peripheral nerve. For the years ended December 31, 2013 and 2012, AxoGen spent approximately $2,125,000 and $1,427,000, respectively, on research and development expenses.

Competition

The medical device and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. As such, AxoGen cannot predict what products may be offered in the future that may compete with AxoGen's products. Currently, AxoGen competes primarily against all transected and non-transected nerve repair approaches including direct suture repair, autograft and hollow-tube nerve cuffs and materials used to wrap and protect nerve tissue. Because the requirements of the biomaterials used in nerve repair can vary based on the severity and location of the injury, the size and function of the nerve, surgical technique and patient preference, AxoGen's products compete against both autograft materials (nerve in the case of a bridging repair and vein or fat in the case of a nerve protection repair) and a limited number of off-the-shelf alternatives. Competitive aspects of our products focus on the overall value proposition of our products and their suitability for specific applications and can include composition and structure of the material, ease of use, clinical evidence, handling, and price. AxoGen's major competitors for off-the-shelf repair options in hollow-tube conduits and bio-absorbable wraps are the following companies:

- Integra LifeSciences Holding Corporation (NASDAQ: IART) ("Integra"). Integra offers NeuraGen®, a hollow bovine collagen tube and NeuraWrap™, a reconstituted bovine collagen biomaterial used for nerve wrapping;
- Baxter International, Inc. (NYSE: BAX) ("Baxter"). Baxter acquired Synovis that offered the Neurotube, which is a hollow tubecomprised of polyglycolic acid; and
- Stryker Corporation (NYSE: SYK), ("Stryker"). Stryker offers the NeuroMatrix and Neuroflex products, both of which are hollow tubes derived from reconstituted bovine collagen NeuroMend, a reconstituted bovine collage biomaterial used for nerve wrapping.

AxoGen believes that surgeons use Avance® Nerve Graft because, it provides them with the natural three-dimensional structure and familiar handling characteristics of a typical nerve for bridging nerve discontinuities (severed nerves) without the comorbidities of an autograft second surgical site as well as confidence in the performance of the product as a result of the growing body of clinical literature. AxoGuard® Nerve Protector and AxoGuard® Nerve Connector provide 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 form a tissue similar to the outermost layer of the nerve (nerve epineurium).

AxoGen believes any current or future competitors face the following important barriers to entry as it relates to the market for its products. AxoGen's intellectual property, and that of its partners, including patents and patents-pending, is believed to be an important barrier. Additionally, AxoGen has developed knowledge and experience in understanding and meeting FDA regulatory requirements for Avance® Nerve Graft, including having made a substantial investment in validating, testing for, and meeting and preparing a submission for a FDA Biologics License Application ("BLA") requirements. However, due to its limited resources, its smaller size and its relatively early stage, AxoGen believes it may face competitive challenges and barriers that are difficult to overcome and could negatively impact its growth.

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Intellectual Property

Overview

AxoGen relies on a combination of patent, trademark, trade secret, and copyright, as well as other intellectual property ("IP") laws, to protect IP rights. In addition, AxoGen utilizes license, non-disclosure, and assignment agreements to protect these IP rights. Specifically, AxoGen requires vendors, contract organizations, consultants, advisors and employees to execute nondisclosure agreements. AxoGen also requires consultants, advisors and employees who develop IP to assign to AxoGen any of their rights to all IP conceived in connection with their relationship with AxoGen.

License Agreements

AxoGen has entered into license agreements with University of Florida Research Foundation (the "UFRF") and the University of Texas at Austin ("UTA"). Under the terms of these license agreements, AxoGen has exclusive worldwide licenses for the underlying technologies used by AxoGen in repairing and regenerating nerves. The license agreements include both the right to issued patents and patents pending in the U.S. and international markets. The effective term of the license agreements extends through the term of the related patents. In the event of default, licensors may also terminate an agreement (after written notice) if AxoGen fails to cure a breach. The license agreements contain the following key terms:

- Payment of annual license maintenance fees, some of which may be credited against future royalty payments;
- Payment of royalty fees of 1%-3% based on net sales of the licensed products, the level depending on the agreement, which may include a minimum quarterly royalty payment with discounts off royalty rates when royalty stacking applies;
- Payment of a percentage of sublicense fees received;
- Reimbursement of certain legal expenses incurred for patent prosecution and defense; and
- Other payments of various amounts based on achieving certain milestones.

Currently, AxoGen pays royalties to UFRF and UTA specific to the licensed technologies related to the Avance® Nerve Graft.

Patents

As of the date of this Form 10-K, AxoGen owned or was the exclusive licensee of six issued U.S. patents, four pending U.S. patent applications, three issued international patents and nine pending international patent applications with regard to its peripheral nerve products. Additionally, the granted European Patent No. EP1425390 has been validated in France, Germany, Italy, Spain, Sweden, Switzerland, and the United Kingdom. The following table illustrates the issued U.S. patents owned or licensed by AxoGen with regard to its peripheral nerve products, including the patent number, a description of each patent, and the estimated expiration date of each patent.

Patent No.	Description	Estimated expiration date
US 6,972,168	Materials and Methods for Nerve Grafting, Selection of Nerve Grafts, and in vitro Nerve Tissue Culture	August 13, 2021
US 7,402,319	Cell Free Tissue Replacement for Tissue Engineering	September 26, 2023

US 7,732,200	Materials and Methods for Nerve Grafting, Selection of Nerve Grafts, and in vitro Nerve Tissue Culture	December 21, 2022
US 6,696,575	Biodegradable, electrically conducting polymer for tissue engineering applications	March 27, 2021
US 7,851,447	Materials and Methods for Nerve Repair	November 18, 2023
US 8,545,485	Nerve Elevator and Method of Use	April 21, 2028

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Additionally, AxoGen entered into an exclusive distribution agreement with Cook Biotech in August 2008, as subsequently amended in March 2012, to distribute its ECM technology in the form of the Surgisis® Nerve Cuff, the form of a nerve wrap or patch, or the form of any other mutually- agreed-to configuration in the field of peripheral nervous system and central nervous system use, but excluding use of the AxoGuard® product in the oral cavity for endodontic and periodontal applications and oral and maxillofacial surgery solely as they relate to dental, soft or hard, tissue repair or reconstruction. AxoGen has subsequently rebranded the Surgisis products under the AxoGuard® name. Cook Biotech holds multiple issued and pending U.S. and international patents covering its ECM technology. The following table illustrates the two non-licensed U.S. patents held by Cook Biotech that are specifically identified on AxoGen's AxoGuard® Nerve Connector and AxoGuard® Nerve Protector product labeling. The table includes the U.S. Patent number, a description of each patent, and the estimated expiration date of each patent.

U.S. Patent No.	Description	Estimated expiration date
6,206,931	Graft Prosthesis Material	August 23, 2016
6,241,981	Composition and Method for Repairing Neurological Tissue	September 16, 2016
7,652,077	Graft Prosthesis, Materials and Methods	August 22, 2017
6,358,284	Tubular Grafts from Purified Submucosa	December 10, 2017

Because of the length of time and expense associated with bringing new products through development and the governmental approval process, medical technology companies have traditionally placed considerable importance on obtaining and maintaining patent protection for significant new technologies, products and processes. AxoGen intends to seek patent protection for appropriate proprietary technologies by filing patent applications when possible in the U.S. and selected other jurisdictions. AxoGen's policy is to seek patent protection for the inventions that it considers important to the development of its business. AxoGen also intends to use its scientific expertise to pursue and file patent applications on new developments with respect to uses, methods, and compositions to enhance its intellectual property ("IP") position in the areas that are important to the development of its business.

Finally, AxoGen continues to hold IP, including patents, related to LecTec. AxoGen has not been able to monetize such LecTec IP and has discontinued further payments to maintain it, except that AxoGen continues to take all action necessary to maintain relevant patents licensed to Novartis Consumer Health, Inc. However, Novartis has discontinued sale of products related to the license in certain countries and as such AxoGen has determined that the value of the Novartis license has been impaired.

Trademarks, Trade Secrets, Copyrights and Domain Names

AxoGen has registered and filed numerous trademark applications with the U.S. Patent and Trademark Office and appropriate offices in foreign countries in order to distinguish its products from competitors' products. It possesses trade secrets and material know-how in the following general subject matters: nerve processing, nerve repair, product testing methods, and pre-clinical and clinical expertise. AxoGen has registered copyrights for training tools and artistic renderings. It has entered into an agreement with an independent artistic creator, under which the artistic director retains copyright rights to any copyrighted material under agreement with AxoGen and provides AxoGen a license to such copyrights. AxoGen has also registered approximately 50 domain names.

Government Regulations

U.S. Government Regulation Overview

AxoGen's products are subject to regulation by the FDA, as well as other federal and state regulatory bodies in the U.S. and comparable authorities in other countries. In addition, its Avance® Nerve Graft must comply with the standards of the tissue bank industry's accrediting organization, the American Association of Tissue Banks.

AxoGen distributes for Cook Biotech the AxoGuard® product line and Cook Biotech is responsible for the regulatory compliance of the AxoGuard® product line. AxoGuard® products are regulated as medical devices and subject to premarket notification classification requirements under section 510(k) of the FD&C Act that usually result in the marketing of devices,

21 CFR § 820 ("Quality System Regulation") and related laws and regulations. Cook Biotech has obtained a 510(k) premarket clearance from the FDA for the use of porcine (pig) small intestine submucosa for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. Cook Biotech has also obtained a 510(k) premarket clearance for the AxoGuard® Nerve Protector for the repair of peripheral nerve injuries in which there is no gap or where a gap closure is achieved by flexion of the extremity. We sell the 510(k)-cleared device under the trade name AxoGuard®.

In 2007, AxoGen began to process and distribute its Avance® Nerve Graft pursuant to Section 361 of the PHS Act and 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue Based Products controls. Such action was based on AxoGen's good faith belief that the Avance® Nerve Graft product was a HCT/P tissue product regulated solely under Section 361. From October 2008 through early 2010, AxoGen was in communication with the FDA concerning the regulatory status of the Avance® Nerve Graft product. In April 2010, in response to a Request For Designation filed by AxoGen, the FDA determined that the Avance® Nerve Graft was a biologic product that would be reviewed and regulated by CBER under the biologics licensing provision under section 351 of the PHS Act.

AxoGen met with CBER in July 2010 and, between July 2010 and November 2010, provided information to CBER that resulted in the FDA issuing a letter 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 PHS Act. The conditions and AxoGen's current status with respect to these conditions are:

- AxoGen transitions to compliance with the Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act"), the current good manufacturing practice regulations in 21 CFR § 210 and 211 and the applicable regulations and standards in 21 CFR § 600-610 prior to initiation of a phase 3 clinical trial;
  - AxoGen has performed several gap analyses of its quality system for compliance with 21 CFR §210/211 and 600-610 regulations. The gap analyses indicate that procedural changes are necessary to establish compliance with these regulations. The quality system procedures must be updated to establish compliance with 21 CFR §§ 210/211 and 600-610 regulations. We must review the regulations and update our quality procedures to create appropriate documentation systems, and train personnel on the procedural updates. Once procedures, training, and implementation are accomplished, we will, through internal auditing, verify compliance with these regulations. After such verification, we will retain an external audit firm with experience in auditing to 21 CFR §§ 210/211 and 600-610 regulations to verify quality system compliance to the regulations. The associated costs for these activities are not material and the Company believes it can appropriately implement all necessary changes;
- AxoGen conduct a phase 3 clinical trial to demonstrate safety, purity and potency of the Avance® Nerve Graft under a Special Protocol Assessment ("SPA");
  - AxoGen and the FDA agreed to the SPA in August 2011 and in accordance with FDA regulations 21CFR §312, AxoGen submitted an Investigational New Drug Application ("IND") to the FDA and we are currently responding to FDA comments regarding the IND. We expect enrollment of patients into the phase 3 clinical trial in the later part of 2014; and
- AxoGen continues to comply with the regulations and standard for 21 CFR § 1271 and exercises due diligence in executing the transition
  - AxoGen was audited by the FDA in March 2013 and the quality system was found to be in compliance with 21 CFR §1271.

AxoGen submitted an IND for the Avance® Nerve Graft in April, 2013. AxoGen is working with the FDA to ensure compliance with the applicable regulations by having continual discussions on the transition of the quality system to 21 CFR §210/211 and 600-610 regulations with the FDA and being audited by the FDA for compliance to 21 CFR §1271 regulations.

The FDA will end the period of enforcement discretion upon a final determination of AxoGen's BLA future submission or if the FDA finds that AxoGen does not meet the conditions for the transition plan. Until final FDA action on the Avance® Nerve Graft submission, and assuming AxoGen's compliance with the provisions in the transition plan, AxoGen will be able to continue to distribute the Avance® Nerve Graft. If final action on the BLA is negative or AxoGen is found to not meet the conditions for the transition plan, AxoGen will not be able to continue to distribute the Avance® Nerve Graft.

The BLA application of the Avance® Nerve Graft, if approved, will require a potentially substantial user fee payment to the FDA, although certain exemptions, waivers and discounts of the user fees may apply, including certain waivers or

discounts for small businesses. AxoGen has continued to communicate with CBER since the acceptance of the transition plan on clinical trial design and CMC and continues to move with diligence toward the completion of the BLA. A SPA has been submitted, reviewed and approved by CBER. In compliance with the transition plan established by the FDA, AxoGen is able to continue to distribute the Avance® Nerve Graft.

The Food and Drug Administration Safety and Innovation Act, referred to herein as FDASIA (Public Law 112-144), which was signed into law on July 9, 2012, amended the Federal Food, Drug, and Cosmetic Act. FDASIA includes the Prescription Drug User Fee Amendments of 2012 which authorizes the FDA to continue to collect the following user fees from applicants who submit certain new drug and biological product applications and supplements:

- Application Fee: Each new BLA has a fee required upon submission. In FY 2013, this fee for a BLA requiring clinical data was $1,958,800. The fee is adjusted each year so we cannot provide an accurate estimate of what our fee will be upon submission of our BLA. For small companies (fewer than 500 employees and no other approved biologic product on the market) submitting its first application, a waiver of the application fee is available. AxoGen expects to apply for this waiver for the Avance® Nerve Graft BLA.
- Establishment Fee: Establishment fees (for where the biologic product is manufactured) are based on the FDA budget divided by the total number of establishments. In FY 2013, the Establishment Fee was $526,500. This fee is adjusted each year so we cannot provide an accurate estimate of what our fee will be upon approval of our BLA. AxoGen will have to pay an establishment fee after BLA approval and then pay such fee annually thereafter.

FDA — General

FDA regulations govern nearly all the activities that AxoGen performs, or that are performed on its behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses. The activities the FDA regulates include the following:

- product design, development and manufacture;
- product safety, testing, labeling and storage;
- pre-clinical testing in animals and in the laboratory;
- clinical investigations in humans;
- premarketing clearance or approval and licensing;
- record-keeping and document-retention procedures;
- advertising and promotion;
- the import and export of products;
- product marketing, sales and distribution;
- post-marketing surveillance and medical device reporting, including reporting of deaths, serious injuries, communicable diseases, device malfunctions or other adverse events; and
- corrective actions, removals and recalls.

Failure to comply with applicable FDA regulatory requirements may subject AxoGen to a variety of administrative or judicially-imposed penalties or sanctions and/or prevent it from obtaining or maintaining required approvals, clearances or licenses to manufacture and market its products. Such failure to comply with the applicable FDA requirements may subject AxoGen to stringent administrative or judicial actions or sanctions, such as agency refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution of products, injunctions, or civil or criminal prosecution.

FDA's Premarket Clearance and Approval Requirements - Medical Devices

Unless an exemption applies, each medical device distributed commercially in the U.S. requires either 510(k) premarket notification submission or a Pre-Market Approval ("PMA") from the FDA. Medical devices are classified into one of three classes—Class I, Class II, or Class III—depending on the degree of risk and the level of control necessary to assure the safety and effectiveness of each medical device. Medical devices deemed to pose lower risks are generally placed in either Class I or II. Pre-market review and clearance by the FDA for Class I and II medical devices is accomplished through the 510(k) pre-market notification procedure, unless the device is exempt. Most Class I medical devices are exempt from the 510(k) premarket notification requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, and novel devices, including devices deemed not substantially equivalent to a previously cleared 510(k) device are generally placed in Class III. Class III devices general require an approved PMA to be marketed.

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A PMA must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction, the safety and effectiveness of the device.

FDA's Premarket Approval Requirements - Biologic Products

Biologics License Application (BLA) Pathway

Biological products require FDA approval of a BLA to be marketed. In order to be approved, a BLA must demonstrate the safety, purity and potency of the product candidate based on results of preclinical studies and clinical trials. A BLA must also contain extensive CMC and other manufacturing information, and the applicant must pass an FDA pre-approval inspection of the manufacturing facility or facilities at which the biologic product is produced to assess compliance with the FDA's current good manufacturing practice. Satisfaction of FDA approval requirements for biologics typically takes several years and the actual time required may vary substantially based on the type, complexity and novelty of the product. AxoGen cannot be certain that any BLA approvals for its products will be granted on a timely basis, or at all.

The steps for obtaining FDA approval of a BLA to market a biologic product in the U.S. include:

- completion of preclinical laboratory tests, animal studies and formulation studies under the FDA's good laboratory

practices regulations;

- submission to the FDA of an IND, for human clinical testing, which must become effective before human clinical trials may begin and which must include independent Institutional Review Board, or IRB, approval at each clinical site before the trials may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with Good Clinical Practices to establish the safety and efficacy of the product for each indication;
- submission to the FDA of a BLA, which contains detailed information about the CMC for the product, reports of the outcomes and full data sets of the clinical trials, and proposed labeling and packaging for the product;
- satisfactory review of the contents of the BLA by the FDA, including the satisfactory resolution of any questions raised during the review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP regulations, to assure that the facilities, methods and controls are adequate to ensure the product's identity, strength, quality and purity; and
- FDA approval of the BLA including agreement on post-marketing commitments, if applicable.

Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some preclinical testing may continue after the IND is submitted. The IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials and or supporting preclinical data as outlined in the IND. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. In other words, submission of an IND may not result in the FDA allowing clinical trials to commence.

Biosimilar Biological Products

A new regulatory approval pathway for biosimilars was established by The Biologics Price Competition and Innovation Act ("BPCIA"), as part of the Patient Protection and Affordable Care Act of 2010. An important component of the legislation specified that a manufacturer of a reference biological product would be granted 12 years of exclusive use before a biosimilar could be approved for marketing in the US. An application for a biosimilar product may not be submitted to FDA until 4 years after the approval date of the BLA for the reference biological product. BPCIA provides for an abbreviated licensure process for a biosimilar, which is defined to mean a biological product that is highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency. At its discretion, FDA can waive a requirement for any required element in an application for a biosimilar product. In addition, the legislation distinguished approval of a biosimilar from approval of such a product as a substitute for the reference biologic. Where a product is a substitution for the reference biologic it is considered an interchangeable product. Approval as interchangeable requires that the product is biosimilar and can be expected to produce the same clinical results as the reference product in any given patient, and a demonstration that the risk in terms of safety or diminished efficacy of alternating or switching between

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the use of the interchangeable and reference product is not greater than the risk of using the reference product without such alternation or switch. Several states have enacted or are considering laws that also regulate the use and substitution of biosimilar drugs. For example, Virginia requires licensure as interchangeable by FDA for a pharmacist to dispense a biosimilar in place of a prescribed biological product (Virginia § 54.1-3408.04).

FDA's Pre-Approval and Pre-Licensing Requirements.

Before approving a BLA, the FDA generally inspects the facility or the facilities at which the product is manufactured. The FDA will not approve the product if it finds that the facility does not appear to be in cGMP compliance. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will either not approve the application or issue an approvable letter in which it will outline the deficiencies in the BLA and provide the applicant an opportunity to meet with FDA representatives and subsequently to submit additional information or data to address the deficiencies. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. AxoGen may encounter difficulties or unanticipated costs in its efforts to secure necessary governmental approvals, which could delay or preclude it from marketing its products. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

After regulatory approval of a product is obtained, AxoGen will be required to comply with a number of post-approval requirements. For example, as a condition of approval of a BLA, the FDA may require post marketing testing and surveillance to monitor the product's safety or efficacy. In addition, holders of an approved BLA are required to keep extensive records, to report certain adverse reactions and

production problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP regulations as well as the manufacturing conditions of approval set forth in the BLA. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP regulations, which imposes certain procedural, substantive and recordkeeping requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Future FDA inspections may identify compliance issues at AxoGen's facilities or at the facilities of its contract manufacturers that may disrupt production or distribution, or require substantial resources to correct and prevent recurrence of any deficiencies. In addition, discovery of problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Finally, new government requirements, including those resulting from new legislation, may be established that could delay or prevent regulatory approval of AxoGen products that are currently under development or regulatory activity.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that AxoGen failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, such as issuing a FDA Form 483 notice of inspectional observations, warning letter, or untitled letter, imposing civil money penalties, suspending or delaying issuance of approvals, requiring product recall, imposing a total or partial shutdown of production, withdrawal of approvals or clearances already granted, and pursuing product seizures, consent decrees or other injunctive relief, and criminal prosecution through the Department of Justice. The FDA can also require AxoGen to repair, replace or refund the cost of devices that it manufactured or distributed. If any of these events were to occur, it could materially adversely affect AxoGen's business.

Clinical Trials

Clinical trials are required to support a BLA and are sometimes required for 510(k) clearance. Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials

are conducted under strict requirements to ensure the protection of human subjects participating in the trial and under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring and safety, and the effectiveness criteria to be evaluated. Clinical trials for biological products require the submission and FDA approval of an IND and clinical trials for medical devices require the submission and FDA approval of an Investigational Device Exemption application, or IDE, unless the device regulations would not require an IDE for a study. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND or IDE, for significant risk devices. In addition, for these studies, an IRB at each site at which the study is conducted must approve the protocol, subject consent form and any amendments for each site at which the study is conducted. All research subjects must be informed, among other things, about the risks and benefits of the investigational product and provide their informed consent in writing.

Clinical trials under an IND typically are conducted in three sequential phases, but the phases may overlap or be combined. In AxoGen's case, AxoGen believes that the Phase 3 clinical trial study for the Avance® Nerve Graft represents the only new clinical data that will be required to evaluate safety and effectiveness. Phase 1 clinical trials usually involve the initial introduction of the investigational product into a small group of healthy volunteers (e.g., 10 to 20) to evaluate the product's safety, (dosage tolerance and pharmacokinetics if a biologic product) and, if possible, to gain an early indication of its effectiveness. Phase 2 clinical trials usually involve controlled trials in a larger but limited patient population (e.g., a few hundred) to:

- evaluate dosage tolerance and appropriate dosage;
- identify possible adverse effects and safety risks; and
- provide a preliminary evaluation of the efficacy of the product for specific indications.

Phase 3 clinical trials usually further evaluate clinical efficacy and test further for safety in an expanded patient population (e.g., a hundred to several thousand). Phase 3 clinical trials usually involve comparison with placebo, standard treatments or other comparators. Usually at least one well-controlled large Phase 3 or pivotal clinical trial demonstrating safety and efficacy is required to support a BLA. These trials are intended to establish the overall risk-benefit profile of the product and provide an adequate basis for physician labeling. Phase 3 trials are almost always larger, more time consuming, complex and costly than Phase 1 and Phase 2 clinical trials. Phase 1, Phase 2 and Phase 3 clinical testing may not be completed successfully within any specified period, if at all. Furthermore, the FDA or AxoGen may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk, have experienced a serious and unexpected adverse event, or that continued use in an investigational setting may be unethical. Similarly, an IRB can suspend or terminate approval of research if the research is not being conducted in accordance with the IRB's requirements or if the research has been associated with unexpected serious harm to patients.

Investigational New Drug Application

For a biologic product, an IND must be submitted prior to the initiation of the clinical study. The IND application must contain information in three broad areas:

- Animal Pharmacology and Toxicology Studies - Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experiences with the product in humans (often

foreign use).

- Manufacturing Information - Information pertaining to the composition, manufacturer, stability, and controls used for manufacturing of the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.
- Clinical Protocols and Investigator Information - Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators —professionals (generally physicians) who oversee the administration of the experimental compound—to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an IRB, and to adhere to the investigational new drug regulations.

Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

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AxoGen Clinical Trials

AxoGen 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 RANGER® Study is an observational study in current enrollment. It is designed to allow enrollment of up to a total of 1000 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 BLA submission, if 1000 subjects have not been enrolled and follow-up completed, AxoGen will submit an interim report in the BLA for the enrolled subjects.

The CHANGE study is being run as a pilot comparative study. Subject enrollment and follow-up have been completed and report development is in process. The study regarding prostatectomy has also completed enrollment.. The study has a 24 month follow-up post nerve repair which will be completed in June 2014. After the completion of the follow-up period, data management and report development are anticipated to take an additional 9 months.

Clinical trials are subject to extensive recordkeeping and reporting requirements. AxoGen's clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. AxoGen is also required to obtain the patients' written informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. AxoGen, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the biological product or device, or may otherwise not be sufficient to obtain FDA approval to market the product in the U.S. Similarly, in Europe, the clinical study for a medicine product must be authorized by the Competent Authority in each Member State in which the clinical trial is to be conducted, and must receive a favorable opinion from an ethics committee.

Pervasive and Continuing Regulation

There are numerous regulatory requirements that apply after a product is cleared or approved. For medical devices, these include, but are not limited to: the FDA's regulations for device labeling (21 CFR § 801), medical device reporting (21 CFR § 803), reporting of corrections and removals (21 CFR § 806), establishment registration and device listing requirements (21 C.F.R. § 807); and compliance with the Quality System Regulation (QSR) per 21 CFR § 820. For tissue and biologic products, these include: the FDA's registration and listing requirements, donor eligibility, and Good Tissue Practices (GTP) per 21 CFR §1271 for human tissue products, the FDA's Good Manufacturing Practices (GMP) per 21 CFR § 210, 211, and 600 for biologic products, and postmarket BLA requirements (21 CFR § 601). Among other things, these regulations require manufacturers, including third-party manufacturers:

- to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- to comply with labeling regulations and FDA prohibitions against the false or misleading promotion or the promotion of products for uncleared, unapproved or off-label uses or indications;
- to comply with requirements to obtain clearance or approval for certain changes affecting the product, including changes to the product's manufacturing, labeling, or intended use;
- to report to the FDA certain adverse events, adverse reactions and deviations: (a) for medical devices, a report to FDA is required if the device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; (b) for biologics, a deviation from current GMP or an unexpected or unforeseeable event that may affect the safety, purity, or potency of the product must be reported; and (c) for human tissue products, FDA requires reporting of certain adverse reactions involving a communicable disease related to an HCT/P that the company made available for distribution;
- to comply with post-approval restrictions or conditions, including post-approval study commitments and post-market safety and annual reporting requirements;
- to follow post-market surveillance regulations that may apply when necessary to protect the public health or to provide

additional safety and effectiveness data for the device; and

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- to follow requirements to issue notices of correction or removal, or conduct market withdrawals or recalls where quality or other issues arise.

AxoGen has not had any adverse events concerning the Avance® Nerve Graft product and one adverse event was reported in 2013 for the AxoGuard® products. AxoGen has not had to submit any Medical Device Reports ("MDRs"), biological deviation reports, or tissue adverse reaction reports to the FDA. Cook Biotech submitted an MDR for the AxoGuard® adverse event in 2013. Although AxoGen's AxoGuard® products have had just one adverse event reported to date, there may have been other incidents, including patient deaths, which may have occurred during procedures utilizing AxoGen's products without AxoGen being aware of any such incidents. In addition, there can be no assurance that in the future AxoGen will not have an adverse event or will not submit any MDRs, biological deviation reports, or tissue adverse reaction reports to the FDA.

The advertising and promotion of medical products are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, some promotional activities for FDA-regulated products have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the Federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

AxoGen is registered with the FDA as a tissue establishment for the Avance® Nerve Graft. The FDA has broad post-market and regulatory enforcement powers. AxoGen is subject to unannounced inspections by the FDA to determine compliance with the GTP, GMP and other regulations, and these inspections may also include the manufacturing facilities of suppliers.

Failure by AxoGen or by AxoGen's suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other federal or state authorities, which may include any of the following sanctions, among others:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- suspension or termination of our clinical trials;
- refusing our PMA or BLA for new products, new intended uses or modifications to existing products; and
- withdrawing premarket approvals that have already been granted; and criminal prosecution.

Education Grants, U.S. Anti-kickback, False Claims and Other Healthcare Fraud and Abuse Laws

Educational Grants

A medical product manufacturer may provide financial support, including support by way of grants, to third-parties for the purpose of conducting medical educational activities. If these funded activities are considered by the FDA to be independent of the manufacturer, then the activities fall outside the FDA restrictions on promotion to which the manufacturer is subject.

The FDA considers several factors in determining whether an educational event or activity is independent from the substantive influence of the product manufacturer and therefore non-promotional, including, but not limited to, the following:

- whether the intent of the funded activity is to present clearly defined educational content, free from commercial influence or bias;
- whether the third-party grant recipient and not the manufacturer has maintained control over selecting the faculty, speakers, audience, program content and materials;
- whether the program focuses on a single product of the manufacturer without a discussion of other relevant existing competitive products or treatment options;
- whether there was meaningful disclosure to the audience, at the time of the program, regarding the manufacturer's funding of the program, any significant relationships between the provider, presenters, or speakers and the supporting manufacturer; whether any unapproved uses will be discussed;
- whether there are legal, business, or other relationships between the supporting manufacturer and provider or its employees that could permit the supporting manufacturer to exert influence over the content of the program;

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- whether the individuals employed by the provider and involved in designing or conducting the educational activities are also involved in advising or assisting the company with respect to sales or marketing;
- whether the information about the company's products is further disseminated after the initial program, by or at the direction of the company, other than in response to an unsolicited request or through an independent provider;
- whether the provider is compliant with standards for independence, balance, objectivity, and scientific rigor when putting

on ostensibly independent educational programs.

AxoGen seeks to ensure that the activities it supports pursuant to educational grants program are in accordance with these criteria for independent educational activities. However, AxoGen cannot provide assurance that the FDA or other government authorities would view the programs supported as being independent.

Fraud, Abuse and False Claims

AxoGen is directly and indirectly subject to various federal and state laws governing relationships with healthcare providers and pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG") has issued a series of regulations, known as the "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable element of a safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

The Federal False Claims Act ("FCA") imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the U.S. Government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity with knowledge of past or present fraud against the federal government to sue on behalf of the government to recover the civil penalties and treble damages. The U.S. Department of Justice ("DOJ") on behalf of the government has previously alleged that the marketing and promotional practices of pharmaceutical and medical device manufacturers included the off-label promotion of products or the payment of prohibited kickbacks to doctors violated the FCA resulting in the submission of improper claims to federal and state healthcare entitlement programs such as Medicaid. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

AdvaMed is one of the primary voluntary U.S. trade associations for medical device manufacturers. This association has established guidelines and protocols for medical device manufacturers in their relationships with healthcare professionals on matters including research and development, product training and education, grants and charitable contributions, support of third-party educational conferences, and consulting arrangements. Adoption of the AdvaMed Code by a medical device manufacturer is voluntary, and while the OIG and other federal and state healthcare regulatory agencies encourage its adoption and may look to the AdvaMed Code, they do not view adoption of the AdvaMed Code as proof of compliance with applicable laws. AxoGen has incorporated the principles of the AdvaMed Code in its standard operating procedures, sales force training programs, and relationships with doctors. Key to the underlying principles of the AdvaMed Code is the need to focus the relationships between manufacturers and healthcare professionals on matters of training, education and scientific research, and limit payments between manufacturers and healthcare professionals to fair market value for legitimate services provided and payment of modest meal, travel and other expenses for a healthcare professional under limited circumstances. AxoGen has incorporated these principles into its relationships with healthcare professionals under its consulting agreements, payment of travel and lodging expenses, research and educational grant procedures and sponsorship of third-party conferences. In addition, AxoGen has conducted training sessions on these principles. However, AxoGen cannot provide any assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws.

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Regulation Outside of the United States

Sales of medical products outside of the U.S. are subject to foreign governmental regulations that vary substantially from country to country. The time required to obtain certification or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval and the requirements may be different.

There are restrictions under U.S. law on the export from the U.S. of medical devices and biologic product that cannot be legally distributed in the U.S. If a Class I or Class II medical device does not have 510(k) clearance, and the manufacturer reasonably believes that the device could obtain 510(k) clearance in the U.S., then the device can be exported to a foreign country for commercial marketing without the submission of any type of export request or prior FDA approval, if the device is not sold or offered for sale in the U.S., is labeled for export only and satisfies certain criteria relating primarily to specifications of the foreign purchaser and compliance with the laws of the country to which it is being exported, known as Importing Country Criteria. An unapproved Class III medical device can be exported if it complies with the criteria discussed above for devices that could obtain 510(k) clearance, meets certain other quality and labeling requirements, and has a valid marketing authorization from one of a list of countries listed in the Federal Food, Drug, and Cosmetic Act. If an unapproved Class III medical device does not have a valid marketing authorization from one of the listed countries, an export permit from the FDA is required in order to export it. An unapproved biologic product can be exported without submitting an export request to FDA if the product has received a marketing authorization in one of a list of countries listed in the FD&C Act and it meets applicable requirements of the FD&C Act and the laws of the country to which it is exported. An investigational biologic product may also be exported under an IND if a listed investigator is in a foreign country and certain requirements specified in FDA's regulations are met. AxoGen currently complies with applicable regulations when exporting its products and intends to continue such compliance in the event there are any regulatory

changes regarding its products in the United States.

The primary regulatory body in Europe is that of the European Union ("E.U."), which has adopted numerous directives and promulgated voluntary standards regulating the design, manufacture and labeling of, and clinical trials and adverse event reporting for, medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the E.U. and other countries that comply with or mirror these directives. The method for assessing conformity varies depending on the type and class of the product, but normally involves an assessment by the manufacturer and a third-party assessment by a notified body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's device. Such an assessment is required for a manufacturer to commercially distribute the product throughout these countries. AxoGen has prepared the Quality System and is ready for an assessment by the International Organization for Standardization, (ISO) 13485:2003 Quality Management System. AxoGen has started the registration process (selecting a registering body, scheduling audits and report completion) and expects ISO 13485 for distribution by third quarter of 2014.

Cook Biotech is responsible for all regulatory filings for the AxoGuard products including international registrations. AxoGen works with Cook Biotech by providing the countries for Cook to register or get approval for the AxoGuard® products. Cook Biotech prepares the product filing documentation and submits this documentation to the Ministry of Health ("MOH") for the country. Each country or region has its own regulations and the documentation required for submission varies. It typically takes less than 9 months from the initiation of the project to obtain AxoGuard® clearance in a given country or region. To date, the AxoGuard® product line has been registered in Canada for distribution (May 2013) and has been awarded the CE Mark (April 2013) allowing distribution into the European Union and other countries that accept the CE Mark.

Tissue products are not currently regulated under the CE Mark

Although some standards of harmonization exist, each country in which AxoGen conducts business has its own specific regulatory requirements. AxoGen procures and processes its tissue products in the U.S., and markets in the U.S., the United Kingdom, the Netherlands, Israel, Canada, Switzerland, Austria and Italy under compliance with the individual country regulations. These requirements are dynamic in nature and, as such, are continually changing. New regulations may be promulgated at any time and with limited notice. AxoGen will review the regulations at the time of submission of the product dossier for regulatory review. This review involves reviewing the appropriate MOH regulations, discussion with in-country distributors and use of consultants. It typically takes less than 9 months from the initiation of the product to develop a product dossier (specific for that country), submission of the documentation and MOH review of the product filing. While AxoGen believes that it is in compliance with all existing pertinent international and domestic laws and regulations, there can be no assurance that changes in governmental administrations and regulations will not negatively impact AxoGen's operations.

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The FDA and international regulatory bodies conduct periodic compliance inspections of AxoGen's U.S. processing facilities. AxoGen's operations are registered with the U.S. FDA Center for Biologics Evaluation and Research, (CBER), as a tissue establishment. AxoGen is also accredited by the AATB and is licensed in the states of Florida, New York, California, Maryland, Delaware, Oregon and Illinois. AxoGen believes that worldwide regulation of tissue products is likely to intensify as the international regulatory community focuses on the growing demand for these implant products and the attendant safety and efficacy issues of citizen recipients. Changes in governing laws and regulations could have a material adverse effect on AxoGen's financial condition and results of operations. AxoGen management further believes that it can help to mitigate this exposure by continuing to work closely with government and industry regulators.

Environmental

AxoGen's products, as well as the chemicals used in processing, are handled and disposed of in accordance with country-specific, federal, state and local regulations. Since 2007, AxoGen has used outside third parties to perform all biohazard waste disposal.

AxoGen contracts with independent, third parties to perform sterilization of its allografts. In view of the engagement of a third party to perform irradiation services, the requirements for compliance with radiation hazardous waste do not apply, and therefore AxoGen does not anticipate that having any material adverse effect upon its capital expenditures, results of operations or financial condition. However, AxoGen is responsible for assuring that the service is being performed in accordance with applicable regulations. Although AxoGen believes it is in compliance with all applicable environmental regulations, the failure to fully comply with any such regulations could result in the imposition of penalties, fines and/or sanctions which could have a material adverse effect on AxoGen's business.

LecTec Corporation Merger

On September 30, 2011, LecTec Corporation ("LecTec") completed its business combination with AxoGen Corporation ("AC") in accordance with the terms of an Agreement and Plan of Merger, dated as of May 31, 2011, by and among LecTec, Nerve Merger Sub Corp., a subsidiary of LecTec ("Merger Sub"), and AC, which the parties amended on September 30, 2011 and August 9, 2011 (as amended, the "Merger Agreement"). Pursuant to the Merger Agreement, Merger Sub merged with and into AC, with AC continuing after the merger as the surviving corporation and a wholly owned subsidiary of LecTec (the "Merger"). Immediately following the Merger, LecTec changed its name to AxoGen, Inc.

PDL BioPharma, Inc. Revenue Interests Purchase Agreement

General

On October 5, 2012, AxoGen entered into a Revenue Interests Purchase Agreement (the "Royalty Contract") with PDL BioPharma, Inc. ("PDL"), pursuant to which AxoGen sold to PDL the right to receive specified royalties on AxoGen's Net Revenues generated by the sale, distribution or other use of AxoGen's products Avance® Nerve Graft, AxoGuard® Nerve Connector and AxoGuard® Nerve Protector. The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments based on a 9.95% royalty rate of AxoGen's Net Revenues, subject to certain agreed upon minimum payment requirements of approximately $1.3 to $2.5 million per quarter, which begin in the fourth quarter of 2014 as provided in the Royalty Contract. The total consideration PDL paid to AxoGen was $20,800,000 (the "Funded Amount"), including $19,050,000 PDL paid to AxoGen on October 5, 2012, and $1,750,000 PDL paid to AxoGen on August 14, 2012 pursuant to an Interim Revenue Interest Purchase Agreement between AxoGen and PDL, dated August 14, 2012 (the "Interim Royalty Contract"). Upon the closing (the "Closing") of PDL's purchase of the specified royalties described above, which was concurrent with the execution of the Royalty Contract, the Interim Royalty Contract was terminated.

Put Option

Under the Royalty Contract, on October 5, 2016, or in the event of the occurrence of a material adverse event, our transfer of revenue interest or substantially all of our interest in the products or AxoGen's bankruptcy or material breach of the Royalty Contract, PDL may require AxoGen to repurchase the Assigned Interests at the "Put Price." The Put Price is equal to the sum of (i) an amount that, when paid to PDL, would generate a 20% rate of return to PDL on the Funded Amount, taking into consideration payments made to PDL by AxoGen, and (ii) any "Delinquent Assigned Interest Payment" (as defined in the Royalty Contract) AxoGen owed to PDL.

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Change of Control; Call Option

In addition, in the event of a "Change of Control" (as defined in the Royalty Contract), AxoGen must repurchase the assigned Interests from PDL for a repurchase price equal to the "Change of Control Price" on or prior to the third business day after the occurrence of the Change of Control. The Change of Control Price is equal to the sum of (i) an amount that, when paid to PDL, would generate a 32.5% rate of return to PDL on the Funded Amount, taking into consideration payments made to PDL by AxoGen, and (ii) any "Delinquent Assigned Interest Payment" (as defined in the Royalty Contract) AxoGen owed to PDL. In addition, at any time after October 5, 2016, AxoGen, at its option, can call the Royalty Contract for a price equal to the Change of Control Price.

Board Designee

Under the Royalty Contract, during the term of the Royalty Contract, PDL is entitled to designate, and AxoGen shall appoint an individual designated by PDL, who shall serve on the Board of Directors of AxoGen (the "Board"). The PDL designee was elected at the Company's 2013 Annual Meeting of Shareholders. At each annual meeting thereafter during the term of the Royalty Contract, the Board shall nominate and recommend the PDL designee as a director nominee to serve on the Board until the next annual meeting and shall include such nomination in AxoGen's proxy statement for each annual meeting thereafter, provided that the election of the PDL designee is subject to shareholders' approval... Should at any time there become a vacancy on the Board as a result of (i) the resignation, death or removal of the PDL designee or (ii) such PDL designee failing to obtain the requisite approval of AxoGen's shareholders at any annual or special meeting of AxoGen's shareholders and where no other individual is elected to such vacancy, PDL shall have the right to designate an individual to fill such vacancy, and AxoGen shall take such actions necessary to appoint, such individual to the Board. AxoGen was required to have taken all actions necessary at or prior to the Closing to ensure there is a vacancy on the Board as of the Closing to permit the appointment of the PDL designee to the Board as of the Closing. PDL has exercised this right and nominated John P. McLaughlin, PDL's President and Chief Executive Officer. On October 5, 2012, upon the Closing, the Board approved to increase its size from seven directors to eight directors, and Mr. McLaughlin was elected to the Board and continues to serve.

Preemptive Rights

Under the Royalty Contract, PDL has preemptive rights with respect to new issuances of AxoGen's equity securities and securities convertible, exchangeable or exercisable into such equity securities, subject to certain restrictions, including restrictions regarding issuance of securities in a registered public offering by the Company.

Restriction on Dividends

Under the Royalty Contract, during the period from the October 5, 2012 to December 4, 2016 (or the payment of the Put Price in the event PDL exercises its put option on or prior to December 4, 2016), AxoGen shall not, nor shall it permit any subsidiary to, declare, pay or make any dividend or distribution on any shares of the common stock or preferred stock of such entity (other than dividends or distributions payable in its stock, or split-ups or reclassifications of its stock) or apply any of its funds, property or assets to the purchase, redemption or other retirement of any common or preferred stock, or of any options to purchase or acquire any such shares of common or preferred stock of any such entity (collectively, "Restricted Payments"), except that: (i) each subsidiary may make direct or indirect Restricted Payments to AxoGen; and (ii) AxoGen and each subsidiary may purchase, redeem or otherwise acquire Equity Interests issued by it solely with the proceeds received from the substantially concurrent issue of new shares of its common stock or other common Equity Interests. For purposes of the Royalty Contract, "Equity Interests" of any person means any and all shares, rights to purchase, options, warrants, general, limited or limited liability partnership interests, member interests, participation or other equivalents of or interest in (regardless of how designated) equity of such entity, whether voting or nonvoting, including common stock, preferred stock, convertible securities or any other "equity security" (as such term is defined in Rule 3a11-1 under the Securities Exchange Act of 1934, as amended).

Guarantee and Collateral Agreement

In connection with the Royalty Contract, on October 5, 2012, AxoGen and AC, entered into a Guarantee and Collateral Agreement (the "Guarantee and Collateral Agreement") with PDL, pursuant to which (i) AC unconditionally and irrevocably guarantees to PDL the prompt and complete payment and performance by AxoGen when due of the "Secured Obligations," which include AxoGen's obligations under the Royalty Contract, and any other obligations that AxoGen may owe to PDL under the Royalty Contract and other transaction documents; and (ii) each of AxoGen and AC grants to PDL a security interest in certain collateral as specified in the Guarantee and Collateral Agreement for the prompt and complete payment and performance when due of the Secured Obligations.

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Employees

At December 31, 2013, AxoGen had 73 full time employees which included 9 in administration, information technology and finance, 10 in manufacturing and quality control, 11 in research and development and regulatory and 43 in sales and marketing. As of the date of this 10-K AxoGen has not had a work stoppage and no employees are represented by a labor union. AxoGen believes its relationship with its employees is satisfactory.

Executive Officers of the Registrant

The following table lists the names and positions of the individuals who are, as of March 4, 2014, executive officers AxoGen:

Name	Title
Karen Zaderej	President, Chief Executive Officer and Director
Gregory G. Freitag, J.D. CPA	Chief Financial Officer, General Counsel and Director
John P. Engels	Vice President
Jill F. Schiaparelli	Senior Vice President, Business Strategy and Marketing
Mark Friedman, Ph.D.	Vice President of Regulatory and Quality
David Hansen	Corporate Controller
Shawn McCarrey	Senior Vice President of Sales
Erick DeVinney	Vice President of Clinical and Translational Sciences

Biographical information for each of our executive officers is included below.

Karen Zaderej, President, Chief Executive Officer and Director (Age 52)

Ms. Zaderej has served as AxoGen's President, Chief Executive Officer and a member of its board of directors since September, 2011. She has served as AxoGen Corporation's Chief Executive Officer and a member of its board of directors since May 2010. Ms. Zaderej joined AxoGen Corporation in May 2006 and served as Vice President of Marketing and Sales from May 2006 to October 2007 and as Chief Operating Officer from October 2007 to May 2010. From October 2004 to May 2006, Ms. Zaderej worked for Zaderej Medical Consulting, a consulting firm she founded, which assisted medical device companies build and execute successful commercialization plans. From 1987 to 2004, Ms. Zaderej worked at Ethicon, Inc., a Johnson & Johnson company, where she held senior positions in marketing, business development, and research & development, as well as ran a manufacturing business. Ms. Zaderej has a MBA from the Kellogg Graduate School of Business and a BS in Chemical Engineering from Purdue University.

AxoGen has a key-person life insurance policy for $3,000,000 insuring the life of Ms. Zaderej.

Gregory G. Freitag, J.D., CPA, Chief Financial Officer, General Counsel and Director (Age 52)

Mr. Freitag, J.D., CPA, has been AxoGen's Chief Financial Officer, General Counsel and a member of its Board of Directors since September 2011 and was LecTec's Chief Executive Officer, Chief Financial Officer and board member from June 2010 through September 2011. From May 2009 to the present, Mr. Freitag has been a principal of FreiMc, LLC, a consulting and advisory firm he founded that provides strategic guidance and business development advisory services. Prior to founding FreiMc, LLC, Mr. Freitag was a Director of Business Development at Pfizer Health Solutions, a former subsidiary of Pfizer, Inc., from January 2006 to May 2009. From July 2005 to January 2006, Mr. Freitag worked for Guidant Corporation in their business development group. Prior to Guidant Corporation, Mr. Freitag was the Chief Executive Officer of HTS Biosystems, a biotechnology tools start-up company, from March 2000 until its sale in early 2005. Mr. Freitag was the Chief Operating Officer, Chief Financial Officer and General Counsel of Quantech, Ltd., a public point of care diagnostic company, from December 1995 to March 2000. Prior to that time, Mr. Freitag practiced corporate law in Minneapolis, Minnesota. Mr. Freitag is also a director of the Foundation Board of HealthEast Care System, a health care system in Minnesota.

John P. Engels, Vice President (Age 42)

Mr. Engels has served as AxoGen's Vice President since September, 2011. He is a co-founder of AxoGen Corporation and has served as AxoGen Corporation's Vice President since June 2006, providing operational and financial leadership and managing AxoGen's strategic and product development partnerships. From 1999 to 2002, Mr. Engels worked as a consultant

for the University of Florida, Saffron Hill Ventures and PA Early Stage Partners, among other companies. From 1993 to 1997, Mr. Engels was an analyst and associate at CACM, a boutique investment banking firm. Mr. Engels is currently a member of the board of directors of Oxicool, Inc., a privately-held company developing new cooling technologies. Mr. Engels holds a MBA in Management and Operations from the Wharton School of Business at the University of Pennsylvania, and a BA from the University of Chicago.

Jill F. Schiaparelli, Senior Vice President, Business Strategy & Marketing (Age 48)

Ms. Schiaparelli has served as AxoGen's Senior Vice President, Business Strategy & Marketing since February 2012. From January 2011 to February 2012 and from June, 2007 to December 2008, Ms. Schiaparelli was employed by JS Strategic Partners, LLC, a consulting firm she founded to provide business strategy, commercialization and marketing services to biotechnology companies and health care providers. From December 2008 to December 2010, Ms. Schiaparelli was the Vice President, Commercial Strategy & Business Development for ApaTech, a venture-back global orthopedic graft company based in the UK that was later acquired by Baxter Healthcare. From 1996 to 2007, Ms. Schiaparelli was employed by Johnson & Johnson family of companies where she held several senior positions in strategic marketing, marketing, sales operations and healthcare analytics within the Ethicon Endo-Surgery, Ethicon and Healthcare Systems operating companies. Prior to working in the healthcare industry, Ms. Schiaparelli worked for 8 years in the investment banking and financial services industry. Ms. Schiaparelli has an MBA from the Stern School of Business at New York University and a BS in Business Administration from Boston University.

Mark Friedman, Ph.D., Vice President of Regulatory and Quality (Age 56)

Dr. Friedman has served as AxoGen's Vice President of Regulatory and Quality since September, 2011. He has served as AxoGen Corporation's Vice President of Regulatory and Quality since June 2011 and served as AxoGen Corporation's Director of Quality Assurance and Regulatory Affairs from September 2006 to June 2011. Prior to joining AxoGen, Dr. Friedman held several regulatory and quality leadership positions at Enable Medical Corporation, a medical device company, including Director of Quality Assurance from 1997 to 1998 and Vice President of Quality and Regulatory from 1998 to 2001 and from 2004 to 2005. Dr. Friedman also worked for AtriCure, Inc., a company that develops, manufactures and sells surgical ablation systems to treat atrial fibrillation, as Vice President of Quality and Regulatory from 2001 to 2004 and as Vice President of Operations in 2004. AtriCure acquired Enable Medical in 2005. Mr. Friedman has over 24 years of experience in developing and directing regulatory strategy and quality systems for medical products, including 15 years with start-up medical product firms. Dr. Friedman has a Ph.D. in Chemistry specializing in protein biochemistry from the University of Cincinnati.

David Hansen, Corporate Controller (Age 53)

Mr. Hansen has served as AxoGen's Corporate Controller since September, 2011. He has served as AxoGen Corporation's Corporate Controller since June 2006. Mr. Hansen was Vice President of Finance—Corporate Controller and Treasurer of Perma-Fix Environmental Services, Inc., a publicly-traded environmental services company, and held other corporate and regional accounting positions at Perma-Fix Environmental Services from 1995 to 2005. Mr. Hansen was also Controller at Kraft Foodservice, Inc. from 1994 to 1995 and held other accounting and procurement positions at Kraft Foodservice, Inc. from 1985 to 1994. Mr. Hansen has over 20 years of experience in senior financial positions at both publicly traded and private companies. Mr. Hansen holds a Bachelor of Business Administration degree in Accounting from the University of Oklahoma.

Shawn McCarrey, Vice President of Sales (Age 56)

Mr. McCarrey has served as AxoGen's Senior Vice President of Sales since February, 2013. Mr. McCarrey was Executive Vice President of North American Cardiovascular Sales at Bayer Interventional/MEDRAD Interventional from January, 2009 to May 2012. Bayer HealthCare, a subgroup of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry. Bayer Interventional, now doing business as part of Bayer Medical Care's Radiology and Interventional business, is the Interventional franchise formerly operated under Bayer's MEDRAD brand. From 1998 to 2009, Mr. McCarrey held multiple escalating positions with Possis Medical, Inc., a company that developed, manufactured, and marketed medical devices for the cardiovascular and vascular treatment markets, and served as Director or Sales, VP of US Sales, VP of Worldwide Sales and EVP of Worldside Sales & Marketing. For more than 15 years prior to joining Possis, Mr. McCarrey served in a series of progressively responsible roles with two divisions of C.R. Bard, United States Catheter and Instrument Corporation (USCI) which specialized in the treatment of coronary disease in the cardiac catheterization laboratory and Davol, an operating room division that promoted Thoraclex and Simpulse to cardiovascular and orthopedic surgeons. Mr. McCarrey holds a Bachelor of Science degree in Marketing from Central Michigan University.

Erick DeVinney, Vice President of Clinical and Translational Sciences (Age 38)

Mr. DeVinney has served as Vice President of Clinical and Translational Sciences since January 2014. Prior to this he was Director of Clinical and Translational Sciences for AxoGen since April 2007. Erick has over fourteen years of experience in the successful planning and management of clinical development. Prior to joining AxoGen he served as Manager of Clinical Operations for Angiotech Pharmaceuticals from 2005 to 2007 and Clinical Program Lead for Pharmaceutical Research Associates International from 2001-2005. He has been involved in the successful submission of numerous 510(k), IDE and NDA applications. He has a BS in Chemistry from Virginia Commonwealth University.

ITEM 1A. RISK FACTORS

AxoGen's business involves a number of risks, some of which are beyond its control. The risk and uncertainties described below are not the only ones the Company faces. Set forth below is a discussion of the risks and uncertainties that management believes to be material to AxoGen.

Risks Related To Company

AxoGen has not experienced positive cash flow from its operations, and the ability to achieve positive cash flow from operations will depend on increasing sales of its products, which may not be achievable.

AxoGen has historically operated with negative cash flow from its operations. As of December 31, 2013, AxoGen had an accumulated deficit of approximately $72.4 million. If AxoGen product sales do not increase as anticipated, then it will continue to experience negative cash flows and adverse operating conditions. AxoGen's continuing capital needs and other factors could cause the Company to raise additional funds through public or private equity offerings, debt financings or from other sources. The sale of additional equity may result in dilution to AxoGen's shareholders. There is no assurance that AxoGen will be able to secure funding on terms acceptable to it, or at all.

AxoGen's revenue growth depends on its ability to expand its sales force and develop new customers, and there can be no assurance that these efforts will result in significant increase in sales.

AxoGen is in the process of investing in its sales channel composed of a combination of its direct sales force and independent distributors to allow it to reach new customers. There can be no assurance that these efforts will be successful in expanding AxoGen's product sales. AxoGen currently sells products directly through its employees and indirectly through distributor relationships. AxoGen is engaged in a major initiative to build and further expand sales and marketing capabilities. The incurrence of these expenses impacts AxoGen's operating results, and there can be no assurance of their effectiveness. If AxoGen is unable to develop its sales force and new customers, or increase sales to existing customers, it may not be able to grow revenue or maintain its current level of revenue generation.

AxoGen's revenue depends solely on three products.

All of AxoGen's revenue is currently derived from only three products, the Avance® Nerve Graft, AxoGuard® Nerve Protector and AxoGuard® Nerve Connector, for the treatment of peripheral nerve damage. Its ability to generate revenue is dependent on the success of these products. Accordingly, any disruption in AxoGen's ability to generate revenue from the sale of these products will have a material adverse impact on its business, results of operations, financial condition and growth prospects. In addition, AxoGen's expenditures for research and development are minimal and funding to develop, or increase efforts to find collaboration or licensing opportunities to obtain, additional products will be necessary.

The AxoGuard® products are only available through an exclusive distribution agreement with Cook Biotech. Such contract is for an initial seven year term and following such initial term, the agreement automatically renews for an additional seven (7) year period provided that the parties agree to meet at least ninety (90) days before the end of such initial term to review whether the purchase price of the products obtained from Cook Biotech need to be adjusted and reasonably agree to such adjustment in writing, where such agreement shall not be unreasonably withheld. However, there are conditions for continuation of the agreement, including payment terms and minimum purchase requirements, that if breached could result in an earlier termination of the agreement; except that through mutual agreement the parties have not established such minimums and to date have not enforced such minimum purchase provision. Additionally, in the event that AxoGen and Cook Biotech were to fail to reach an agreement as to minimum purchase quantities, Cook Biotech could terminate the agreement if it was deemed that AxoGen had failed to generate commercially reasonable sales of AxoGuard® as measured by sales similar to a competitive product at the same stage in its commercial launch as verified by a mutually acceptable third-party. Although there are products that AxoGen believes it could develop or obtain that would replace the AxoGuard® products, the loss of the ability to sell the AxoGuard® products could have a material adverse effect on AxoGen's business until other replacement products are available.

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AxoGen's success will be dependent on continued acceptance of its products by the medical community.

Continued market acceptance of AxoGen's products will depend on its ability to demonstrate that its products are an attractive alternative to existing nerve reconstruction treatment options. Its ability to do so will depend on surgeons' evaluations of clinical safety, efficacy, ease of use, reliability, and cost-effectiveness of AxoGen's nerve repair products. For example, although AxoGen's Avance® Nerve Graft follows stringent safety standards, including sterilization by gamma irradiation, AxoGen believes that a small portion of the medical community has lingering concerns over the risk of disease transmission through the use of allografts in general. Furthermore, AxoGen believes that even if its products receive general acceptance within the medical community, acceptance and clinical recommendations by influential surgeons will be important to the commercial success of AxoGen's products.

Negative publicity concerning methods of donating human tissue and screening of donated tissue, in the industry in which AxoGen operates, may reduce demand for its Avance© Nerve Graft product and negatively impact the supply of available donor tissue.

AxoGen is highly dependent on its ability to recover cadaveric nerves from tissue donors for its Avance® Nerve Graft product. The availability of acceptable donors is relatively limited, and this availability is impacted by regulatory changes, general public opinion of the donation process and AxoGen's reputation for its handling of the donation process. Media reports or other negative publicity concerning both improper methods of tissue recovery from donors and disease transmission from donated cadaver tissue (allografts) including bones, tendon, etc. may limit widespread acceptance of AxoGen's Avance® Nerve Graft. Unfavorable reports of improper or illegal tissue recovery

practices, both in the U.S. and internationally, as well as incidents of improperly processed tissue leading to transmission of disease, may broadly affect the rate of future tissue donation and market acceptance of allograft technologies. Potential patients may not be able to distinguish AxoGen products, technologies, and tissue recovery and processing procedures from others engaged in tissue recovery. In addition, unfavorable reports could make families of potential donors from whom AxoGen is required to obtain consent before processing tissue reluctant to agree to donate tissue to for-profit tissue processors. Any disruption in the supply could have negative consequences for AxoGen's revenue, operating results and continued operations.

AxoGen is highly dependent on the continued availability of its facilities and could be harmed if the facilities are unavailable for any prolonged period of time.

Any failure in the physical infrastructure of AxoGen's facilities, including the facility it leases from LifeNet Health, could lead to significant costs and disruptions that could reduce its revenues and harm its business reputation and financial results. Any natural or man-made event that impacts AxoGen's ability to utilize its facilities could have a significant impact on its operating results, reputation and ability to continue operations. This includes termination of the LifeNet Health facility lease which can occur upon six months' notice from either party. Although AxoGen believes it can find and make operational a new facility in less than six months, the regulatory process for approval of facilities is time-consuming and unpredictable. AxoGen's ability to rebuild or find acceptable lease facilities would take a considerable amount of time and expense and could cause a significant disruption in service to its customers. Although AxoGen has business interruption insurance which would, in instances other than lease termination, cover certain costs, it may not cover all costs nor help to regain AxoGen's standing in the market.

AxoGen must maintain high quality manufacturing and processing.

AxoGen's Avance® Nerve Graft is processed through its Avance® Process which requires careful calibration and precise, high-quality processing and manufacturing. Achieving precision and quality control requires skill and diligence by its personnel. If it fails to achieve and maintain these high quality controls, processing and manufacturing standards, including avoidance of manufacturing errors, defects or product failures, AxoGen could experience recalls or withdrawals of its product, delays in delivery, cost overruns or other problems that would adversely affect its business. AxoGen cannot completely eliminate the risk of errors, defects or failures. In addition, AxoGen may experience difficulties in scaling-up manufacturing of its Avance® product, including problems related to yields, quality control and assurance, tissue availability, adequacy of control policies and procedures, and lack of skilled personnel. If AxoGen is unable to process and produce its allografts on a timely basis, at acceptable quality and costs, and in sufficient quantities, or if it experiences unanticipated technological problems or delays in production, its business would be adversely affected.

AxoGen relies on third-party suppliers, some of which are currently the only source for the respective components or materials they supply to it.

Most of the raw materials used in the Avance® Process for the production of Avance® Nerve Graft are available from more than one supplier. However, one of the chemicals AxoGen uses in the manufacture of Avance® Nerve Graft is no longer provided by the original single source provider. AxoGen has inventory of such chemical which it believes provides more than one year of production. AxoGen is currently evaluating multiple avenues including a new supplier of the chemical and

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acceptable substitutes for the chemical. In addition, some of the test results, packaging and reagents/chemicals AxoGen uses in its manufacturing process are also obtained from single suppliers. We do not have written contracts with any of our single source suppliers, and at any time they could stop supplying our orders. FDA approval of a new supplier may be required if these materials become unavailable from AxoGen's current suppliers. Although there may be other suppliers that have equivalent materials that would be available to AxoGen, FDA approval of any alternate suppliers if required could take several months or years to obtain, if able to be obtained at all. Any delay, interruption or cessation of production by AxoGen's third-party suppliers of important materials, or any delay in qualifying new materials, if necessary, would prevent or delay AxoGen's ability to manufacture products. In addition, an uncorrected impurity, a supplier's variation in a raw material or testing, either unknown to AxoGen or incompatible with its manufacturing process, or any other problem with AxoGen's materials, testing or components, would prevent or delay its ability to manufacture products. These delays may limit AxoGen's ability to meet demand for its products and delay its clinical trial, which would have a material adverse impact on its business, results of operations and financial condition.

AxoGen relies on third parties to perform many necessary services for the commercialization of Avance® Nerve Graft, including services related to the recovery, distribution, storage and transportation.

AxoGen relies upon third parties for certain recovery, distribution, and transportation services. In accordance with product specifications, these third parties ship Avance® Nerve Graft in specially validated shipping containers at frozen temperatures. If any of the third parties that AxoGen relies upon in its recovery, distribution, storage or transportation process fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to AxoGen, or encounter physical damage or natural disaster at their facilities, AxoGen's ability to deliver product to meet commercial demand may be significantly impaired.

AxoGen is dependent on its relationships with distributors to generate revenue.

AxoGen derives material revenues through its relationships with distributors. If such distributor relationships were terminated for any reason, it could materially and adversely affect AxoGen's ability to generate revenues and profits. AxoGen intends to obtain the assistance of additional distributors to continue its sales growth. It may not be able to find additional distributors who will agree to market and distribute its products on commercially reasonable terms, if at all. If it is unable to establish new distribution relationships or renew current distribution

agreements on commercially acceptable terms, operating results could suffer.

Loss of key members of management, who it needs to succeed, could adversely affect its business.

AxoGen's future success depends on the continued efforts of the members of its senior management team. Competition for experienced management personnel in the healthcare industry is intense. If one or more of AxoGen's senior executives or other key personnel are unable or unwilling to continue in their present positions, or if AxoGen is unable to attract and retain high quality senior executives or key personnel in the future, its business may be adversely affected.

AxoGen's operating results will be harmed if it is unable to effectively manage and sustain its future growth.

There can be no assurance that AxoGen will be able to manage its future growth efficiently or profitably. Its business is unproven on a large scale and actual revenue and operating margins, or revenue and margin growth, may be less than expected. If AxoGen is unable to scale its production capabilities efficiently, it may fail to achieve expected operating margins, which would have a material and adverse effect on its operating results. Growth may also stress AxoGen's ability to adequately manage its operations, quality of products, safety and regulatory compliance. If growth significantly decreases AxoGen's cash reserves, it may be required to obtain additional financing, which may increase indebtedness or result in dilution to shareholders. Further, there can be no assurance that AxoGen would be able to obtain additional financing on acceptable terms if all at.

There may be significant fluctuations in AxoGen's operating results.

Significant quarterly fluctuations in AxoGen's results of operations may be caused by, among other factors, its volume of revenues, seasonal changes in nerve repair activity, timing of sales force expansion and general economic conditions. There can be no assurance that the level of revenues and profits, if any, achieved by AxoGen in any particular fiscal period, will not be significantly lower than in other comparable fiscal periods. AxoGen's expense levels are based, in part, on its expectations as to future revenues. As a result, if future revenues are below expectations, net income or loss may be disproportionately affected by a reduction in revenues, as any corresponding reduction in expenses may not be proportionate to the reduction in revenues.

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AxoGen's revenues depend upon prompt and adequate reimbursement from public and private insurers and national health systems.

Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental change. The ability of hospitals to pay fees for AxoGen's products depends in part on the extent to which reimbursement for the costs of such materials and related treatments will continue to be available from governmental health administration authorities, private health coverage insurers and other organizations. Major third-party payers of hospital services and hospital outpatient services, including Medicare, Medicaid and private healthcare insurers, annually revise their payment methodologies, which can result in stricter standards for reimbursement of hospital charges for certain medical procedures or the elimination of reimbursement. Further, Medicare, Medicaid and private healthcare insurer cutbacks could create downward price pressure on AxoGen's products.

AxoGen may be subject to future product liability litigation that could be expensive and its insurance coverage may not be adequate.

Although AxoGen is not currently subject to any product liability proceedings, and it has no reserves for product liability disbursements, it may incur material liabilities relating to product liability claims in the future, including product liability claims arising out of the usage of AxoGen products. AxoGen currently carries product liability insurance in an amount consistent with industry averages, however, its insurance coverage and any reserves it may maintain in the future for product related liabilities may not be adequate and AxoGen's business could suffer material adverse consequences.

Technological change could reduce demand for AxoGen's products.

The medical technology industry is intensely competitive. AxoGen competes with both U.S. and international companies that engage in the development and production of medical technologies and processes including:

- biotechnology, orthopedic, pharmaceutical, biomaterial, chemical and other companies;
- academic and scientific institutions; and
- public and private research organizations.

AxoGen products compete with autograft and hollow-tube conduits and commercially available wraps, as well as with alternative medical procedures. For the foreseeable future, AxoGen believes a significant number of surgeons will continue to choose to perform autograft procedures when feasible, despite the necessity of performing a second operation and its drawbacks. In addition, many members of the medical community will continue to prefer the use of hollow-tube conduits due in part to their familiarity with these products and the procedures required for their use. Also, steady improvements have been made in synthetic human tissue substitutes, which could compete with AxoGen's products. Unlike allografts, synthetic tissue technologies are not dependent on the availability of human or animal tissue. Although AxoGen's growth strategy contemplates the introduction of new technologies, the development of these technologies is a complex and uncertain process, requiring a high level of innovation, as well as the ability to accurately predict future technology and market trends. AxoGen may not be able to respond effectively to technological changes and emerging industry standards, or to successfully identify,

develop or support new technologies or enhancements to existing products in a timely and cost effective manner, if at all. Finally, there can be no assurance that in the future AxoGen's competitors will not develop products that have superior performance or are less expensive relative to its products rendering them obsolete or noncompetitive.

AxoGen may be unsuccessful in commercializing its products outside the U.S.

To date, AxoGen has focused its commercialization efforts in the U.S., except for minor revenues in the United Kingdom, the Netherlands, Switzerland, Italy, Austria, Israel and Canada. It intends to expand sales beyond these countries outside the U.S. and will need to comply with applicable foreign regulatory requirements, including obtaining the requisite approvals to do so. Additionally, AxoGen will need to either enter into distribution agreements with third parties or develop a direct sales force in these foreign markets. If it does not obtain adequate levels of reimbursement from third-party payers outside of the U.S., it may be unable to develop and grow its product sales internationally. Outside of the U.S., reimbursement systems vary significantly by country. Many foreign markets have government-managed healthcare systems that govern reimbursement for medical devices and procedures. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If AxoGen is unable to successfully commercialize its products internationally, its long term growth prospects may be limited.

If AxoGen does not manage tissue and tissue donation in an effective and efficient manner, it could adversely affect its business.

Many factors affect the supply, quantity and timing of donor medical releases, such as effectiveness of donor screening (currently performed by donor recovery groups), the effective recovery of tissue, the timely receipt, recording and review of

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required medical documentation, and employee loss and turnover in AxoGen's and its contractor's recovery department. AxoGen can provide no assurance that tissue recovery or donor medical releases will occur at levels that will maximize processing efficiency and minimize AxoGen's cost per allograft processed.

If AxoGen does not manage product inventory in an effective and efficient manner, it could adversely affect profitability.

Many factors affect the efficient use and planning of product inventory, such as effectiveness of predicting demand, effectiveness of preparing manufacturing to meet demand, efficiently meeting product mix and product demand requirements and product expiration. AxoGen may be unable to manage its inventory efficiently, keep inventory within expected budget goals, keep its work-in-process inventory on hand or manage it efficiently, control expired product or keep sufficient product on hand to meet demand, and AxoGen can provide no assurance that it can keep inventory costs within its target levels. Failing to do so may require AxoGen to raise additional cash resources or may harm long term growth prospects.

AxoGen is a party to a Royalty Contract which requires it to pay royalty fees that could materially adversely affect its financial position.

On October 5, 2012, AxoGen entered into a Royalty Contract with PDL, pursuant to which AxoGen sold to PDL the right to receive specified royalties on AxoGen's Net Revenues generated by the sale, distribution or other use of AxoGen's products Avance® Nerve Graft, AxoGuard® Nerve Protector and AxoGuard® Nerve Connector (the Assigned Interests as defined in the Royalty Contract). The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments, currently paid weekly, based on a 9.95% royalty rate of AxoGen's Net Revenues, subject to certain agreed upon minimum guaranteed quarterly payment amounts of approximately $1.3 to $2.5 million per quarter that commence in the quarter ending December 31, 2014. The minimum annual payment amounts are as follows: 2014—$1,250,805, 2015—$6,781,440, 2016—$9,232,642, 2017 and 2018—$9,000,000, 2019—$9,063,000 and 2020—$6,939,000. Further, on October 5, 2016, or in the event of the occurrence of a material adverse event, our transfer of revenue interest or substantially all of our interest in the products or AxoGen's bankruptcy or material breach of the Royalty Contract, PDL may require AxoGen to repurchase the Assigned Interests (the "Put") at the Put Price (as defined in the Royalty Contract). The Put Price is equal to the sum of (i) an amount that, when paid to PDL, would generate a 20% internal rate of return to PDL (the "Put Rate") on the Funded Amount, taking into consideration payments made to PDL by AxoGen, and (ii) any "Delinquent Assigned Interests Payment" (as defined in the Royalty Contract) AxoGen owed to PDL. For purposes of estimating the effective interest rate of the Royalty Contract, we considered that the effective rate of 20% (currently the Put Rate) is currently slightly higher than the implicit rate of return and, as a result, we assume for accounting purposes that PDL will exercise its put option in order to receive the higher rate of return. However we have no actual knowledge or other indications of PDL's intent to do so.

During 2013, AxoGen's monthly expenses exceeded its revenues and thus it operated at a cash loss. Royalty payments to PDL are owed without consideration to any negative affect it has on AxoGen's cash or loss position. In addition, minimum payments under the Royalty Contract start in October 2014 and AxoGen believes that the required minimum payment will be greater than the royalty fee, increasing AxoGen's cash burden. Finally, there is no assurance that AxoGen will have sufficient capital to pay the Put Price if it was exercised. If AxoGen does not have sufficient cash to pay PDL, AxoGen would need to raise additional capital. The sale of additional equity to further finance the company may result in dilution to AxoGen's shareholders. There is no assurance that if AxoGen is required to secure funding it can do so on terms acceptable to it, or at all. The increasing need for capital as the PDL transaction matures could also make it more difficult to obtain funding through either equity or debt. See "Notes to Consolidated Financial Statements — Footnote 7 Long-Term Debt/Note Payable."

PDL Royalty Contract has Change of Control provision that could have material impact on price received by AxoGen shareholders in the event of a Change of Control.

In the event of a "Change of Control" (as defined in the Royalty Contract), AxoGen must repurchase the Assigned Interests from PDL for a repurchase price equal to the "Change of Control Price" on or prior to the third business day after the occurrence of the Change of Control. The Change of Control Price is the sum of (i) an amount that, when paid to PDL, would generate an internal rate of return to PDL of thirty-two and one half percent (32.5%) on all payments made by PDL pursuant to the Royalty Contract as of the date of the Change of Control Payment (as defined in the Royalty Contract), taking into account the amount and timing of all payments made by AxoGen to PDL (and retained by PDL) prior to and as of the date of payment of the Change of Control Payment, plus (ii) any Delinquent Assigned Interests Payment owed. Payment of the Change of Control Price could materially reduce the consideration to be received by AxoGen shareholders if the Change of Control event was in conjunction with the acquisition of the Company.

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AxoGen incurs costs as a result of operating as a public company, and its management is required to devote substantial time to compliance initiatives.

As a public company, AxoGen incurs legal, accounting and other expenses to comply with relevant securities laws and regulations, including, without limitation, the requirement of establishment and maintenance of effective disclosure and financial controls and corporate governance practices. AxoGen's management devotes substantial time and financial resources to these compliance initiatives. Failure to comply with public company requirements could have a material adverse effect on AxoGen's business.

Our Business and Stock Price May Be Adversely Affected if Our Internal Controls Are Not Effective.

Section 404 of the Sarbanes-Oxley Act of 2002 requires companies to conduct a comprehensive evaluation of their internal control over financial reporting. To comply with this statute, each year we are required to document and test our internal control over financial reporting and our management is required to assess and issue a report concerning our internal control over financial reporting.

In our annual report for the period ended December 31, 2011, we reported a material weakness in our internal control over financial reporting, which related to an instance in which the accounting for a contract was inappropriately treated as an expense as opposed to a prepaid asset. Although we believe we took appropriate actions to remediate the control deficiencies we identified and to strengthen our internal control over financial reporting, we cannot assure you that we will not discover other material weaknesses in the future or that no material weakness will result from any difficulties, errors, delays or disruptions while we implement and transition to new internal systems. The existence of one or more material weaknesses could result in errors in our financial statements, and substantial costs and resources may be required to rectify these or other internal control deficiencies. If we cannot produce reliable financial reports, investors could lose confidence in our reported financial information, the market price of our common stock could decline significantly, we may be unable to obtain additional financing to operate and expand our business, and our business and financial condition could be harmed.

Our business and financial performance could be adversely affected, directly or indirectly, by disasters, by terrorist activities or by international hostilities.

Neither the occurrence nor the potential impact of disasters, terrorist activities and international hostilities can be predicted. However, these occurrences could impact us directly as a result of damage to our facilities or by preventing us from conducting our business in the ordinary course, or indirectly as a result of their impact on our customers, suppliers or other counterparties. We could also suffer adverse consequences to the extent that disasters, terrorist activities or international hostilities affect the financial markets or the economy in general or in any particular region.

Our ability to mitigate the adverse consequences of such occurrences is in part dependent on the quality of our resiliency planning, and our ability, if any, to anticipate the nature of any such event that occurs. The adverse impact of disasters or terrorist activities or international hostilities also could be increased to the extent that there is a lack of preparedness on the part of national or regional emergency responders or on the part of other organizations and businesses that we deal with, particularly those that we depend upon but have no control over.

Risks Related to the Regulatory Environment in which AxoGen Operates

AxoGen's business is subject to continuing regulatory compliance by the FDA and other authorities which is costly and could result in negative effects on its business.

AxoGen is subject to extensive regulation. Its products are subject to regulation by the FDA in the U.S., the Center for Medicare Services of the U.S. Department of Health and Human Services and other federal governmental agencies and, in some jurisdictions, by state and foreign governmental authorities. The FDA regulates the development, clinical testing, marketing, distribution, manufacturing, labeling, and promotion of biological products, such as that of AxoGen's Avance® Nerve Graft product. The FDA also regulates medical devices, such as the AxoGuard® products. The FDA requires the approval of a biological product, such as the Avance® Nerve Graft product, through a biological license application, or BLA, prior to marketing. Although the Avance® Nerve Graft product has not yet been approved by FDA through a BLA, FDA is permitting the product to be sold pursuant to a transition plan while AxoGen performs clinical testing and prepares a BLA submission for the Avance® Nerve Graft. See "Business — Government Regulations — U.S. Government Regulation Review." The FDA also regulates medical devices and requires that certain medical devices, such as the AxoGuard® products, be cleared through the 510(k) premarket notification process prior to marketing. The FDA's premarket review process for new and modified existing devices that precedes product marketing can be time consuming and expensive. Some of the future products and enhancements to such products that AxoGen expects to develop and market may require marketing clearance or approval from the FDA. There can be no assurance, however, that clearance or approval will be granted with respect to any of AxoGen's products or enhancements or that FDA review will not involve delays that would adversely affect AxoGen's ability to market such products or enhancements. In addition, there can be no assurance that

AxoGen products,

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including the Avance® Nerve Graft, or enhancements will not be subject to a lengthy and expensive approval process with the FDA.

It is possible that if regulatory clearances or approvals to market a product are obtained from the FDA, the clearances or approvals may contain limitations on the indicated uses of such product and other uses may be prohibited. Product approvals by the FDA can also be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval. Also, the FDA could limit or prevent the distribution of AxoGen products and has the power to require the recall of such products. FDA regulations depend heavily on administrative interpretation, and there can be no assurance that future interpretations made by the FDA or other regulatory bodies will not adversely affect AxoGen's operations. AxoGen, and its facilities, may be inspected by the FDA from time to time to determine whether it is in compliance with various regulations relating to specification, development, documentation, validation, testing, quality control, and product labeling. A determination that AxoGen is in violation of such regulations could lead to imposition of civil penalties, including fines, product recalls or product seizures and, in certain cases, criminal sanctions.

The use, misuse or off-label use of AxoGen's products may harm its reputation or the image of its products in the marketplace, or result in injuries that lead to product liability suits, which could be costly to AxoGen's business or result in FDA sanctions if the company is deemed to have engaged in off-label promotion. AxoGen is seeking a biologics license through the BLA process for specific uses of Avance® Nerve Graft under specific circumstances. Its promotional materials and training methods must comply with FDA requirements and other applicable laws and regulations, including the prohibition against off-label promotion. AxoGen's promotion of the AxoGuard® products, which are regulated as medical devices, also must comply with FDA's requirements and must only use labeling that is consistent with the specific indication(s) for use included in FDA's substantial equivalence order that results in marketing the devices. The FDA does not restrict or regulate a physician's use of a medical product within the practice of medicine, and AxoGen cannot prevent a physician from using its products for an off-label use. However, the Federal Food, Drug, and Cosmetic Act, referred to herein as the FD&C Act, and the FDA's regulations restrict the kind of promotional communications that may be made about AxoGen's products and if the FDA determines that AxoGen's promotional or training materials constitute the unlawful promotion of an off-label use, it could request that AxoGen modify its training or promotional materials and/or subject the Company to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, civil money penalties, or criminal fines and penalties. Other federal, state or foreign governmental authorities might also take action if they consider AxoGen promotion or training materials to constitute promotion of an uncleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement, or exclusion from participation in federal health programs. In that event, AxoGen's reputation could be damaged and the use of its products in the marketplace could be impaired.

In addition, there may be increased risk of injury if physicians or others attempt to use AxoGen products off-label. Furthermore, the use of AxoGen's product for indications other than those for which its products have been approved, cleared or licensed by the FDA may not effectively treat the conditions not referenced in product indications, which could harm AxoGen's reputation in the marketplace among physicians and patients. Physicians may also misuse AxoGen's product or use improper techniques if they are not adequately trained in the particular use, potentially leading to injury and an increased risk of product liability. Product liability claims are expensive to defend and could divert management's attention from its primary business and result in substantial damage awards against AxoGen. Any of these events could harm AxoGen's business, results of operations and financial condition.

AxoGen's Avance® Nerve Graft product is currently allowed to be sold pursuant to a transition plan with the FDA and a change in position by the FDA regarding its use of enforcement discretion to permit the sale of Avance would have a material adverse effect on AxoGen.

The FDA considers the AxoGen's Avance® Nerve Graft product to be a biological product, subject to BLA approval requirements. Although the Avance® Nerve Graft product has not yet been approved by FDA through a BLA, AxoGen's Avance® Nerve Graft product is currently sold under the controls applicable to a HCT/P pursuant to section 361 of the Public Health Service Act and 21 CFR Part 1271 of FDA's regulations, in accordance with a transition plan with the FDA in which the agency will monitor AxoGen's compliance with 21 CFR Part 1271. See "Business — Government Regulations — U.S. Government Regulation Review." AxoGen has continued to communicate with FDA's CBER since the acceptance of the transition plan on clinical trial design and Chemistry, Manufacturing, and Controls ("CMC") for the Avance® Nerve Graft. AxoGen can commercially distribute the Avance® Nerve Graft subject to the controls HCT/Ps until FDA makes a final determination on an Avance® Nerve Graft BLA submission, assuming AxoGen remains in compliance with the transition plan. In the event that the FDA becomes dissatisfied with AxoGen's progress or actions with respect to the transition plan or FDA otherwise changes its position regarding its use of enforcement discretion to permit AxoGen to provide the Avance® Nerve Graft product in accordance with the transition plan, AxoGen would no longer be able to sell the Avance® Nerve Graft product, which would have a material adverse effect on AxoGen's operations and financial viability. In addition, if AxoGen does not meet the conditions for the transition plan, fails to comply with applicable regulatory requirements or fails to comply

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with the ongoing requirements of the premarket submission to transition to a biological product, the FDA could deny approval of the premarket application, or impose civil penalties, including fines, product seizures, injunctions or product recalls and, in certain cases, criminal sanctions.

AxoGen's AxoGuard® products are subject to FDA and other regulatory requirements.

AxoGen's AxoGuard® product line is regulated as a medical device under the FD&C Act and subject to premarket notification and clearance requirements under section 510(k) of the FD&C Act, 21 CFR Part 820 (Quality System Regulation) and other FDA regulations. AxoGen distributes for Cook Biotech Incorporated the AxoGuard® product line and Cook Biotech is responsible for the regulatory compliance of the AxoGuard® product line. Cook Biotech has obtained a 510(k) premarket clearance from the FDA for porcine (pig) small intestine submucosa for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. Cook Biotech has also obtained a 510(k) premarket clearance for the AxoGuard® Nerve Protector for the repair of peripheral nerve injuries in which there is no gap or where a gap closure is achieved by flexion of the extremity. If AxoGen or Cook Biotech Incorporated fails to comply with applicable regulatory requirements the FDA could deny or withdraw 510(k) clearance for the AxoGuard® products, or impose civil penalties, including fines, product seizures or product recalls and, in certain cases, criminal sanctions.

Defective AxoGen product could lead to recall or other negative business conditions.

If AxoGen's products are defective or otherwise pose safety risks, the FDA could require their recall, or AxoGen may initiate a voluntary recall of its products. The FDA may require recall of a marketed medical device product, such as the AxoGuard® products, in the event that it determines that due to material deficiencies or defects that use of the medical device product would pose a reasonable probability of serious adverse health consequences or death. However, FDA does not have authority to require most device recalls because they do not rise to this level of health significance. FDA may request, but not require, the recall of a biological product, such as the Avance® Nerve Graft. However, if a company does not comply with an FDA request for a recall, FDA can pursue other enforcement actions, such as product seizure. In addition, manufacturers may, on their own initiative, recall a product to remove or correct a deficiency or to remedy a violation of the Federal Food, Drug, and Cosmetic Act that may pose a risk to health. A government-mandated, government-requested or voluntary recall could occur as a result of an unacceptable risk to health, reports of safety issues, failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls and other field corrections for any of AxoGen's products would divert managerial and financial resources and have an adverse effect on its business, results of operations and financial condition. A recall could harm AxoGen's reputation with customers and negatively affect its sales. AxoGen may initiate recalls involving some of its products in the future that it determines do not require notification of the FDA. If the FDA were to disagree with AxoGen's determinations, it could request that it report those actions as recalls, and take regulatory or enforcement action against AxoGen or the product.

If AxoGen's products cause or contribute to a death, a serious injury or any adverse reaction involving a communicable disease related to its products, or malfunction in certain ways, it will be subject to reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. See "Business — Regulation — Education Grants, U.S. Anti-kickback, False Claims and Other Healthcare Fraud and Abuse Laws — Pervasive and Continuing Regulation." If AxoGen fails to report these events to the FDA within the required timeframes, or at all, the FDA could take regulatory or enforcement action against AxoGen. Any adverse event involving AxoGen's products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as AxoGen defending itself in a lawsuit, would require the dedication of time and capital, distract management from operating its business, and may harm AxoGen's reputation, business, results of operations and financial condition.

AxoGen's manufacturing operations must comply with FDA and other governmental requirements.

AxoGen's manufacturing operations require it to comply with the FDA's and other governmental authorities' laws and regulations regarding the manufacture and production of medical products, which is costly and could subject AxoGen to enforcement action. See Business — Government Regulations — Education Grants, U.S. Anti-kickback, False Claims and Other Healthcare Fraud and Abuse Laws — Pervasive and Continuing Regulation. Any of these actions could impair AxoGen's ability to produce its products in a cost-effective and timely manner in order to meet customer demands. AxoGen may also be required to bear other costs or take other actions that may have an adverse impact on its future sales and its ability to generate profits. Furthermore, AxoGen key material suppliers, licensors and or other contractors may not continue to be in compliance with all applicable regulatory requirements, which could result in AxoGen's failure to produce its products on a timely basis and in the required quantities, if at all.

Sales of AxoGen products outside the U.S. are subject to foreign regulatory requirements that vary from country to country. In the E.U., regulations, if applicable, differ from one E.U. member state to the next. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the E.U., as well

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as for other countries, the approval process for human derived cell or tissue based medical products may be extensive, lengthy, expensive and unpredictable. AxoGen products will be subject to E.U. member states' regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage, and distribution of human tissues and cells and cellular or tissue-based products. In addition, some E.U. member states have their own tissue banking regulations. The inability to meet foreign regulatory requirements could materially affect AxoGen's future growth and compliance with such requirements could place a significant financial burden on AxoGen.

Clinical trials can be long, expensive and ultimately uncertain which could jeopardize AxoGen's ability to obtain regulatory approval and continue to market its Avance® Nerve Graft product.

AxoGen is required to perform a clinical trial for its Avance® Nerve Graft pursuant to requirements of the FDA to obtain approval of a BLA for the product. This trial is expensive, is expected to take several years to execute, and is subject to factors within and outside of AxoGen's control. The outcome of this trial is uncertain.

AxoGen has continued to communicate with the FDA regarding clinical trial design, preclinical studies and CMC for the Avance® Nerve Graft, and will have significant work to continue to meet the requirements asked of AxoGen by the FDA for each of these components to begin its clinical study and receive approval of its BLA. If AxoGen is unable to agree with FDA, or unable to meet the standards required of it by the FDA, regarding preclinical studies, clinical studies and CMC, the approval of AxoGen's BLA may be impossible, delayed and/or may add significant costs to the ongoing production of Avance® Nerve Graft.

The results of non-clinical studies do not necessarily predict future clinical trial results, and predecessor clinical trial results may not be repeated in subsequent clinical trials. Additionally, the FDA may disagree with AxoGen's interpretation of the data from its non-clinical studies and clinical trials and may require it to pursue additional non-clinical studies or clinical trials, or not approve AxoGen's BLA or future supplements, which could further delay the BLA for the Avance® Nerve Graft of AxoGen's products. If AxoGen is unable to demonstrate the safety and efficacy of its product through its clinical trials, it will be unable to obtain regulatory approval to market the Avance® Nerve Graft and will not be able to continue to sell it.

AxoGen will rely on third parties to conduct its clinical trial and they may not perform as contractually required or expected.

AxoGen will rely on third parties, such as contract research organizations ("CROs"), medical institutions, clinical investigators and contract laboratories to conduct its clinical trial and certain nonclinical studies. AxoGen and its CROs are required to comply with all applicable regulations governing clinical research, including good clinical practice, or GCP. The FDA enforces these regulations through periodic inspections of trial sponsors, principal investigators, CROs and trial sites. If AxoGen or its CROs fail to comply with applicable FDA regulations, the data generated in its clinical trials may be deemed unreliable and the FDA may require AxoGen to perform additional clinical trials before approving its applications. AxoGen cannot be certain that, upon inspection, the FDA and similar foreign regulatory authorities will determine that AxoGen's clinical trial complies or complied with clinical trial regulations, including GCP. In addition, AxoGen's clinical trial must be conducted with product produced under applicable current Good Manufacturing Practice, or GMP, regulations. Failure to comply with the clinical trial regulations may require AxoGen to repeat clinical trials, which would delay the regulatory approval process. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to AxoGen's clinical protocols or regulatory requirements or for other reasons, AxoGen's non-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and it would not be able to obtain regulatory approval for, its products on a timely basis, if at all, and its business, results of operations, financial condition and growth prospects would be adversely affected. Furthermore, AxoGen's third-party clinical trial investigators may be delayed in conducting its clinical trials for reasons outside of their control.

U.S. governmental regulation could restrict the use of AxoGen's Avance® Nerve Graft product, restrict AxoGen's procurement of tissue or increase costs.

In addition to the FDA requirements for biological products, the Avance® Nerve Graft will continue to be subject to various requirements for human tissue under 21 CFR Part 1271 controls. Human tissues intended for transplantation have been regulated by the FDA since 1993. In May 2005, three new comprehensive regulations went into effect that address manufacturing activities associated with HCT/P. The first requires that companies that produce and distribute HCT/Ps register with the FDA. The second provides criteria that must be met for donors to be eligible to donate tissues and is referred to as the "Donor Eligibility" rule. The third rule governs the processing and distribution of the tissues and is often referred to as the Current Good Tissue Practices rule. The Current Good Tissue Practices rule covers all stages of allograft processing, from procurement of tissue to distribution of final allografts. Together, they are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients. These regulations increased regulatory scrutiny within the industry in which AxoGen operates and have led to increased

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enforcement action, which affects the conduct of its business. See "Business — Government Regulations." These regulations can also increase the cost of tissue recovery activities. Additionally, the Avance® Nerve Graft is subjected to certain state and local regulations, as well as compliance to the standards of the tissue bank industry's accrediting organization, the American Association of Tissue Banks ("AATB").

The procurement and transplantation of allograft nerve tissue is also subject to federal law pursuant to the National Organ Transplant Act ("NOTA"), a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including nerve and related tissue, for "valuable consideration." NOTA only permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human nerve tissue. AxoGen makes payments to certain of its clients and tissue banks for their services related to recovering allograft nerve tissue on its behalf. If NOTA is interpreted or enforced in a manner which prevents AxoGen from receiving payment for services it renders, or which prevents it from paying tissue banks or certain of its clients for the services they render for AxoGen, its business could be materially and adversely affected.

AxoGen has engaged, through its marketing employees, independent sales agents and sales representatives, in ongoing efforts designed to educate the medical community as to the benefits of AxoGen products, and AxoGen intends to continue its educational activities. Although AxoGen believes that NOTA permits payments in connection with these educational efforts as reasonable payments associated with the processing, transportation and implantation of AxoGen products, payments in connection with such education efforts are not exempt from NOTA's restrictions and AxoGen's inability to make such payments in connection with its education efforts may prevent it from paying AxoGen sales representatives for their education efforts and could adversely affect AxoGen's business and prospects. No federal agency or court has determined whether NOTA is, or will be, applicable to every allograft nerve tissue-based material which AxoGen's processing technologies may generate. Assuming that NOTA applies to AxoGen's processing of allograft nerve tissue, AxoGen believes that it complies with NOTA, but there can be no assurance that more restrictive interpretations of, or amendments to, NOTA will not be

adopted in the future, which would call into question one or more aspects of AxoGen's method of operations.

Other regulatory entities include state agencies with statutes covering tissue banking. Regulations issued by Florida, New York, California and Maryland, among others, will be particularly relevant to AxoGen's business. Most states do not currently have tissue banking regulations. However, incidents of allograft related infections in the industry may stimulate the development of regulation in other states. It is possible that others may make allegations against AxoGen or against donor recovery groups or tissue banks about non-compliance with applicable FDA regulations or other relevant statutes or regulations. Allegations like these could cause regulators or other authorities to take investigative or other action, or could cause negative publicity for AxoGen's business and the industry in which it operates.

Healthcare policy changes may have a material adverse effect on AxoGen.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which substantially changes the way healthcare is financed by both governmental and private insurers, and encourages improvements in the quality of healthcare items and services. This Act significantly impacts the biotechnology and medical device industries and could have a material adverse impact on numerous aspects of AxoGen's business.

This Act includes, among other things, the following measures:

- a 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the U.S., with limited exceptions, beginning in 2013, referred to as the Device Tax;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research;
- new reporting and disclosure requirements on healthcare manufacturers for any "transfer of value" made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests, with the first of such reports due March 31, 2014 for calendar year 2013 ("Sunshine Act");
- payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models which began January 2013;
- an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate; and
- a new abbreviated pathway for the licensure of biologic products that are demonstrated to be biosimilar or interchangeable with a licensed biologic product.

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Because the Avance® Nerve Graft is a biological product and is not a medical device it is not subject to the Device Tax. Cook Biotech is the manufacturer of the AxoGuard® products and AxoGen is the distributor. As such, Cook Biotech is responsible for payment of the Device Tax on the transfer price of the AxoGuard® products from Cook Biotech to AxoGen and AxoGen has no further Device Tax obligations with respect to its resale. Although AxoGen currently has no Device Tax obligations, there can be no assurance that changes in regulations will not subject it to such obligations in the future.

There are also a number of states (such as Vermont, Massachusetts, Minnesota) with their own Sunshine Acts that implement the reporting and disclosure requirements on healthcare manufacturers for any "transfer of value" made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests.

In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system. Certain of these proposals could limit the prices AxoGen is able to charge for its products or the amounts of reimbursement available for its products and could also limit the acceptance and availability of its products. The adoption of some or all of these proposals could have a material adverse effect on AxoGen's business, results of operations and financial condition.

Additionally, initiatives sponsored by government agencies, legislative bodies and the private sector to limit the growth of healthcare costs, including price regulation and competitive pricing, are ongoing in markets where AxoGen does business. AxoGen could experience an adverse impact on operating results due to increased pricing pressure in the U.S. and in other markets. Governments, hospitals and other third-party payors could reduce the amount of approved reimbursement for AxoGen's products or deny coverage altogether. Reductions in reimbursement levels or coverage or other cost-containment measures could unfavorably affect AxoGen's future operating results.

Risks Related to AxoGen's Intellectual Property

Failure to protect AxoGen's Intellectual Property rights could result in costly and time consuming litigation and its loss of any potential competitive advantage.

AxoGen's success will depend, to a large extent, on its ability to successfully obtain and maintain patents, prevent misappropriation or infringement of intellectual property, or IP, maintain trade secret protection, and conduct operations without violating or infringing on the IP rights of third parties. See "Business — Intellectual Property." There can be no assurance that AxoGen's patented and patent pending technologies will provide it with a competitive advantage, that AxoGen will be able to develop or acquire additional technology that is patentable, or that third parties will not develop and offer technologies which are similar to AxoGen's. Moreover, AxoGen can provide no assurance that confidentiality agreements with its employees, consultants and other parties, trade secrecy agreements or similar agreements intended to protect unpatented technology will provide the intended protection. IP litigation is extremely expensive and time-consuming, and

it is often difficult, if not impossible, to predict the outcome of such litigation. A failure by AxoGen to protect its IP could have a materially adverse effect on its business and operating results and its ability to successfully compete in its industry.

Future protection for AxoGen's proprietary rights is uncertain which may impact its ability to successfully compete in its industry.

The degree of future protection for AxoGen's proprietary rights is uncertain. AxoGen cannot ensure that:

- it, or its licensors, were the first to make the inventions covered by each of AxoGen's patents;
- it, or its licensors, were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of AxoGen's technologies;
- any of AxoGen's pending patent applications will result in issued patents;
- any of AxoGen's issued patents or those of its licensors will be valid and enforceable;
- any patents issued to AxoGen or its collaborators will provide any competitive advantages or will not be challenged by third parties;
- it will develop additional proprietary technologies that are patentable;
- the patents of others will not have a material adverse effect on its business rights; or
- the measures AxoGen relies on to protect its IP underlying their products may not be adequate to prevent third parties from using its technology, all of which could harm its ability to compete in the market.

AxoGen's commercial success depends in part on its ability and the ability of its collaborators and licensors to avoid infringing patents and proprietary rights of third parties which could expose it to litigation or commercially unfavorable licensing arrangements. Third parties may accuse AxoGen or collaborators and licensors of employing their proprietary technology in AxoGen products, or in the materials or processes used to research or develop AxoGen products, without authorization. Any legal action against AxoGen collaborators, licensors or it claiming damages and/or seeking to stop AxoGen's commercial activities relating to the affected products, materials and processes could, in addition to subjecting AxoGen to potential liability for damages, require it or its collaborators and licensors to obtain a license to continue to utilize

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the affected materials or processes or to manufacture or market the affected products. AxoGen cannot predict whether AxoGen or its collaborators and licensors would prevail in any of these actions or whether any license required under any of these patents would be made available on commercially reasonable terms, if at all. If AxoGen were unable to obtain such a license, it and its collaborators and licensors may be unable to continue to utilize the affected materials or processes, or manufacture or market the affected products, or AxoGen may be obligated by a court to pay substantial royalties and/or other damages to the patent holder. Even if AxoGen were able to obtain such a license, the terms of such a license could substantially reduce the commercial value of the affected product or products and impair AxoGen's prospects for profitability. Accordingly, AxoGen cannot predict whether, or to what extent, the commercial value of the affected product or products, or AxoGen's prospects for profitability may be harmed as a result of any of the liabilities discussed above. Furthermore, infringement and other IP claims, with or without merit, can be expensive and time-consuming to litigate and can divert management's attention from its core business. AxoGen and its licensors may be unable to obtain and enforce IP rights to adequately protect its products and related IP.

The patent protection for our products may expire before we are able to maximize their commercial value which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.

The patents for our commercialized products and products in development have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. For example, the two U.S. patents covering the formulations used in our AxoGuard® product line, which are held by Cook Biotech, are scheduled to expire in August and September 2016. Although we expect that Cook Biotech is using best efforts to take any action possible to extend the life of these patents, there can be no assurance that any action is possible or action taken will be successful. If these patents expire while we have the right to distribute and market the AxoGuard® products, it could adversely affect our ability to successfully execute our business strategy to maximize the value of AxoGuard® products and could likely negatively impact our future financial condition and results of operations.

Others may claim an ownership interest in AxoGen IP which could expose it to litigation and have a significant adverse effect on its prospects.

A third party may claim an ownership interest in one or more of AxoGen's patents or other IP. A third party could bring legal actions against AxoGen claiming it infringes their patents or proprietary rights, and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While AxoGen believes it owns the right, title and interest in the patents for which it or its licensors have applied and AxoGen's other IP (including that which is licensed from third parties), and is presently unaware of any claims or assertions by third-parties with respect to AxoGen's patents or IP, it cannot guarantee that a third-party will not assert a claim or an interest in any of such patents or IP. If AxoGen becomes involved in any litigation, it could consume a substantial portion of AxoGen's resources, and cause a significant diversion of effort by AxoGen's technical and management personnel regardless of the outcome of the litigation. If any of these actions were successful, in addition to any potential liability for damages, AxoGen could be required to obtain a license to continue to manufacture or market the affected product, in which case AxoGen may be required to pay substantial royalties or grant cross-licenses to AxoGen's patents. AxoGen cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, AxoGen could be prevented from commercializing a product, or be forced to cease some aspect of its

business operations as a result of claims of patent infringement or violation of other IP rights, which could have a material and adverse effect on AxoGen's business, financial condition, and results of operations. Further, the outcome of IP litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party. This is especially true in IP cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

AxoGen depends on maintenance of exclusive licenses.

AxoGen depends fundamentally on keeping and satisfying the terms of exclusive licenses of its nerve repair technologies from UFRF and UT where the original technologies are purported to be invented. Though AxoGen makes an effort to follow these agreements strictly, a disagreement between AxoGen and either party could have negative impacts on its ability to operate its business effectively. In addition, AxoGen could learn that the technologies it has licensed from UFRF and UT do not perform as purported, are not efficacious, or are not the property of UFRF or UT, or some similar problem with the license, any of which would have an immediate and negative impact on AxoGen's business.

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Risk Related to Our Common Stock

The price of AxoGen's common shares could be highly volatile due to a number of factors, which could lead to losses by investors and costly securities litigation.

Our common shares are listed on the NASDAQ Capital Market under the symbol "AXGN." The trading price of our common shares has experienced substantial volatility and is likely to continue to be highly volatile in response to a number of factors including, without limitation, the following:

- limited daily trading volume resulting in the lack of a liquid market;
- fluctuations in price and volume due to investor speculation and other factors that may not be tied to the financial performance of AxoGen;
- performance by AxoGen in the execution of its business plan;
- financial viability; actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors;
- market conditions in our industry;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- sales of our common shares or other securities in the open market;
- regulatory developments in both the United States and foreign countries;
- performance of products sold and advertised by licensees in the marketplace;
- economic and other external factors;
- period-to-period fluctuations in financial results; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, and several recent situations, following periods of volatility in the market price of a company's securities, securities class action litigation has been initiated against such company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

We do not anticipate paying any cash dividends in the foreseeable future.

The continued operation and expansion of our business will require substantial funding. In addition, the PDL Royalty Contract places certain restrictions on our ability to pay dividends. Accordingly, we do not anticipate that we will pay any cash dividends on our common shares for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Accordingly, if you purchase shares, realization of a gain on your investment will depend on the appreciation of the price of our common shares, which may never occur. Investors seeking cash dividends in the foreseeable future should not purchase our common shares.

Anti-takeover provisions in Minnesota law may deter acquisition bids for us that you might consider favorable.

We are governed by the provisions of Sections 302A.671, 302A.673 and 302A.675 of the Minnesota Business Corporation Act (the "MBCA"). These provisions may discourage a negotiated acquisition or unsolicited takeover of us and deprive our shareholders of an opportunity to sell their shares at a premium over the market price.

In general, Section 302A.671 of the MBCA provides that a corporation's shares acquired in a control share acquisition have no voting

rights unless voting rights are approved in a prescribed manner. A "control share acquisition" is a direct or indirect acquisition of beneficial ownership of shares that would, when added to all other shares beneficially owned by the acquiring person, entitle the acquiring person to have voting power of 20% or more in the election of directors.

In general, Section 302A.673 of the MBCA prohibits a public Minnesota corporation from engaging in a business combination with an interested shareholder for a period of four years after the date of the transaction in which the person became an interested shareholder, unless the business combination is approved in a prescribed manner. The term "business combination" includes mergers, asset sales and other transactions resulting in a financial benefit to the interested shareholder. An "interested shareholder" is a person who is the beneficial owner, directly or indirectly, of 10% or more of a corporation's voting stock, or who is an affiliate or associate of the corporation, and who, at any time within four years before the date in

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question, was the beneficial owner, directly or indirectly, of 10% or more of the corporation's voting stock. Section 302A.673 does not apply if a committee of our Board of Directors consisting of all of its disinterested directors (excluding current and former officers) approves the proposed transaction or the interested shareholder's acquisition of shares before the interested shareholder becomes an interested shareholder.

If a tender offer is made for our common shares, Section 302A.675 of the MBCA precludes the offeror from acquiring additional shares of stock (including in acquisitions pursuant to mergers, consolidations or statutory share exchanges) within two years following the completion of the tender offer, unless shareholders selling their shares in the later acquisition are given the opportunity to sell their shares on terms that are substantially the same as those contained in the earlier tender offer. Section 302A.675 does not apply if a committee of our Board of Directors consisting of all of its disinterested directors (excluding its current and former officers) approves the proposed acquisition before any shares are acquired pursuant to the earlier tender offer.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Prior to December 1, 2013, AxoGen's corporate headquarters was a facility of 4,742 square feet located in Alachua, Florida. On November 12, 2013, AxoGen Corporation, a wholly owned subsidiary of AxoGen, entered into the Third Amendment to Lease with SNH Medical Office Properties Trust ("SNH"). SNH was the landlord of AxoGen's corporate headquarters leased facility in Alachua, Florida and AxoGen and SNH agreed to the amendment by which AxoGen relocated and expanded its corporate headquarters to a new space owned by SNH within the same office park. The lease amendment provides for 11,761 square feet of office space until October 31, 2018, renewable thereafter by agreement of the parties, subject to AxoGen's right to earlier termination after three years from the effective date of the lease. AxoGen's annual cost of such property ranges from approximately $200,000 to $212,000 per year. AxoGen moved into the new headquarters in December 2013.

AxoGen also leases 2,224 square feet of laboratory and distribution space in University of Florida's Sid Martin Biotechnology Incubator in Alachua, Florida on a month to month basis.

On October 25, 2013, AxoGen entered into a Commercial Lease with Ja-Cole. Under the terms of the Commercial Lease AxoGen leased 5,400 square feet of warehouse/office space in Burleson, Texas until November 30, 2016, renewable thereafter by agreement of the parties, at an annual cost of $43,200 per year. The Burleson facility will house raw material storage, a function that is currently provided by a third party vendor, and product distribution, allowing AxoGen to fulfill same day orders for both east and west coasts of the United States.

In Addition, AxoGen leases space and maintains records at certain facilities, which includes the Company's prior corporate headquarters at 1407 South Kings Highway, Texarkana, Texas 75501.

The Company's aggregate cost of such properties is approximately $197,000 per year. AxoGen believes that these facilities are sufficient to operate its business for the next 12 months and that lease obligations will not change materially.

ITEM 3. LEGAL PROCEEDINGS

AxoGen does not have any active or pending material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Prior to August 16, 2013, the Company's common stock was traded on the OTCQB Marketplace, operated by OTC Markets Group, under the symbol "AXGN." Since August 16, 2013, the Company's common stock has been traded on the NASDAQ Capital Market under the symbol "AXGN." On March 4, 2014, the last reported closing sale price of the Company common stock on the NASDAQ Capital Market was $3.99 per share.

The following table sets forth, for each of the calendar periods indicated, the range of the following:

(i) Prior to August 16, 2013, the high and low closing bid prices for the Company's common stock quoted on the OTCQB Marketplace. The prices in the table represent prices between dealers and do not include adjustments for retail mark-up, markdown or commission and may not represent actual transactions; and

(ii) Since August 16, 2013, the high and low closing sales price of the Company's common stock on the NASDAQ Capital Market.

	Year Ended December 31, 2013		Year Ended December 31, 2012	
	High	Low	High	Low
First Quarter	$ 4.25	$ 2.75	$ 3.49	$ 2.60
Second Quarter	$ 5.08	$ 3.66	$ 3.99	$ 2.51
Third Quarter	$ 4.53	$ 2.97	$ 3.25	$ 2.50
Fourth Quarter	$ 4.54	$ 3.35	$ 3.10	$ 2.25

Dividend Policy

AxoGen currently intends to retain earnings, if any, to finance the growth and development of its business, and does not expect to pay any cash dividends to its shareholders in the foreseeable future. In addition, the PDL Royalty Contract places certain restrictions on AxoGen's ability to pay dividends.

Shareholders

As of March 4, 2014, the Company had 17,373,620 shares of common stock outstanding, and approximately 313 common shareholders of record, based upon information received from our stock transfer agent. However, this number does not include beneficial owners whose shares were held of record by nominees or broker dealers. The Company estimates that there are approximately less than 1,000 individual owners.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our securities during the year of 2013.

Recent Sales of Unregistered Securities

We had no sales of unregistered securities during 2013 that have not been previously disclosed in a Current Report on Form 8-K or Quarterly Reports on Form 10-Q.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following information should be read in conjunction with "Selected Financial Data" contained in Item 6 of this Report, our consolidated financial statements and the notes thereto contained in Item 8 of this Report, the "Cautionary Notice Regarding Forward-Looking Statements" contained in Part 1 of this Report, "Risk Factors" contained in Item 1A of this Report, and the other information appearing elsewhere in, or incorporated by reference into, in this Report.

Overview

AxoGen is a leading medical technology company dedicated to advancing the science and commercialization of peripheral nerve repair solutions. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body and their damage can result in the loss of function and feeling. In order to improve surgical repair and regeneration of peripheral nerves, AxoGen has developed and licensed patented and patent pending regenerative medicine technologies. AxoGen's innovative approach to regenerative medicine has resulted in first-in-class products that will define their product categories. AxoGen's products offer a full suite of surgical nerve repair solutions including Avance® Nerve Graft, the only 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 coaptation sites while preventing soft tissue attachments.

Revenue from the distribution of these products is the main contributor to AxoGen's total reported sales and has been the key component of its growth to date. AxoGen revenues increased in 2013 compared to 2012 primarily as a result of sales to new accounts and increased product usage by existing accounts. AxoGen has continued to broaden its sales and marketing focus which is expected to have a positive contribution to its revenue growth in the long term. In the near term revenue growth lags behind the expense increases for market development such as hiring and training of new sales representatives and surgeon education programs.

Results of Operations

Critical Accounting Policies and Estimates

The discussion and analysis of the Company's financial condition and results of operations is based upon the Company's consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and reported amount of expenses during the period reported. Management bases its estimates and judgments on historical experience, observance of trends in the industry, information provided by outside sources and on various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

We have identified the following policies as critical to our business operations and the understanding of our consolidated results of operations:

Accounts Receivable and Concentration of Credit Risk — Doubtful Accounts

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The carrying amount of accounts receivable is reduced by an allowance for doubtful accounts which reflects management's best estimate of the amounts that are uncollectable. In establishing the required allowance, management considers customers' financial condition, credit history and current economic conditions. In 2013, we established a reserve for doubtful accounts as we did have some accounts deemed uncollectible. Such accounts, however, have been immaterial both in number and dollar amount. Account balances are charged off after all means of collection have been exhausted and the potential for recovery is considered remote. Our internal financial operations have primary responsibility for billing and collecting our accounts receivable. We utilize various processes and procedures in our collection efforts; these efforts include monthly statements, written collection notices and telephonic follow-ups. In the event the current conditions as to doubtful accounts negatively changes, management will consider increasing the reserve for doubtful accounts. Management judgment as to identifying negative trends is important in its assumption of exposure to uncollectable receivables requiring a reserve and if revenues expand as expected accounts receivable will rise potentially causing management to reevaluate its underlying assumptions.

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Goodwill

Goodwill represents the excess of the purchase price over the net tangible and intangible assets acquired in business combinations. The Company is required to perform a review for impairment of goodwill in accordance with FASB ASC 350, Intangibles — Goodwill and Other. Goodwill is considered to be impaired if it is determined that the carrying value of goodwill exceeds its fair value. The Company conducted an impairment test during the year ended December 31, 2012 and determined the goodwill was impaired. The full amount of goodwill was written off in 2012.

Effective Interest Rate on Note Payable

The PDL Royalty Contract is accounted for as long-term debt. AxoGen records interest using its best estimate of the effective interest rate. This estimate takes into account both the internal rate of return (IRR) of the PDL agreement and the rate of return as the result of exercise of the Put option. The IRR of the PDL Royalty Contract is based on the actual payments to date, projected future revenues and required minimum payments, and is calculated at 20.535%. The PDL Royalty Contract Put option provides PDL a 20% return, if exercised. As a result of the return of the Put option being higher than the IRR of the PDL agreement, management believes the best estimate of the effective interest rate on this instrument would be the Put rate. As a result, AxoGen is accruing interest using the specified internal rate of return for the Put which is 20%. We currently have no knowledge of PDL's intent to exercise the Put, but will monitor this on an ongoing basis. From time to time, AxoGen will reevaluate the expected cash flows and may adjust the effective interest rate. Determining the effective interest rate requires judgment and is based on significant assumptions related to estimates of the amounts and timing of future revenue streams and PDL's ultimate decision to exercise the Put. Determination of these assumptions is highly subjective and different assumptions could lead to materially different outcomes.

Income Taxes

Deferred income taxes reflect the impact of temporary differences between the reported amounts of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws and regulations. The deferred tax assets and liabilities represent the future tax return consequences of those differences, which will either be taxable or deductible when the assets and liabilities are recovered or settled. A valuation allowance is provided for deferred tax assets when management concludes it is more-likely-than-not that some portion of the deferred tax assets will not be recognized. We have a full valuation allowance established on the deferred tax asset upon management's best estimate of final outcomes based upon estimated future revenue and changes in business capitalization. Factors used to establish the valuation allowance are complicated and could cause variability in application over time.

Comparison of the Years Ended December 31, 2013 and 2012

Revenues

Revenues for the year ended December 31, 2013 increased 42.3% to approximately $10,947,000 as compared to approximately $7,692,000 for the year ended December 31, 2012. This increase was primarily a result of sales to new accounts, increased product usage by existing accounts and grant revenue received of approximately $67,000. Each new customer in a defined period has the potential to become an established customer with repeat orders and increased account penetration. As such, revenue growth occurs from both new customers who purchase for the first time in a period and increased purchasing from established customers. Each new period of measurement is thus benefited from the additional new customers added in the prior period and growth, if any, realized from established customers.

Gross Profit

Gross profit for the year ended December 31, 2013 increased 48.5% to approximately $8,508,000 as compared to approximately $5,730,000 for the year ended December 31, 2012. This increase is primarily attributable to the increased revenues in 2013, manufacturing efficiencies and a product price increase instituted in March 2013. As a result, gross margin also improved to 77.7% in 2013 as compared to 74.5% for 2012. Product sales mix has an effect on gross profit changes between periods.

Costs and Expenses

Total cost and expenses increased 33.8% to approximately $18,100,000 for the year ended December 31, 2013 as compared to approximately $13,532,000 for the year ended December 31, 2012. These increases were primarily due to increasing sales and marketing activities, which includes salaries and increased commissions as a result of increased sales, increases in research and development in preparation for AxoGen's Investigational New Drug (IND) Application with the FDA and the subsequent start of its phase 3 trial, expenses associated with being a public company and increases in salaries as AxoGen hires to meet growth needs, offset by a non-recurring expense incurred in the third quarter of 2012 related to a license agreement and reduced depreciation and amortization expenses. As a percentage of revenues, total operating expenses were 165.3% for the year ended December 31, 2013 compared to 175.9% for the year ended December 31, 2012. Such lower total costs and expenses as a percentage of revenue were primarily a result of AxoGen's revenue increase outpacing costs and expenses increase.

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Sales and marketing expenses increased 49.0% to approximately $10,259,000 for the year ended December 31, 2013 as compared to approximately $6,884,000 for the year ended December 31, 2012. This increase was primarily due to increased commissions attributable to higher sales and the expansion of AxoGen's direct sales force and marketing efforts. Increased marketing efforts included expansion of surgeon education, including training events and materials, public relations and additional materials, and increased resources for the expanding sales force and independent distributors. As a percentage of revenues, sales and marketing expenses were 93.7% for the year ended December 31, 2013 compared to 89.5% for the year ended December 31, 2012. Such higher sales and marketing expenses as a percentage of revenue were a result of the costs and expenses increase outpacing the revenue increase, primarily due to the fact that the direct sales force personnel require time to become effective in their territory and provide a positive financial contribution.

General and administrative expenses increased 9.5% to approximately $5,715,000 for the year ended December 31, 2013 as compared to approximately $5,221,000 for the year ended December 31, 2012. As a percentage of revenues, general and administrative expenses were 52.2% for the year ended December 31, 2013 compared to 67.9% the year ended December 31, 2012. The increase in aggregate dollars spent were a result of hiring and costs related to being a public company, offset by a savings in finance costs, a non-recurring expense incurred in the third quarter of 2012 related to a license agreement and reduced depreciation and amortization expenses. As a percentage of revenue, general and administrative expenses decreased as a result of AxoGen being able to limit increases in such expenses while sales continue to increase.

Research and development expenses increased 48.9% to approximately $2,125,000 in the year ended December 31, 2013 as compared to approximately $1,427,000 for the year ended December 31, 2012. Because AxoGen's products are developed for sale in their current use, it conducts limited direct research and product development, but intends to pursue new products and new applications for existing products in the future that may result in increased spending. Research and development includes AxoGen's clinical efforts and substantially all of the increase in research and development expenses from 2012 to 2013 related to expenditures for such clinical activity, including increase in personnel and associated expenses.

Other Income and Expenses

Interest expense increased 246.4% to approximately $4,820,000 in 2013 as compared to approximately $1,391,000 for the year ended

December 31, 2012. This increase was primarily due to the interest accrued related to PDL for the full year in 2013. As a result of the accounting treatment for the PDL transaction, interest expense for 2013 included approximately $3,783,000 of non-cash expense that is expected to be paid in the future based upon the terms of the PDL transaction and increases in AxoGen revenues. The $3,783,000 of non-cash expense was derived from taking the total amount of imputed interest for 2013 on the PDL agreement less the actual cash payment made to PDL for the year. Other than the $3,783,000 non-cash expense, the remaining $1,030,000 in interest expense for 2013 is related to cash paid for interest on the note payable.

Interest expense— deferred financing costs decreased 81.9% to approximately $179,000 for 2013 as compared to approximately $987,000 in 2012. This decrease is primarily due to lower deferred financing cost amortization associated with the PDL agreement when compared to the previous bank debt.

Income Taxes

AxoGen had no income tax expenses or income tax benefit for 2013 due to incurrence of net operating loss for the year. However, AxoGen did have an income tax benefit of approximately $738,000 for 2012 which was the result of AxoGen's ability to utilize net operating losses and franchise tax adjustments which resulted in tax refunds. The entire amount of the tax refund was received in 2012. AxoGen does not believe there are any additional tax refund opportunities currently available.

Effect of Inflation

Inflation has not had a significant impact on AxoGen's operations or cash flows.

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Liquidity and Capital Resources

Long-Term Debt / Note Payable

On October 5, 2012, AxoGen entered into the Royalty Contract with PDL. Proceeds from the PDL transaction were used to fully repay the MidCap Loan, as defined below, and extinguish AxoGen's long-term debt obligations thereunder. The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments currently paid weekly based on a 9.95% royalty rate of certain of AxoGen's Net Revenues (the "Assigned Interests"), subject to certain guaranteed quarterly payment amounts of approximately $1.3 to $2.5 million per quarter that commence in the quarter ending December 31, 2014. The minimum annual payment amounts are as follows: 2014 - $1,250,805, 2015 - $6,781,440, 2016 - $9,232,642, 2017 and 2018 - $9,000,000, 2019 - $9,063,000 and 2020 - $6,939,000. The royalty payment is based on only that portion of Company Net Revenue that is generated by the sale, distribution or other use of AxoGen's products Avance® Nerve Graft, AxoGuard® Nerve Protector and AxoGuard® Nerve Connector (the "Acquired Revenues"), which at this time represents all of AxoGen's Net Revenue with the exception of shipping and handling fees which represent less than 2.3% of total revenues. Future revenue, if any, from other products or services will not be subject to the PDL royalty payment. Further, on October 5, 2016, or in the event of the occurrence of a material adverse event, AxoGen's transfer of revenue interest or substantially all of its interest in the products or bankruptcy or material breach of the Royalty Contract, PDL may require AxoGen to repurchase the Assigned Interests at the Put Price. The Put Price is equal to the sum of (i) an amount that, when paid to PDL, would generate a 20% internal rate of return to PDL on the Funded Amount, taking into consideration payments made to PDL by AxoGen, and (ii) any Delinquent Assigned Interests Payment AxoGen owed to PDL. Although we have no knowledge of PDL's intent to exercise the Put, based on actual payments to date, projected future revenues and the required minimum payments, we currently believe the Put Rate is the best estimate of the effective interest rate of the Royalty Contract. Finally, in the event of a Change of Control, AxoGen must repurchase the Assigned Interests from PDL for a repurchase price equal to the Change of Control Price on or prior to the third business day after the occurrence of the Change of Control. The Change of Control Price is the sum of (i) an amount that, when paid to PDL, would generate an internal rate of return to PDL of thirty-two and one half percent (32.5%) on all payments made by PDL pursuant to the Royalty Contract as of the date of the Change of Control Payment, taking into account the amount and timing of all payments made by AxoGen to PDL (and retained by PDL) prior to and as of the date of payment of the Change of Control Payment, plus (ii) any Delinquent Assigned Interests Payment owed. The total consideration PDL paid to AxoGen was $20,800,000 (the "Funded Amount"), including $19,050,000 PDL paid to AxoGen on October 5, 2012, and $1,750,000 PDL paid to AxoGen on August 14, 2012 pursuant to the Interim Royalty Contract. Upon the closing of PDL's purchase of the specified royalties described above, which was concurrent with the execution of the Royalty Contract, the Interim Royalty Contract was terminated. There are no financial covenants or other restrictions on the use of capital by AxoGen as a result of the Royalty Contract, however, PDL has a first perfected security interest in the Assigned Interests.

Under the Royalty Contract, AxoGen sold to PDL the Acquired Revenues and PDL is to receive for eight years the Assigned Interests, i.e., a royalty payment based on a 9.95% royalty rate of AxoGen's Net Revenues, subject to certain agreed upon minimum payments of approximately $1.3 to $2.5 million per quarter starting in October 2014, was provided the Put and receives certain payments in the event of a Change of Control. The total consideration PDL paid to AxoGen was $20,800,000, including $19,050,000 PDL paid to AxoGen on October 5, 2012, and $1,750,000 PDL paid to AxoGen on August 14, 2012, pursuant to the Interim Royalty Contract. Upon the closing of PDL's purchase of the specified royalties under the Royalty contract, which was concurrent with its execution, the Interim Royalty Contract was terminated. Proceeds from the PDL Royalty Contract transaction where used to fully repay the MidCap Loan and extinguish AxoGen's obligations thereunder. There are no financial covenants or other restrictions on the use of capital by AxoGen as a result of the Royalty Contract. In the event that AxoGen is unable to generate revenue in excess of its PDL Assigned Interests payments and other expenses, or PDL were to exercise the Put at a time when AxoGen did not have sufficient capital to pay the Put Price, AxoGen would need to raise additional capital. There is no assurance that if AxoGen is required to secure funding it can do so on terms acceptable to it, or at all, and its liquidity would be severely compromised.

On September 30, 2011, AxoGen, entered into the Loan and Security Agreement with MidCap Financial SBIC, LP ("MidCap"), as administrative agent, and the Lenders listed on Schedule 1 thereto (the "MidCap Loan"). The MidCap Loan had a principal amount of $5.0 million and a term of 42 months, and was subject to prepayment penalties. Under this agreement, AxoGen was required to make interest only payments for the first 12 months, and payments of both interest and straight line amortization of principal for the remaining 30 months. The interest rate was 9.9% per annum, and interest was computed on the basis of a 360-day year and the actual number of days elapsed during which such interest accrues.

The MidCap Loan contained customary affirmative and negative covenants, including, without limitation, (i) covenants requiring AxoGen to comply with applicable laws, provide to MidCap copies of AxoGen's financial statements, maintain appropriate levels of insurance and protect, defend and maintain the validity and enforceability of AxoGen's material intellectual property, (ii) covenants restricting AxoGen's ability to dispose of all or any part of its assets (subject to certain

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exceptions), engage in other lines of business, changes in its senior management, enter into merger or consolidation transactions, incur or assume additional indebtedness, or incur liens on its assets, and (iii) covenants requiring AxoGen to meet certain minimum Net Invoiced Revenue, as defined in the agreement, or maintain a cash balance of 80% of the loan principal amount.

The MidCap Loan was secured by all of AxoGen's assets. The Lenders also received a ten-year warrant to purchase 89,686 shares of AxoGen's common shares at $2.23 per share. Proceeds from the PDL transaction were used to fully repay the MidCap Loan, along with a $172,581 prepayment penalty, and extinguish AxoGen's obligations thereunder.

The Company had no material commitments for capital expenditures at December 31, 2013 or 2012.

Cash Flow Information

AxoGen had working capital of approximately $23.56 million and a current ratio of 12.23 at December 31, 2013, compared to working capital of $16.82 million and a current ratio of 12.36 at December 31, 2012. The increase in working capital at December 31, 2013 as compared to December 31, 2012 was primarily due to AxoGen on August 14, 2013 completing an underwritten offering of 6,000,000 shares of its common stock at a price to the public of $3.00 per share. AxoGen granted the underwriters a 30-day option to purchase up to an aggregate of 900,000 additional shares of Company common stock at the public offering price, less the underwriting discount, to cover over-allotments, if any. On September 11, 2013, the underwriters exercised their option to purchase an additional 184,332 shares. AxoGen received net proceeds of approximately $16.7 million, after deducting approximately $1.8 million in underwriting discounts and commissions and offering expenses payable by AxoGen, and including the underwriters' over-allotment option. AxoGen believes it has sufficient cash resources to meet its liquidity requirements for the next 12 months.

AxoGen's future capital requirements depend on a number of factors, including, without limitation, revenue increases consistent with its business plan, and the corresponding royalty payments of approximately $1.3 to $2.5 million per quarter, starting in October 2014, due to PDL and pursuant to AxoGen's licensing agreements in connection with Avance® Nerve Graft, cost of products and acquisition and/or development of new products. In particular, if revenue does not increase by fourth quarter 2014 to a level whereby the 9.95% royalty owed to PDL on AxoGen's gross revenues exceeds the PDL minimum royalty payments at such time of approximately $1.3 million, and such differential continues, or grows larger as the PDL minimum royalty payments increase, AxoGen would face increasing capital needs. Such capital needs could be substantial depending on the extent to which AxoGen is unable to increase revenue.

If AxoGen needs additional capital in the future, it may raise additional funds through public or private equity offerings, debt financings or from other sources. The sale of additional equity may result in dilution to AxoGen's shareholders. There is no assurance that AxoGen will be able to secure funding on terms acceptable to it, or at all. The increasing need for capital as the PDL transaction matures could also make it more difficult to obtain funding through either equity or debt. Should additional capital not become available to AxoGen as needed, AxoGen may be required to take certain action, such as, slowing sales and marketing expansion, delaying regulatory approvals or reducing headcount. During the year ended December 31, 2013, AxoGen had a net increase in cash and cash equivalents of approximately $6,162,000 as compared to a net increase of cash and cash equivalents of approximately $5,717,000 in the year ended December 31, 2012. AxoGen's principal sources and uses of funds are explained below:

Net Cash used in operating activities

AxoGen used approximately $10,445,000 of cash for operating activities in 2013, as compared to using approximately $8,662,000 of cash for operating activities in 2012. This increase in cash used in operating activities is primarily attributed to the net loss generated in 2013, net of significant non-cash interest added to the note payable, an increase in the stock based compensation along with an increase in our accounts payable offset by increases in accounts receivable and inventory.

Net Cash used in investing activities

Investing activities for 2013 used approximately $244,000 of cash as compared to 2012 which used approximately $127,000. This increase in cash used is attributable to the purchase of property and equipment related to the new facility in Burleson, Texas.

Net Cash provided by financing activities

Financing activities in 2013 provided approximately $16,851,000 of cash as compared to approximately $14,506,000 of cash in 2012. This increase in cash provided is primarily attributed to approximately $16,778,000 of cash provided in 2013 as a result of the sale of

Common Stock compared to the issuance of $20,800,000 of additional debt, partially offset by the repayment of approximately $5,000,000 of debt (of which approximately $4.8 million is non-cash proceeds and payments) during 2012 and fees associated therewith.

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Off-Balance Sheet Arrangements

AxoGen does not have any off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and
Board of Directors of
AxoGen, Inc.

We have audited the accompanying consolidated balance sheets of AxoGen, Inc. and subsidiary as of December 31, 2013 and 2012, and the related consolidated statements of operations, shareholders' equity (deficit), and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of AxoGen, Inc. and subsidiary as of December 31, 2013 and 2012, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ LURIE BESIKOF LAPIDUS & COMPANY, LLP

Minneapolis, Minnesota
March 6, 2013

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AXOGEN, INC.
CONSOLIDATED BALANCE SHEETS
December 31, 2013 and 2012

	December 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 20,069,750	$ 13,907,401
Accounts receivable, net of allowance for doubtful accounts of approximately $58,000 and $0, respectively	1,893,699	1,050,089
Inventory	3,398,438	3,151,109
Prepaid expenses and other	296,719	187,256
Total current assets	25,658,606	18,295,855
Property and equipment, net	381,689	108,534
Intangible assets	570,396	573,731
Deferred financing costs	1,073,579	1,252,443
	$ 27,684,270	$ 20,230,563
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,083,942	1,479,752
Current Deferred Revenue	14,118	—
Total current liabilities	2,098,060	1,479,752
Long-term debt		
Note Payable — Revenue Interest Purchase Agreement	25,363,695	21,580,252
Long Term Deferred Revenue	85,882	—
Total liabilities	27,547,63	23,060,004
Shareholders' equity (deficit):		
Common stock, $.01 par value; 50,000,000 shares authorized; 17,339,561 and 11,122,573 shares issued and outstanding	173,395	111,226
Additional paid-in capital	72,369,016	54,908,226
Accumulated deficit	(72,405,778)	(57,848,893)
Total shareholders' equity (deficit)	136,633	(2,829,441)
	$ 27,684,270	$ 20,230,563

The accompanying notes are an integral part of these consolidated financial statements.

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AXOGEN, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
Years ended December 31, 2013 and 2012

	2013	2012
Revenues	$ 10,947,361	$ 7,691,704
Cost of goods sold	2,439,818	1,961,877
Gross profit	8,507,543	5,729,827
Costs and expenses:		
Sales and marketing	10,259,153	6,883,953
Research and development	2,125,476	1,427,211
General and administrative	5,715,119	5,220,599
Total costs and expenses	18,099,748	13,531,763
Loss from operations	(9,592,205)	(7,801,936)

Other income (expense):		
Interest expense	(4,819,708)	(1,391,342)
Interest expense — deferred financing costs	(178,864)	(986,844)
Other income	33,892	23,972
Total other income (expense)	(4,964,680)	(2,354,214)
Loss before income taxes	(14,556,885)	(10,156,150)
Income tax benefit	—	738,192
Net Loss	(14,556,885)	(9,417,958)
Weighted Average Common Shares outstanding — basic and diluted	13,499,793	11,089,425
Loss Per Common share — basic and diluted	$ (1.08)	$ (0.85)

The accompanying notes are an integral part of these consolidated financial statements.

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AXOGEN, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
Years ended December 31, 2013 and 2012

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity/(Deficit)
Balance, December 31, 2011	11,062,188	$ 110,622	$ 54,391,784	$ (48,430,935)	$ 6,071,471
Stock-based compensation	—	—	495,077	—	495,077
Exercise of stock options	58,340	583	15,069	—	15,652
Stock Grant for Services	7,500	75	21,300	—	21,375
Cancellation of shares	(5,455)	(54)	(14,946)	—	(14,999)
Merger Closing — Fractional shares	—	—	(58)	—	(58)
Net loss	—	—	—	(9,417,958)	(9,417,958)
Balance, December 31, 2012	11,122,573	$ 111,226	$ 54,908,226	$ (57,848,893)	$ (2,829,441)
Stock-based compensation	—	—	671,887	—	671,887
Exercise of stock options	32,656	326	73,000	—	73,326
Issuance of common shares	6,184,332	61,843	16,715,903	—	16,777,746
Net loss	—	—	—	(14,556,885)	(14,556,885)
Balance, December 31, 2013	17,339,561	173,395	72,369,016	(72,405,778)	136,633

The accompanying notes are an integral part of these consolidated financial statements.

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AXOGEN, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended December 31, 2013 and 2012

	2013	2012
Cash flows from operating activities:		
Net loss	$ (14,556,885)	$ (9,417,958)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	79,232	187,749
Amortization of intangible assets	59,100	127,080
Loss on impairment	9,424	299,654
Loss on abandonment of license	—	147,826
Amortization of deferred financing costs	178,864	352,667
Amortization of debt discount	—	161,529
Provision for bad debt	58,617	—
Stock-based compensation	671,887	495,077
Stock grant for service	—	21,375

Cancellation of shares	—	(14,999)
Interest added to note payable	3,783,443	780,252
Change in assets and liabilities:		
Accounts receivable	(902,227)	(252,435)
Inventory	(247,329)	(1,390,570)
Prepaid expenses and other	(109,463)	(53,757)
Accounts payable and accrued expenses	430,579	(105,348)
Deferred Revenue	100,000	—
Net cash used for operating activities	(10,444,758)	(8,661,858)
Cash flows from investing activities:		
Purchase of property and equipment	(178,776)	(48,459)
Acquisition of intangible assets	(65,189)	(78,825)
Net cash used for investing activities	(243,965)	(127,284)
Cash flows from financing activities:		
Proceeds from issuance of note payable	—	15,961,294
Proceeds from issuance of common stock	16,777,746	—
Repayments of long-term debt	—	(161,292)
Debt issuance costs	—	(1,309,834)
Proceeds from exercise of stock options	73,326	15,652
Merger	—	(58)
Net cash provided by financing activities	16,851,072	14,505,762
Net increase in cash and cash equivalents	6,162,349	5,716,620
Cash and cash equivalents, beginning of year	13,907,401	8,190,781
Cash and cash equivalents, end of period	$ 20,069,750	$ 13,907,401
Supplemental disclosures of cash flow activity:		
Cash paid for interest	$ 1,030,219	$ 649,108
Supplemental disclosure of non-cash investing and financing activities:		
Payments of fixed assets in accounts payable	$ 173,611	$ —
Payments of long term debt with proceeds from note payable	—	4,838,706

The accompanying notes are an integral part of these consolidated financial statements.

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AXOGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2013 and 2012

1. Basis of Presentation

The accompanying consolidated financial statements include the accounts of AxoGen, Inc. (the "Company" or "AxoGen") and its wholly owned subsidiary AxoGen Corporation ("AC") as of December 31, 2013 and December 31, 2012 and for the years then ended. The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. All significant intercompany accounts and transactions have been eliminated in consolidation.

2. Organization and Business

Business Summary

The Company is a leading medical technology company dedicated to advancing the science and commercialization of peripheral nerve repair solutions. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body and their damage can result in the loss of muscle function and/or feeling. In order to improve the options available for the surgical repair and regeneration of peripheral nerves, the Company has developed and licensed, patented and patent pending regenerative medicine technologies. The Company's innovative approach to regenerative medicine has resulted in first-in-class products that the Company believes will define their product categories. AxoGen's products offer a full suite of surgical nerve repair solutions including Avance® Nerve Graft, the only off-the-shelf commercially available processed nerve allograft human nerve tissue obtained from a donor for bridging severed nerves without the comorbidities of an autograft second surgical site, such resulting in a loss of feeling where the nerve was removed and potential pain at the donor site. The Company's AxoGuard® line of products are derived from pig tissue and are natural scaffolds of the body called ExtraCellular

Matrix, or ECM. AxoGuard® Nerve Connector is used to facilitate the tensionless repair of severed nerves, and AxoGuard® Nerve Protector is used to wrap and protect injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments.

3. **Summary of Significant Accounting Policies**

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. Revenues for manufactured products and products sold to a customer or under a distribution agreement are recognized when the product is delivered to the customer or distributor, at which time title passes to the customer or distributor, provided, however, that in the case of revenues from consigned sales delivery is determined when the product is utilized in a surgical procedure. Once a product is delivered, the Company has no further performance obligations. Delivery is defined as delivery to a customer location or segregation of product into a contracted distribution location. At such time, this product cannot be sold to any other customer. Fees charged to customers for shipping are recognized as revenues when products are shipped to the customer, distributor or end user.

Cash and Cash Equivalents and Concentration

For purposes of the statement of cash flows, the Company considers all highly liquid debt instruments purchased with a maturity of three months or less to be cash equivalents. Cash and cash equivalents are maintained at financial institutions and, at times, balances may exceed federally insured limits. The

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Company has never experienced any losses related to these balances and does not believe it is exposed to any significant credit risk on cash and cash equivalents.

Accounts Receivable and Concentration of Credit Risk

Accounts receivable are carried at the original invoice amount less an estimate made for doubtful accounts based on a review of all outstanding amounts on a monthly basis. Management determines the allowance for doubtful accounts by regularly evaluating individual customer receivables and considering a customer's financial condition, credit history and current economic conditions. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

In 2013, we established a reserve for doubtful accounts as we did have some accounts deemed uncollectible. We regularly review all accounts that exceed 60 days from the invoice date and based on an assessment of current credit worthiness, estimate the portion, if any, of the balance that will not be collected. The analysis excludes certain government related receivables due to our past successful experience in collectability. Specific accounts that are deemed uncollectible are reserved at 100% of their outstanding balance. The remaining balances outstanding over 60 days have a percentage applied by aging category (5% for balances 61-90 days and 20% for balances over 90 days aged), based on a historical valuation that allows us to calculate the total reserve required. The reserve balance was determined by applying a percentage to the cumulative balance between 60 and 90 days and a higher percentage to the balance over 90 days. In the event that we exhaust all collection efforts and deem an account uncollectible, we would subsequently write off the account. The write off process involves approval by senior management based on the write off amount. The allowance for doubtful accounts reserve balance was $58,617 and $0 at December 31, 2013 and 2012, respectively.

Concentrations of credit risk with respect to accounts receivable are limited because a large number of geographically diverse customers make up the Company's customer base, thus spreading the trade credit risk. The Company also controls credit risk through credit approvals, credit limits and monitoring procedures.

Inventories

Inventories are comprised of implantable tissue, nerve grafts, Avance® Nerve Graft, AxoGuard® Nerve Connector, AxoGuard® Nerve Protector, and supplies and are valued at the lower of cost (first-in, first-out) or market and consist of the following:

	December 31, 2013	December 31, 2012
Finished goods	$ 2,131,336	$ 2,143,176
Work in process	235,966	145,156
Raw materials	1,031,136	862,777
	$ 3,398,438	$ 3,151,109

Inventories are net of reserve of $382,545 and $537,798 at December 31, 2013 and 2012, respectively.

Property and Equipment

Depreciation and amortization is computed using the straight-line method over the estimated useful lives of the assets as follows:

Furniture and equipment	2-5 years
Leasehold improvements	5 years (or lease term if less)
Processing equipment	5-7 years

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Major additions and improvements are capitalized, while replacements, maintenance and repairs, which do not improve or extend the life of the respective assets, are expensed as incurred. When assets are retired or otherwise disposed of, related costs and accumulated depreciation and amortization are removed and any gain or loss is reported as other income or expense.

Intangible Assets

Intangible assets consist primarily of license agreements for exclusive rights to use various patented and patent-pending technologies described in Note 5 and other costs related to the license agreements, including patent prosecution and protection costs. Such costs are capitalized and amortized on a straight-line basis over the underlying terms of the license agreements or estimated useful life of patents, ranging from 5 to 20 years.

Impairment of Long-lived Assets, Including License Agreements

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. For the years ended December 31, 2013 and 2012, the Company recorded an impairment loss of $9,424 and $129,667, respectively.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of net assets acquired. Goodwill is not amortized, but is tested for impairment annually. The Company utilizes the income approach in estimating fair value. The Company's 2012 annual goodwill impairment analysis indicated a significant decrease in the carrying value of goodwill, due to declines in the associated revenues, resulting in a full $169,887 impairment loss being recorded for the year ended December 31, 2012.

Deferred Financing Costs

The Company capitalizes all third-party costs incurred, including equity-based payments, associated with the issuance of long-term debt. The costs are amortized to interest expense over the term of the debt using the effective interest method.

Advertising

Advertising costs are expensed as incurred. Advertising costs were $37,000 and $56,000 for the years ended December 31, 2013 and 2012, respectively, and are included in sales and marketing expense on the accompanying consolidated statements of operations.

Research and Development Costs

Research and Development costs are expensed as incurred and were approximately $2,125,000 and $1,427,000 for the years ended December 31, 2013 and 2012, respectively.

Income Taxes

The Company has not recorded current income tax expense due to the generation of net operating losses. Deferred income taxes are accounted for using the balance sheet approach which requires recognition of deferred tax assets and liabilities for the expected future consequences of temporary differences between the financial reporting basis and the tax basis of assets and liabilities. A valuation allowance is provided when it is more likely than not that a deferred tax asset will not be realized. A full valuation allowance has been established on the deferred tax asset as it is more likely than not that future tax benefit will not be realized. In addition, future utilization of the available net operating loss carryforward may be limited under Internal Revenue Code Section 382 as a result of changes in ownership.

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The Company identifies and evaluates uncertain tax positions, if any, and recognizes the impact of uncertain tax positions for which there is a less than more-likely-than-not probability of the position being upheld when reviewed by the relevant taxing authority. Such positions are deemed to be unrecognized tax benefits and a corresponding liability is established on the balance sheet. The Company has not recognized a liability for uncertain tax positions. If there were an unrecognized tax benefit, the Company would recognize interest accrued related to unrecognized tax benefits in interest expense and penalties in operating expenses. The Company's remaining open tax years subject to examination by the Internal Revenue Service include the years ended December 31, 2009 through 2013; there currently are no examinations in process.

Fair Value of Financial Instruments

The respective carrying value of certain on-balance-sheet financial instruments approximated their fair values due to the short-term nature of these instruments. These financial instruments include cash, accounts receivable, accounts payable and accrued expenses. The fair value of the Company's long-term debt approximates its carrying value based upon current rates available to the Company.

Stock-Based Compensation

Stock-based compensation cost related to stock options granted under the AC 2002 Stock Option Plan and AxoGen 2010 Stock Incentive Plan (see Note 10) is measured at grant date, based on the fair value of the award, and is recognized as an expense over the employee's requisite service period. The Company estimates the fair value of each option award issued under the Plan on the date of grant using a Black-Scholes-Merton option-pricing model that uses the assumptions noted in the table below. The Company estimates the volatility of its common stock at the date of grant based on the volatility of comparable peer companies which are publicly traded, for the periods prior to the merger, and based on the Company's common stock for periods subsequent to the merger. The Company determines the expected life based on historical experience with similar awards, giving consideration to the contractual terms, vesting schedules and post-vesting forfeitures. The Company uses the risk-free interest rate on the implied yield currently available on U.S. Treasury issues with an equivalent remaining term approximately equal to the expected life of the award. The Company has never paid any cash dividends on its common stock and does not anticipate paying any cash dividends in the foreseeable future. The Company used the following weighted-average assumptions for options granted during the year ended December 31:

Years ended December 31,	2013	2012
Expected term (in years)	4.0	4.0
Expected volatility	83.15%	117.2%
Risk free rate	0.79%	0.61%
Expected dividends	0.0%	0.0%

The Company estimates forfeitures when recognizing compensation expense and this estimate of forfeitures is adjusted over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative catch-up adjustment, which is recognized in the period of change, and also impact the amount of unamortized compensation expense to be recognized in future periods. The Company did not apply a forfeiture allocation to its unvested options outstanding during the years ended December 31, 2013 and 2012 as they were deemed insignificant.

Earnings (Loss) Per Common Share

Earnings (loss) per common share (EPS) is calculated for basic EPS by dividing net income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period.

There were no dilutive instruments as of December 31, 2013 and 2012. The basic and diluted weighted average shares outstanding were 13,499,793 and 11,089,425 for the years ended December 31, 2013 and 2012.

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Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Recent Accounting Pronouncements

The Company's management has reviewed and considered all recent accounting pronouncements and believe there are none that could potentially have a material impact on the Company's consolidated financial condition, results of operations, or disclosures.

4. Property and Equipment

Property and equipment consist of the following:

	December 31, 2013	December 31, 2012
Furniture and equipment	$ 893,973	$ 572,459
Leasehold improvements	53,864	42,564
Processing equipment	1,015,388	995,815
Less: accumulated depreciation and amortization	(1,581,536)	(1,502,304)
Property and equipment	$ 381,689	$ 108,534

5. Intangible Assets

The Company's intangible assets consist of the following:

	December 31, 2013	December 31, 2012
License agreements	$ 816,300	$ 772,230
Patents	62,553	63,429
Less: accumulated amortization	(308,457)	(261,928)
Intangible assets, net	$ 570,396	$ 573,731

License agreements are being amortized over periods ranging from 17-20 years. Patent costs were being amortized over three years. As of December 31, 2013, the patents were fully amortized, the remaining patents of $62,553 are pending patent costs and are not amortizable. Amortization expense for 2013 and 2012 was approximately $59,000 and $127,000, respectively. As of December 31, 2013, future amortization of license agreements is expected to be $48,000 for 2014, through 2018.

In 2013 and 2012, the Company performed an evaluation of certain patents and determined that the carrying value of such patents were not recoverable and exceeded their estimated fair value. As a result, the Company recorded in the year ended December 31, 2013 and 2012 an impairment loss of $9,424 and $129,667, respectively, to reduce these patents to their estimated fair value.

License Agreements

The Company has entered into license agreements (the "License Agreements") with the University of Florida Research Foundation ("UFRF") and University of Texas at Austin ("UTA") and Emory University

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("Emory"). Under the terms of the License Agreements, the Company acquired exclusive worldwide licenses for underlying technology used in repairing and regenerating nerves. The licensed technologies include the rights to issued patents and patents pending in the United States and international markets. The effective term of the License Agreements extends through the term of the related patents and the agreements may be terminated by the Company with 60 days prior written notice. Additionally, in the event of default, licensors may terminate an agreement if the Company fails to cure a breach after written notice. The License Agreements contain the key terms listed below:

- AxoGen pays royalty fees ranging from 1% to 3% under the License Agreements based on net sales of licensed products. One of the agreements also contains a minimum royalty of $12,500 per quarter, which may include a credit in future quarters in the same calendar year for the amount the minimum royalty exceeds the royalty fees. Also, when AxoGen pays royalties to more than one licensor for sales of the same product, a royalty stack cap applies, capping total royalties at 3.75%;

- Under one of the agreements, if AxoGen does not achieve certain regulatory milestones, which AxoGen has not achieved, AxoGen would have owed an annual license maintenance fee starting on August 31, 2012 of $120,000, escalating to $240,000 on August 31, 2013 and August 31, 2014. In 2012, AxoGen decided to abandon the license and as a result recorded a $147,826 loss on abandonment of license.

- If AxoGen sublicenses technologies covered by the License Agreements to third parties, AxoGen would pay a percentage of sublicense fees received from the third party to the licensor. Currently, AxoGen does not sublicense any technologies covered by License Agreements. The Company is not considered a sub-licensee under the License Agreements and does not owe any sub-licensee fees for its own use of the technologies;

- AxoGen reimburses the licensors for certain legal expenses incurred for patent prosecution and defense of the technologies covered by the License Agreements; and

- Currently, under one of the License Agreements, AxoGen would owe a $15,000 milestone fee upon receiving a Phase II Small Business Innovation Research or Phase II Small Business Technology Transfer grant involving the licensed technology. The Company has not received either grant and does not owe such a milestone fee. Other milestone fees are due if AxoGen develops certain pharmaceutical or medical device products under the License Agreements. No such products are currently under development.

Royalty fees were approximately $230,000 and $167,000 during 2013 and 2012 and are included in sales and marketing expense on the accompanying consolidated statements of operations.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses includes $203,380 and $137,329 for accrued payroll at December 31, 2013 and 2012, respectively, and $417,825 and $121,746 for accrued commissions at December 31, 2013 and 2012, respectively.

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7. Long-Term Debt / Note Payable

Long-term debt / note payable consists of the following:

	December 31, 2013	December 31, 2012
Revenue Interest Purchase Agreement with PDL BioPharma, Inc. ("PDL") for aggregate of $20,800,000 with amounts payable monthly at 9.95% of Net Revenues through September 2014; and the greater of (i) 9.95% of product revenue or (ii) specific quarterly amounts varying from approximately $1.3 million to $2.5 million per quarter through September 2020. The minimum annual payment amounts are as follows: 2014 - $1,250,805, 2015 - $6,781,440, 2016 - $9,232,642, 2017 and 2018 - $9,000,000, 2019 - $9,063,000 and 2020 - $6,939,000.	$ 25,363,695	$ 21,580,252
Long-term portion	$ 25,363,695	$ 21,580,252

Note Payable

On October 5, 2012, AxoGen entered into a Revenue Interests Purchase Agreement (the "Royalty Contract") with PDL BioPharma, Inc. ("PDL"), pursuant to which the Company sold to PDL the right to receive royalties equal to 9.95% of the Company's Net Revenues (as defined in the Royalty Contract) generated by the sale, distribution or other use of AxoGen's products Avance® Nerve Graft, AxoGuard® Nerve Connector and AxoGuard® Nerve Protector. Proceeds from the PDL transaction were used to fully repay the MidCap Loan, as defined below, and extinguish AxoGen's long-term debt obligations thereunder. The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments based on a royalty rate 9.95% of the Company's Net Revenues, subject to certain agreed upon minimum payment requirements, currently anticipated to be operative, of approximately $1.3 to $2.5 million per quarter which begin in the fourth quarter of 2014 through the third quarter of 2020 as provided in the Royalty Contract. The total consideration PDL paid to the Company was $20,800,000 (the "Funded Amount"), including $19,050,000 PDL paid to the Company on October 5, 2012, and $1,750,000 PDL paid to the Company on August 14, 2012 pursuant to an Interim Revenue Interest Purchase Agreement between the Company and PDL, dated August 14, 2012 (the "Interim Royalty Contract"). Upon the closing (the "Closing") of PDL's purchase of the specified royalties described above, which was concurrent with the execution of the Royalty Contract, the Interim Royalty Contract was terminated.

The Company records interest using its best estimate of the effective interest rate. Currently the Company is accruing interest using the specified internal rate of return of the put option of 20%. From time to time, the Company will reevaluate the expected cash flows and may adjust the effective interest rate. Determining the effective interest rate requires judgment and is based on significant assumptions related to estimates of the amounts and timing of future revenue streams.

Put Option

Under the Royalty Contract, on October 5, 2016, or in the event of the occurrence of a material adverse event, our transfer of revenue interest or substantially all of our interest in the products or AxoGen's bankruptcy or material breach of the Royalty Contract, PDL may require AxoGen to repurchase the Assigned Interests at the "Put Price." The Put Price is equal to the sum of (i) an amount that, when paid to PDL, would generate a specified internal rate of return to PDL of 20% on the Funded Amount, taking into consideration payments made to PDL by the Company, and (ii) any "Delinquent Assigned Interest Payment" (as defined in the Royalty Contract) the Company owed to PDL.

Change of Control; Call Option

In addition, in the event of a "Change of Control" (as defined in the Royalty Contract), the Company must repurchase the assigned Interests from PDL for a repurchase price equal to the "Change of Control

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Price" on or prior to the third business day after the occurrence of the Change of Control. The Change of Control Price is equal to the sum of (i) an amount that, when paid to PDL, would generate a specified internal rate of return to PDL of thirty-two and one half percent (32.5%) on the Funded Amount, taking into consideration payments made to PDL by the Company, and (ii) any "Delinquent Assigned Interest Payment" (as defined in the Royalty Contract) the Company owed to PDL. In addition, at any time after October 5, 2016, the Company, at its option, can call the Royalty Contract for a price equal to the Change of Control Price.

Board Designee

Under the Royalty Contract, during the term of the Royalty Contract, PDL is entitled to designate, and AxoGen shall appoint an individual designated by PDL, who shall serve on the Board of Directors of the Company (the "Board"). The PDL designee was elected at the Company's 2013 Annual Meeting of Shareholders. At each annual meeting thereafter during the term of the Royalty Contract, the Board shall nominate and recommend the PDL designee as a director nominee to serve on the Board until the next annual meeting and shall include such nomination in AxoGen's proxy statement for each annual meeting thereafter, provided that the election of the PDL designee is subject to shareholders' approval.

Should at any time there become a vacancy on the Board as a result of (i) the resignation, death or removal of the PDL designee or (ii) such PDL designee failing to obtain the requisite approval of the Company's shareholders at any annual or special meeting of the Company's shareholders and where no other individual is elected to such vacancy, PDL shall have the right to designate an individual to fill such vacancy, and AxoGen shall take such actions necessary to appoint, such individual to the Board.

Preemptive Rights

Under the Royalty Contract, PDL has preemptive rights with respect to certain new issuances of AxoGen's equity securities and securities convertible, exchangeable or exercisable into such equity securities.

Restriction on Dividends

Under the Royalty Contract, during the period from the October 5, 2012 to December 4, 2016 (or the payment of the Put Price in the event PDL exercises its put option on or prior to December 4, 2016), AxoGen shall not, nor shall it permit any subsidiary to, declare, pay or make any dividend or distribution on any shares of the common stock or preferred stock of such entity (other than dividends or distributions payable in its stock, or split-ups or reclassifications of its stock) or apply any of its funds, property or assets to the purchase, redemption or other retirement of any common or preferred stock, or of any options to purchase or acquire any such shares of common or preferred stock of any such entity (collectively, "Restricted Payments"), except that: (i) each subsidiary may make direct or indirect Restricted Payments to the Company; and (ii) the Company and each subsidiary may purchase, redeem or otherwise acquire Equity Interests issued by it solely with the proceeds received from the substantially concurrent issue of new shares of its common stock or other common Equity Interests. For purposes of the Royalty Contract, "Equity Interests" of any person means any and all shares, rights to purchase, options, warrants, general, limited or limited liability partnership interests, member interests, participation or other equivalents of or interest in (regardless of how designated) equity of such entity, whether voting or nonvoting, including common stock, preferred stock, convertible securities or any other "equity security" (as such term is defined in Rule 3a11-1under the Securities Exchange Act of 1934, as amended).

Guarantee and Collateral Agreement

In connection with the Royalty Contract, on October 5, 2012, AxoGen and AC, entered into a Guarantee and Collateral Agreement (the "Guarantee and Collateral Agreement") with PDL, pursuant to which (i) AC unconditionally and irrevocably guarantees to PDL the prompt and complete payment and performance by AxoGen when due of the "Secured Obligations," which include the Company's obligations under the Royalty Contract, and any other obligations that AxoGen may owe to PDL under the Royalty

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Contract and other transaction documents; and (ii) each of the Company and AC grants to PDL a security interest in certain collateral as specified in the Guarantee and Collateral Agreement for the prompt and complete payment and performance when due of the Secured Obligations.

Long-Term Debt

On September 30, 2011, the Company entered into the Loan and Security Agreement with MidCap Financial SBIC, LP ("MidCap"), as administrative agent, and the Lenders listed on Schedule 1 thereto (the "MidCap Loan"). The credit facility under the MidCap loan had a principal amount of $5.0 million and a term of 42 months, and is subject to prepayment penalties. Under the MidCap Loan, AxoGen was required to make interest only payments for the first 12 months, and payments of both interest and straight line amortization of principal for the remaining 30 months. The interest rate was 9.9% per annum, and interest was computed on the basis of a 360-day year and the actual number of days elapsed during which such interest accrues.

The agreement contained customary affirmative and negative covenants, including, without limitation, (i) covenants requiring AxoGen to comply with applicable laws, provide to MidCap copies of AxoGen's financial statements, maintain appropriate levels of insurance, protect, defend and maintain the validity and enforceability of AxoGen's material intellectual property, (ii) covenants restricting AxoGen's ability to dispose of all or any part of its assets (subject to certain exceptions), engage in other lines of business, change its senior management, enter into merger or consolidation transactions, incur or assume additional indebtedness, or incur liens on its assets, and (iii) covenants requiring the Company to meet certain minimum Net Invoiced Revenue as defined in the agreement, or maintain a cash balance of 80% of the loan principal amount.

The MidCap Loan was secured by all of AxoGen's assets. The lenders also received a ten-year warrant to purchase 89,686 shares of AxoGen's common stock at $2.23 per share. The fair value of the warrant was $173,736 and was recorded as debt discount and was being amortized through interest expense using the effective interest method over the term of the debt. Amortization of debt discount was $12,207 for 2011. The Company also recorded $317,990 in deferred financing costs which were being amortized over the term of the loan. Amortization of the deferred financing cost was $22,714 for 2011.

8. Stockholders' Equity (Deficit) and Temporary Equity

AxoGen, Inc. Classes of Stock

AxoGen, Inc.'s authorized capital stock consists of 50,000,000 shares, par value $0.01 per share. The authorized capital stock is divisible into the classes and series, has the designation, voting rights, and other rights and preferences and is subject to the restrictions that the AxoGen Board of Directors may from time to time establish. Unless otherwise designated by the AxoGen Board of Directors, all shares are common stock. AxoGen has not designated any shares other than common stock.

9. Stock Options

AC has a 2002 Stock Option Plan ("the AC Plan"), which allows for issuance of incentive stock options and non-qualified stock options to employees, directors and consultants at an exercise price equal to or greater than fair market value. Under the provisions of the AC Plan, AC authorized for issuance 18,144,658 shares for purchase pursuant to options.

AxoGen, Inc. has a AxoGen 2010 Stock Incentive Plan (the "AxoGen Plan"), which allows for issuance of incentive stock options and non-qualified stock options to employees, directors and consultants at an exercise price equal to or greater than fair market value. On September 27, 2011, LecTec amended and restated the AxoGen Plan to, among other things, increase the number of shares of common stock authorized for issuance under the plan by 2,300,000 shares. The total number of shares authorized for issuance under the AxoGen Plan is 2,750,000 shares. As a result of the Merger, options granted under the AC Plan were assumed by the Company so that each stock option pursuant to the AC Plan so assumed continued to have, and be subject to, the same terms and conditions of such stock option immediately prior to the Merger, except that (i) each AC Plan stock option is exercisable for that number of shares of

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Company common stock equal to the product of the number of shares of AC common stock that were issuable upon exercise of such stock option immediately prior to the Merger multiplied by the Closing Ratio ("as defined in the Merger Agreement") and (ii) the per share exercise price for the shares of Company common stock issuable upon the exercise of such assumed stock option will be equal to the quotient determined by dividing the exercise price per share of AC common stock at which such stock option was exercisable immediately prior to the Merger by the Closing Ratio. The options to employees typically vest 12.5% every six months over a four-year period and those to directors and certain executive officers have vested 25% per quarter over one year or had no vesting period. Options issued to consultants vest over the service period ranging from three to ten years. Options have terms ranging from seven to ten years.

Stock-based compensation expense was $671,887 and $495,077 for 2013 and 2012, respectively.

The following is a summary of stock option activity:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term(Years)
Outstanding at December 31, 2011:	1,945,688	2.41	7.35
Granted	267,576	2.99	
Forfeited	(354,932)	(2.48)	
Exercised	(58,341)	(0.27)	
Outstanding at December 31, 2012:	1,799,991	2.54	7.66
Granted	261,000	3.72	
Forfeited	(58,843)	(3.48)	
Exercised	(32,656)	(2.25)	
Outstanding at December 31, 2013	1,969,492	2.68	6.61
Exercisable at December 31, 2013	1,294,290	2.57	6.37

The average fair value of options granted at market during 2013 and 2012 was $3.72 and $2.99 per option, respectively.

The intrinsic value of options exercised during the years ended December 31, 2013 and 2012 was approximately $48,000 and $173,000, respectively. The intrinsic value of options outstanding at December 31, 2013 and 2012 was approximately $3,571,000 and $288,000, respectively. The intrinsic value of options exercisable at December 31, 2013 and 2012 was approximately $2,487,000 and $0, respectively.

Total future compensation expense related to nonvested awards is expected to be approximately $1,233,000 at December 31, 2013 which is expected to be recognized over a weighted average period of 2.06 years. The following table represents non-vested share-based payment activity with employees for the year ended December 31, 2013 and 2012:

	Number of Options	Weighted Average Grant Date Fair Value
Nonvested options - December 31, 2011:	1,263,205	1.41
Granted	267,576	2.99
Vested	(317,734)	(1.92)
Forfeited	(354,932)	(2.48)
Nonvested options - December 31, 2012:	858,115	2.36

Granted	261,000	3.72
Vested	(385,076)	(2.22)
Forfeited	(58,843)	(3.48)
Nonvested options - December 31, 2013	675,196	2.88

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10. Income Taxes

The Company has temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and their respective income tax basis, as measured by enacted state and federal rates as follows:

December 31	2013	2012
	$	$
Deferred tax assets:		
Net operating loss carryforwards	23,075,700	18,182,000
Charitable contributions	500	2,800
Inventory Reserves	144,000	365,600
Stock-based compensation	101,500	52,300
Total deferred tax assets	23,321,700	18,602,700
Deferred tax liabilities:		
Depreciation	(84,100)	(154,900)
Amortization	121,000	(51,700)
Total deferred tax assets (liabilities)	36,900	(206,600)
Net deferred tax assets	23,358,600	18,396,100
Valuation allowance	(23,358,600)	(18,396,100)

As of December 31, 2013, the Company had net operating loss carry forwards of approximately $62 million to offset future taxable income which expire in various years through 2033. A valuation allowance is recorded to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that a portion or none of the deferred tax assets will be realized. After consideration of all the evidence, including reversal of deferred tax liabilities, future taxable income and other factors, management has determined that a full valuation allowance is necessary as of December 31, 2013 and 2012. The valuation allowance increased by $4,962,500 and $3,015,100 during 2013 and 2012, respectively.

The net income tax benefit of approximately $738,000 for 2012 was the result of the Company's ability to utilize net operating losses and franchise tax adjustments which resulted in tax refunds. The Company had no income tax expense or income tax benefit for 2013 due to incurrence of net operating losses. The Company does not believe there are any additional tax refund opportunities currently available.

11. Employee Benefit Plan

The Company adopted the AxoGen Simple IRA plan in 2007. All full-time employees who have attained the age of 18 are eligible to participate in the Plan. Eligibility is immediate upon employment and enrollment is available any time during employment. Participating employees may make annual pretax contributions to their accounts up to a maximum amount as limited by law. The simple IRA plan requires the Company to make matching contributions of between 1% and 3% of the employee's annual salary as long as the employee participates in the Plan. Additionally, the matching has to be at least 3% for three of the first five years of the Plan. Both employee contributions and Company contributions vest immediately. In 2013 and 2012, the Company match was 3% of the participating employee's annual salary. The Company contributed $126,322 and $102,189 in matching funds during 2013 and 2012, respectively.

12. Commitments and Contingencies

Operating Leases

On November 12, 2013, AxoGen entered into the Third Amendment to Lease with SNH Medical Office Properties Trust ("SNH"). SNH was the landlord of AxoGen's corporate headquarters leased facility in Alachua, Florida and AxoGen and SNH agreed to the amendment by which AxoGen relocated and expanded its corporate headquarters to a new space owned by

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SNH within the same office park. The lease amendment provides for 11,761 square feet of office space until October 31, 2018, renewable thereafter by agreement of the parties, subject to AxoGen's right to earlier termination after three years from the effective date of the lease. AxoGen's annual cost of such property ranges from approximately $200,000 to $212,000 per year.

In addition, on October 25, 2013, AxoGen entered into a Commercial Lease with Ja-Cole. Under the terms of the Commercial Lease, AxoGen leased 5,400 square feet of warehouse/office space in Burleson, Texas until November 30, 2016, renewable thereafter by agreement

of the parties, at an annual cost of $43,200 per year. The Burleson facility will house raw material storage, a function that is currently provided by a third party vendor, and product distribution, allowing AxoGen to fulfill same day orders for both coasts of the United States.

The Company leases its lab space on a month to month basis.

Estimated future minimum rental payments on the leases are as follows:

Year ending December 31	
2014	$ 243,000
2015	243,000
2016	241,000
2017	207,000
2018	177,000
TOTAL	$ 1,111,000

Total rent expense for the Company's leased office and lab space for the years ended December 31, 2013 and 2012 was approximately $197,000 and $171,000, respectively.

Service Agreements

In 2008, the Company entered into a biostorage and management services agreement with a vendor. The agreement specifies monthly administration fees, storage fees based on volume, and retrieval fees per specimen based on lead times. The agreement can be terminated with 30 days written notice.

In 2009, the Company also entered into a two-year tissue processing agreement with another vendor. Tissue processing fees are based on a combination of a per week and a per donor batch rate. In 2012 the parties agreed to an extension for an additional twelve months and amended the agreement to provide for automatic twelve month renewals.

In August 2008, the Company entered into an agreement to distribute the AxoGuard® product worldwide in the field of peripheral nerve repair, and the parties subsequently amended the agreement in March, 2012. The agreement has an initial seven-year term from the date of the original agreement and following such initial term, the agreement automatically renews for an additional seven (7) year period provided that the parties agree to meet at least ninety (90) days before the end of such initial term to review whether the purchase price of the products obtained from Cook Biotech need to be adjusted and reasonably agree to such adjustment in writing, where such agreement shall not be unreasonably withheld. The Cook Biotech agreement also requires certain minimum purchases, although through mutual agreement the parties have not established such minimums and to date have not enforced such provision, and establishes a formula for the transfer cost of the AxoGuard® products.

In December 2011, the Company also entered into a Master Services Agreement for Clinical Research and Related Services. The Company was required to pay $151,318 upon execution of this agreement and $20,416 per month for 42 months starting in January 2012 through August 2015.

Certain executive officers of the Company are parties to employment contracts. All such contracts have severance payments in the event of a Company change of control, provided certain conditions are met. One contract has a severance provision in the event of termination without cause.

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Concentrations

Vendor

All of AxoGen's revenue is currently derived from three products, the Avance® Nerve Graft, AxoGuard® Nerve Protector and AxoGuard® Nerve Connector. AxoGen has an exclusive distribution agreement with Cook Biotech for the purchase of AxoGuard®. This contract is in year six of the initial seven year term and following such initial term, the agreement automatically renews for an additional seven years provided that the parties have met all the required provisions of the contract. The agreement allows for termination provisions for both parties. Although there are products that AxoGen believes it could develop or obtain that would replace the AxoGuard® products, the loss of the ability to sell the AxoGuard® products could have a material adverse effect on AxoGen's business until other replacement products would be available.

Processor

AxoGen is highly dependent on the continued availability of its processing facilities at LifeNet Health and could be harmed if the physical infrastructure of this facility is unavailable for any prolonged period of time. In addition, disruptions could lead to significant costs and reductions in revenues, as well as a potential harm to the AxoGen's business reputation and financial results. Termination of the LifeNet Health facility lease can occur upon six months' notice from either party. Although AxoGen believes it can find and make operational a new facility in less than six months, the regulatory process for approval of facilities is time-consuming and unpredictable. AxoGen's ability to rebuild or find acceptable lease facilities would take a considerable amount of time and expense and could cause a significant disruption in service to its customers. Although AxoGen has business interruption insurance which would, in instances other than lease termination, cover certain costs, it may not cover all costs nor help to regain AxoGen's standing in the market.

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

The Company maintains "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, (the "Exchange Act"), that are designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, and Board of Directors, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable assurance of achieving the desired objectives, and we necessarily are required to apply our judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures.

Our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2013 and concluded that our disclosure controls and procedures were effective as of December 31, 2013.

MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management is responsible for establishing and maintaining internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. The Company's internal control system is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of inherent limitations, a system of internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate due to change in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

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Based on its evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2013.

This Form 10-K does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to rules of the SEC that permit the Company to provide only management's report in this annual report.

CHANGES IN INTERNAL CONTROLS OVER FINANCIAL REPORTING

During the year ended December 31, 2013, there were no changes in the Company's internal control over financial reporting (as defined in Rule 13a-15(f) and 15d—15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Information required by this item concerning our directors will be set forth under the caption "Election of Directors" in our definitive proxy statement for our 2014 annual meeting, and is incorporated herein by reference.

Information required by this item concerning compliance with Section 16(a) of the Exchange Act, as amended, will be set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for our 2014 annual meeting, and is incorporated herein by reference.

Information required by this item concerning the audit committee of the Company, the audit committee financial expert of the Company and any material changes to the way in which security holders may recommend nominees to the Company's Board of Directors will be set forth under the caption "Corporate Governance" in our definitive proxy statement for our 2014 annual meeting, and is incorporated herein by reference.

The Board of Directors adopted a Code of Ethics, which is posted on our website http://ir.axogeninc.com/governance.cfm that is applicable to all employees and directors. We will provide copies of our Code of Business Conduct and Ethics without charge upon request. To obtain a copy, please visit our website or send your written request to Investors Relations, 13631 Progress Blvd., Suite 400, Alachua, FL 32615. With respect to any amendments or waivers of this Code of Business Conduct and Ethics (to the extent applicable to the Company's chief executive officer, principal accounting officer or controller, or persons performing similar functions) the Company intends to either post such amendments or waivers on its website or disclose such amendments or waivers pursuant to a Current Report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION.

Information required by this item will be set forth under the caption "Executive Compensation" in our definitive proxy statement for our 2014 annual meeting, and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

Information required by this item concerning ownership will be set forth under the caption "Security Ownership of Certain Beneficial Owners", "Security Ownership of Directors and

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Executive Officers" and " Equity Compensation Plan Information" in our definitive proxy statement for our 2014 annual meeting, and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required by this item concerning ownership will be set forth under the caption "Corporate Governance — Director Independence" and "Certain Relationships and Related Transactions" in our definitive proxy statement for our 2014 annual meeting, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information required by this item concerning ownership will be set forth under the caption "Proposal 2 — Ratification of Appointment of Independent Registered Public Accounting Firm" in our definitive proxy statement for our 2014 annual meeting, and is incorporated herein by reference.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this Report

(1) The following financial statements are filed herewith in Item 8 of Part II of this annual report on Form 10-K:

(i) Consolidated Balance Sheets
(ii) Consolidated Statement of Operations
(iii) Consolidated Statements of Stockholders' Equity (Deficit)
(iv) Consolidated Statements of Cash Flows
(v) Notes to Consolidated Financial Statements

(3) Exhibits

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of May 31, 2011, among LecTec Corporation, Nerve Merger Sub Corp. and AxoGen Corporation (incorporated by reference to Exhibit 2.1 to LecTec Corporation's Current Report on Form 8-K filed on June 2, 2011)
2.2	Amendment No. 1 to Agreement and Plan of Merger, dated as of June 30, 2011, among LecTec Corporation, Nerve Merger Sub Corp. and AxoGen Corporation (incorporated by reference to Appendix A2 to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
2.3	Amendment No. 2 to Agreement and Plan of Merger, dated as of August 9, 2011, among LecTec Corporation, Nerve Merger Sub Corp. and AxoGen Corporation (incorporated by reference to Appendix A3 to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
3.1	Amended and Restated Articles of Incorporation of AxoGen, Inc. (incorporated by reference to Appendix B to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
3.2	AxoGen, Inc. Amended and Restated Bylaws. (incorporated by reference to Appendix C to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
**10.1	Patent License Agreement, dated as of August 3, 2005, by and between AxoGen Corporation and the Board of Regents of the University of Texas System (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
**10.2	Amended and Restated Standard Exclusive License Agreement with Sublicensing Terms, dated as of February 21, 2006, by and between AxoGen Corporation and the University of Florida Research Foundation, Inc. (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
**10.3	Sid Martin Biotechnology Development Institute Incubator License Agreement, dated as of September 26, 2006, by and between AxoGen, Inc. and the University of Florida Research Foundation, Inc. (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)

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**10.4.1	Amended and Restated Nerve Tissue Processing Agreement, dated as of February 27, 2008, by and between AxoGen Corporation and LifeNet Health (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
**10.4.2	Second Amendment to Amended and Restated Nerve Tissue Processing Agreement, dated as of August 9, 2011, by and between AxoGen Corporation and LifeNet Health (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
**10.5.1	Distribution Agreement, dated as of August 27, 2008, by and between AxoGen, Inc. and Cook Biotech Incorporated (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
10.5.2	Amendment dated March 14, 2012 to Distribution Agreement, dated as of August 27, 2008, by and between AxoGen, Inc. and Cook Biotech Incorporated (Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2011)
**10.6.1	Revenue Interests Purchase Agreement, dated as of October 5, 2012, by and among AxoGen, Inc. and PDL BioPharma, Inc.
**10.6.2	Guarantee and Collateral Agreement, dated as of October 5, 2012, by and among AxoGen, Inc. and AxoGen Corporation and PDL BioPharma, Inc.
10.6.3	Interim Revenue Interests Purchase Agreement dated August 14, 2012, by and between AxoGen, Inc. and PDL BioPharma, Inc. (Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012)

10.6.4	Amendment dated July 26, 2013 to Revenue Interests Purchase Agreement, dated, dated as of October 5, 2012, by and between AxoGen, Inc. and PDL BioPharma, Inc. (Incorporated by reference to the Company's Amendment No. 3 to Registration Statement on Form S-1 (registration No. 333-188597) filed with the Securities and Exchange Commission on July 30, 2013)
10.7	LecTec Corporation 2010 Stock Incentive Plan, Amended and Restated on September 27, 2011 (incorporated by reference to Appendix E to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
***10.8.1	Executive Employment Agreement, effective as of October 15, 2007, by and between AxoGen Corporation and Karen Zaderej (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
***10.8.2	Amendment to Executive Employment Agreement, effective as of September 29, 2011, by and between AxoGen Corporation and Karen Zaderej (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
***10.9.1	Executive Employment Agreement, effective as of May 6, 2003, by and between AxoGen Corporation and John P. Engels (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
***10.9.2	Amendment to Executive Employment Agreement, effective as of September 29, 2011, by and between AxoGen Corporation and John P. Engels (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
10.10.1	Lease dated as of February 6, 2007, by and between AxoGen Corporation and WIGSHAW, LLC, its successors and assigns (incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on November 14, 2011)
10.10.2	Second Amendment dated February 27, 2013 to lease dated as of February 6, 2007, by and between AxoGen Corporation and WIGSHAW, LLC, its successors and assigns (Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2012)
+10.10.3	Third Amendment dated November 12, 2013 to lease dated as of February 6, 2007, by

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	and between AxoGen Corporation and SHN Medical Office Properties, its successors and assigns
***10.15	Form of Employee Incentive Stock Option Agreement (Incorporated by reference to the Company's Current Report on Form 8-K filed on September 26, 2007)
***10.16	Executive Employment Agreement, effective as of October 1, 2011, by and between AxoGen, Inc. and Gregory G. Freitag (Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2011)
***10.17	Executive Employment Agreement, effective as of February 27, by and between AxoGen, Inc. and Jill Schiaparelli (Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2011)
+10.18	Commercial Lease dated October 25, 2013 by and between AxoGen Corporation and Ja-Cole, as amended December 10, 2013.
10.19.1	Loan and Security Agreement, dated as of September 30, 2011, by and among AxoGen, Inc. and AxoGen Corporation, as borrower, Midcap Financial SBIC, LP, as administrative agent, and the Lenders listed on Schedule 1 thereto (Incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
10.19.2	First Amendment to Loan and Security Agreement dated August 14, 2012, by and between AxoGen, Inc. and Midcap Financial SBIC, LP. (incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012)
10.19.3	Subordination and Intercreditor Agreement dated August 14, 2012, by and between AxoGen, Inc., PDL BioPharma, Inc. and Midcap Financial SBIC, LP. (Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012)
***10.20	Executive Employment Agreement, effective as of February 25, 2013, by and between AxoGen, Inc. and Shawn McCarrey (Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013)
+21.1	Subsidiary of the Registrant
+23.1	Consent of Lurie Besikof Lapidus & Company, LLP
++24.1	Power of Attorney
+31.1	Certification of Principal Executive Officer

+31.2	Certification of Principal Financial Officer
+32.1	Chief Executive Officer Certification Pursuant to 18 U.S.C. 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
+101.INS	XBRL Instance Document.
+101.SCH	XBRL Taxonomy Extension Schema Document.
+101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
+101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
+101.LAB	XBRL Extension Labels Linkbase.
+101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

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** Confidential treatment has been granted for portions of this Exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934 as amended. The confidential portions have been deleted and filed separately with the United States Securities and Exchange Commission.

*** Management contract or compensatory plan or arrangement.

+ Filed herewith.

++ Included on signature page.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AXOGEN, INC

/s/ Karen Zaderej
Karen Zaderej
Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Karen Zaderej (with full power to act alone), as his or her true and lawful attorney-in-fact and agent, with full powers of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to the Annual Report on Form 10-K of LecTec Corporation, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or their substitute or substitutes, lawfully do or cause to be done by virtue hereof.

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Karen Zaderej — March 6, 2014
Karen Zaderej Chief Executive Officer and Director
(Principal Executive Officer)

/s/ Gregory G. Freitag — March 6, 2014
Gregory Freitag Chief Financial Officer, General Counsel and Director
(Principal Financial Officer)
(Principal Accounting Officer)

/s/ Jamie Grooms Jamie Grooms Director	March 6, 2014
/s/ Robert Rudelius Robert Rudelius Director	March 6, 2014
/s/ Dr. Mark Gold Mark Gold, M.D. Director	March 6, 2014
/s/ John Harper John Harper Director	March 6, 2014
/s/ Joe Mandato Joe Mandato Director	March 6, 2014
/s/ John McLaughlin John McLaughlin Director	March 6, 2014

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EXHIBIT INDEX

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2.2	Amendment No. 1 to Agreement and Plan of Merger, dated as of June 30, 2011, among LecTec Corporation, Nerve Merger Sub Corp. and AxoGen Corporation (incorporated by reference to Appendix A2 to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
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**10.2	Amended and Restated Standard Exclusive License Agreement with Sublicensing Terms, dated as of February 21, 2006, by and between AxoGen Corporation and the University of Florida Research Foundation, Inc. (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
**10.3	Sid Martin Biotechnology Development Institute Incubator License Agreement, dated as of September 26, 2006, by and between AxoGen, Inc. and the University of Florida Research Foundation, Inc. (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
**10.4.1	Amended and Restated Nerve Tissue Processing Agreement, dated as of February 27, 2008, by and between AxoGen Corporation and LifeNet Health (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
**10.4.2	Second Amendment to Amended and Restated Nerve Tissue Processing Agreement, dated as of August 9, 2011, by and between AxoGen Corporation and LifeNet Health (incorporated by reference to the Company's Current Report on Form 8-K

filed on October 6, 2011)

**10.5.1	Distribution Agreement, dated as of August 27, 2008, by and between AxoGen, Inc. and Cook Biotech Incorporated (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
10.5.2	Amendment dated March 14, 2012 to Distribution Agreement, dated as of August 27, 2008, by and between AxoGen, Inc. and Cook Biotech Incorporated (Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2011)
**10.6.1	Revenue Interests Purchase Agreement, dated as of October 5, 2012, by and among AxoGen, Inc. and PDL BioPharma, Inc.

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**10.6.2	Guarantee and Collateral Agreement, dated as of October 5, 2012, by and among AxoGen, Inc. and AxoGen Corporation and PDL BioPharma, Inc.
10.6.3	Interim Revenue Interests Purchase Agreement dated August 14, 2012, by and between AxoGen, Inc. and PDL BioPharma, Inc. (Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012)
10.6.4	Amendment dated July 26, 2013 to Revenue Interests Purchase Agreement, dated, dated as of October 5, 2012, by and between AxoGen, Inc. and PDL BioPharma, Inc. (Incorporated by reference to the Company's Amendment No. 3 to Registration Statement on Form S-1 (registration No. 333-188597) filed with the Securities and Exchange Commission on July 30, 2013)
10.7	LecTec Corporation 2010 Stock Incentive Plan, Amended and Restated on September 27, 2011 (incorporated by reference to Appendix E to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
***10.8.1	Executive Employment Agreement, effective as of October 15, 2007, by and between AxoGen Corporation and Karen Zaderej (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
***10.8.2	Amendment to Executive Employment Agreement, effective as of September 29, 2011, by and between AxoGen Corporation and Karen Zaderej (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
***10.9.1	Executive Employment Agreement, effective as of May 6, 2003, by and between AxoGen Corporation and John P. Engels (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
***10.9.2	Amendment to Executive Employment Agreement, effective as of September 29, 2011, by and between AxoGen Corporation and John P. Engels (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
10.10.1	Lease dated as of February 6, 2007, by and between AxoGen Corporation and WIGSHAW, LLC, its successors and assigns (incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on November 14, 2011)
10.10.2	Second Amendment dated February 27, 2013 to lease dated as of February 6, 2007, by and between AxoGen Corporation and WIGSHAW, LLC, its successors and assigns (Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2012)
+10.10.3	Third Amendment dated November 12, 2013 to lease dated as of February 6, 2007, by and between AxoGen Corporation and SHN Medical Office Properties, its successors and assigns
***10.15	Form of Employee Incentive Stock Option Agreement (Incorporated by reference to the Company's Current Report on Form 8-K filed on September 26, 2007)
***10.16	Executive Employment Agreement, effective as of October 1, 2011, by and between AxoGen, Inc. and Gregory G. Freitag (Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2011)
***10.17	Executive Employment Agreement, effective as of February 27, by and between AxoGen, Inc. and Jill Schiaparelli (Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2011)
+10.18	Commercial Lease dated October 25, 2013 by and between AxoGen Corporation and Ja-Cole, as amended December 10, 2013.
10.19.1	Loan and Security Agreement, dated as of September 30, 2011, by and among AxoGen, Inc. and AxoGen Corporation, as borrower, Midcap Financial SBIC, LP, as administrative agent, and the Lenders listed on Schedule 1 thereto (Incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)

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	AxoGen, Inc. and Midcap Financial SBIC, LP. (incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012)
10.19.3	Subordination and Intercreditor Agreement dated August 14, 2012, by and between AxoGen, Inc., PDL BioPharma, Inc. and Midcap Financial SBIC, LP. (Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012)
***10.20	Executive Employment Agreement, effective as of February 25, 2013, by and between AxoGen, Inc. and Shawn McCarrey (Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013)
+21.1	Subsidiary of the Registrant
+23.1	Consent of Lurie Besikof Lapidus & Company, LLP
++24.1	Power of Attorney
+31.1	Certification of Principal Executive Officer
+31.2	Certification of Principal Financial Officer
+32.1	Chief Executive Officer Certification Pursuant to 18 U.S.C. 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
+101.INS	XBRL Instance Document.
+101.SCH	XBRL Taxonomy Extension Schema Document.
+101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
+101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
+101.LAB	XBRL Extension Labels Linkbase.
+101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

** Confidential treatment has been granted for portions of this Exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934 as amended. The confidential portions have been deleted and filed separately with the United States Securities and Exchange Commission.

*** Management contract or compensatory plan or arrangement.

+ Filed herewith.

++ Included on signature page.

Exhibit 10.10.3

THIRD AMENDMENT TO LEASE

This Third Amendment to Lease (this "Third Amendment") is entered into as of October , 2013 by and between SNH MEDICAL OFFICE PROPERTIES TRUST, a Maryland real estate investment trust ("Landlord") and AXOGEN CORPORATION, a Delaware corporation ("Tenant").

WHEREAS, Wigshaw, LLC ("Original Landlord") and Tenant entered into that certain Lease dated February 6, 2007 (the "Original Lease") for certain premises consisting of approximately 4,742 square feet (the "Existing Premises") in the building known as Progress One, located at 13859 Progress Boulevard, Alachua, Florida; and

WHEREAS, Landlord succeeded to the interest of Original Landlord under the Original Lease and, with Tenant, entered into that certain First Amendment to Lease dated March 14, 2012 and that certain Second Amendment to Lease dated February 25, 2013 (the Original Lease, as so amended, the "Lease"); and

WHEREAS, Landlord and Tenant desire to amend the Lease to extend the term thereof and to relocate the premises demised thereunder, subject to and upon the terms and conditions hereinafter provided;

NOW, THEREFORE, in consideration of the foregoing and for other consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree that the Lease is hereby amended as follows:

1. Capitalized terms used and not otherwise defined herein shall have the meanings ascribed to such terms in the Lease. As used herein, the term "Leased Premises" shall refer to the premises demised under the Lease from and after December 1, 2013 (the "Relocation Date").

2. The Term of the Lease is hereby extended and shall expire on October 31, 2018.

3. For the period commencing on the Relocation date, the following definitions set forth in Article 1.1 of the Lease shall be amended as follows:

(a) "Annual Gross Rent" for the period commencing on December 1, 2013 and ending on October 31, 2018 shall be payable in accordance with the following schedule:

Dates	Rent Per Square Foot	Annual Gross Rent	Monthly Payment Rent
12/1/13-10/31/16	$ 17.00	$ 199,937.00	$ 16,661.42
11/1/16-10/31/17	$ 17.51	$ 205,935.11	$ 17,161.26
11/1/17-10/31/18	$ 18.04	$ 212,168.44	$ 17,680.70

All Annual Gross Rent shall be payable in equal monthly installments, in advance. The monthly installment of Annual Gross Rent payable for the month of November, 2013 shall continue to be payable as set forth in Section 3 of the Second Amendment to Lease.

(b) "Building" shall mean the building known as Progress Two, located on certain real property located in the City of Alachua, Alachua County, Florida, having a current address of 13631 Progress Boulevard, Alachua, FL 32615.

(c) "Leased Premises" shall be deemed to mean approximately 11,761 square feet of finished office grade area extending to the exterior faces of all walls or to the centerline of those walls separating the Leased Premises from other leased premises, together with appurtenances specifically granted in the Lease, but reserving and excepting to Landlord the use of the exterior walls and the roof and the right to install, maintain, use, repair and replace pipes, ducts, conduits and wires leading through the Leased Premises in locations which will not materially interfere with Tenant's use thereof, which area shall be located in the Progress Two Building in Progress Corporate Park with its address at 13631 Progress Boulevard, Alachua, FL 32615 and depicted by the plan attached to this Third Amendment to Lease and made a part thereof as Exhibit "A".

(d) "Rentable Area" or "Rentable Square Footage" shall mean the total area (as it exists from time to time). Rentable Area of the Leased Premises is hereby deemed to mean approximately 11,761 square feet.

(e) "Security Deposit" shall mean the sum of $16,661.42. Upon execution of this Third Amendment, Tenant shall deposit with Landlord an additional $8,661.42, so that the total amount of the Security Deposit held by Landlord pursuant to Article 3.7 shall be $16,661.42.

(f) "Term" shall mean the period commencing on the Commencement Date and ending at 11:59 p.m. on October 31, 2018 ("Expiration Date") or such earlier date on which the Term of the Lease shall expire or be canceled or terminated pursuant to any of the conditions or covenants of the Lease or pursuant to law, and furthermore, shall include any renewal term, if such renewal term shall come into existence.

4. Landlord shall deliver and Tenant shall accept the Leased Premises on or before November 1, 2013 (the "Delivery Date") in "as is" condition and with all mechanical, electrical and plumbing systems located in or serving the Leased Premises in good working

order. Prior to the Delivery Date, Landlord shall have the carpets in the Leased Premises cleaned and shall provide touchup painting of the interior walls of the Leased Premises (collectively, the "Relocation Work"). All of the provisions of the Lease applicable to the Existing Premises shall apply to the Leased Premises as if the Relocation Date had occurred, except there shall be no obligation to pay Annual Gross Rent with respect to the Leased Premises prior to the Relocation Date (but Annual Gross Rent with respect to the Existing Premises shall continue to be payable through the day preceding the Relocation Date).

5. Tenant shall deliver possession of the Existing Premises to Landlord on or before December 20, 2013 (the "Surrender Date"), with all of Tenant's furniture, fixtures, equipment and all other personal property removed (at Tenant's sole cost and expenses) and otherwise in the condition the Existing Premises are required to be delivered to Landlord under Article 6.4 of the Lease as if the Term of the Lease had expired with respect to the Existing Premises. Without limiting the foregoing, Tenant, at Tenant's sole cost and expense, shall remove all of Tenant's

furniture, fixtures, equipment and all other personal property from the Existing Premises on or before the Surrender Date. Any failure by Tenant to deliver possession of the Existing Premises to Landlord in the condition required as provided above on or before the Surrender Date shall be treated as a holding over in the Existing Premises as if the Existing Premises were still the premises demised under the Lease and, in addition to all other amounts payable under the Lease, Tenant shall pay to Landlord Five Hundred Nineteen and 67/100 Dollars ($519.67) per day for each day in the period commencing on the day following the Surrender Date and ending on the date Tenant shall deliver possession of the Existing Premises to Landlord in the condition required as set forth above. Tenant shall also pay to Landlord all damages, direct and/or consequential (foreseeable and unforeseeable), sustained by reason of any such holding over following the Surrender Date. Otherwise, all of the covenants, agreements and obligations of Tenant under the Lease shall apply and be performed by Tenant during such period of holding over as if the Existing Premises were still the premises demised thereunder and the Lease were still in effect with respect thereto.

6. The first two paragraphs of Article 3.3 of the Lease are hereby deleted in their entirety and replaced with the following:

3.3. Increases in Insurance Premiums and Ad Valorem Taxes. Tenant shall pay, as Additional Rent, its annual proportionate share of the increase in insurance premiums paid by Landlord for the Building and liabilities pursuant to Article 9.3 in excess of Tenant's annual proportionate share thereof as of the Commencement Date. For the period commencing on the Commencement Date and ending on November 30, 2013, Tenant's annual proportionate share as of the Commencement Date is $1,241.13. For the period commencing on December 1, 2013, Tenant shall pay, as Additional Rent, Tenant's annual proportionate share of the increase in insurance premiums paid by Landlord for the Building and liabilities pursuant to Article 9.3 in excess of the insurance premiums payable for the 2014 calendar year. For purpose of the immediately preceding sentence, "tenant's annual proportionate share" shall be thirty five and 81/100 percent (35.81%).

Tenant shall pay, as Additional Rent, its annual proportionate share of the increases in ad valorem taxes (real estate) paid by Landlord with respect to the Building and the land on which it is situated in excess of Tenant's annual proportionate share thereof as of the Commencement Date. For the period commencing on the Commencement Date and ending on November 30, 2013, Tenant's annual proportionate share as of the Commencement Date is $13,661.00. For the period commencing on December 1, 2013, Tenant shall pay, as Additional Rent, Tenant's annual proportionate share of the increase in ad valorem (real estate) taxes paid by Landlord with respect to the Building in excess of such taxes payable for the 2014 fiscal year (i.e., October 1, 2013-September 30, 2014). For purpose of the immediately preceding sentence, "tenant's annual proportionate share" shall be thirty five and 81/100 percent (35.81%).

7. Provided that no default or breach of the Lease shall have occurred and be continuing beyond all applicable notice and cure periods at the time it gives Landlord notice exercising the option herein granted or thereafter until the Early Termination Date (unless Landlord, in its sole discretion at any time, shall elect to waive such condition by notice to

Tenant), Tenant shall have an option (the "Early Termination Option") to terminate the Term of the Lease effective as of the date (the "Early Termination Date") which is the later of (i) October 31, 2016 or (ii) the last day of the sixth month following Tenant's written notice to Landlord of Tenant's election to exercise the Early Termination Option. Tenant shall pay to Landlord, concurrently with such notice, a fee (the "Termination Fee") equal to the amount shown as the "Ending Balance" on the schedule attached hereto as Exhibit B for the month in which the Early Termination Date occurs (for example, the Termination Fee for an Early Termination Date of December 31, 2016 shall be $28,164.21). Landlord may, in its sole discretion, elect to treat any notice of termination which is not accompanied by the Termination Fee either as null and void or as effective to terminate the Term as of the Early Termination Date (while not discharging Tenant from its obligation to pay the Termination Fee).

8. Tenant, at its sole cost and expense and subject to compliance with the provisions of this Section 8, may install and operate during the Term of the Lease an emergency electrical generator (the "Generator") and any associated fuel tank and natural gas meter in a location on the Common Area reasonably designated by Landlord, install underground conduit between the generator and the Leased Premises, and run necessary cables and wiring from the generator to the Leased Premises within such conduit and within the Leased Premises. The Generator and any associated fuel tank, gas meter, conduit, cables and wiring (both interior and exterior) are hereinafter referred to collectively as the "Generator System."

Tenant shall prepare and submit to Landlord for its approval complete plans and specifications for the Generator System, which

shall show the proposed location of the Generator and all conduits, cabling and wiring (collectively "Lines") to be installed. Upon final approval by Landlord of Tenant's plans and specifications for the Generator System, Tenant may install the Generator System in accordance therewith and in compliance with all applicable permits, laws, codes, ordinances and regulations, any so-called "dig safe" requirements or procedures of local utilities, any requirements of Landlord's insurance carrier(s) and all other provisions of the Lease applicable thereto, including, without limitation, the provisions of Article 7.

Tenant shall require its contractors to prosecute the work performed in connection with the installation of the Generator System (hereinafter the "Work") with diligence once begun, to keep all work areas safe and free of debris at all times, and to confine their activities to the areas where the Generator System is to be installed to the greatest extent possible.

Tenant shall require that its contractors employ those means and methods that cause the least disruption or damage to the Building and the Common Area (including, without limitation, a requirement that all paved surfaces to be trenched shall be saw cut). Tenant shall locate and protect existing utilities and shall ensure that no utility lines are cut or disturbed by the Work. Landlord shall be entitled to inspect the Work as it progresses and to require Tenant's contractor(s) to stop and correct any of the Work that does not conform to the approved plans and specifications or which is not being performed in accordance with the requirements hereof.

Upon completion of the installation of any underground Lines, all landscaped and paved surfaces shall be restored to their original condition and appearance, which shall include, but not be limited to, backfilling all trenches, restoration of sidewalks and other paved surfaces to a smooth and level surface, re-striping of excavated parking areas, restoration of sod and other

landscaping materials, and restoration of all curbing, fencing and other improvements disturbed by the Work. Any future settling of filled trenches occurring during the Term of the Lease shall be repaired promptly by Tenant at its sole expense following notice by Landlord.

Landlord shall have no obligation to make any alterations, repairs or replacements to any portion of the Building or the Common Area in order to accommodate the installation or operation of the Generator System. During the Term, Tenant, at its sole cost and expense, shall perform all repairs and maintenance required to keep the Generator System in good working order, appearance and condition, and Tenant shall promptly repair any damage to the Building or the Common Area caused by the installation or operation of the Generator System. Tenant shall operate the Generator System in compliance with all applicable codes, laws, rules and regulations. Tenant may not relocate or modify any portion of the Generator System without, in each instance, obtaining Landlord's prior written approval to such relocation or modification. All components of the Generator System shall be at the sole risk of Tenant and Landlord shall have no liability to Tenant in the event any portion of the Generator System is damaged for any reason.

Unless Landlord shall agree otherwise in writing, Tenant shall, prior to the expiration or earlier termination of the Term of the Lease, remove the entire Generator System including all Lines, repair any damage caused by such removal, restore the areas where the generator, any fuel tank and Lines were located to a condition substantially the same as existed prior to the installation thereof and, at Landlord's request and at Tenant's expense, provide Landlord with a so-called "Phase I" environmental report from an engineer reasonably acceptable to Landlord, certifying, subject to customary limitations and standards, that the areas in which the generator and any fuel tank have been located contain no Hazardous Substances (as defined in Article 20.1).

Landlord reserves the right, upon reasonable notice to Tenant, to require Tenant to relocate the Generator System or any of its constituent components, at Tenant's sole cost and expense, if necessary in connection with any repairs, renovations, improvements or additions to the Building or the Common Area. In addition, Landlord reserves the right to require Tenant to relocate the generator and any fuel tank to another portion of the Common Area designated by Landlord for any other reason in Landlord's sole discretion, provided such other portion of the Common Area is adequate for Tenant's purposes and Landlord pays the reasonable costs of such relocation.

Tenant shall secure, pay for and keep in force a contract with a qualified and reputable maintenance contractor, reasonably acceptable to Landlord, providing for regularly scheduled maintenance of the Generator System which shall include such service as shall be customary or recommended by the manufacturer of the Generator or by such contractor to keep such system in good operating condition and repair, and Tenant shall furnish Landlord with a copy of such contract and any replacements thereof.

In addition to all other indemnities under the Lease, Tenant hereby agrees to indemnify and hold Landlord harmless from any and all claims, costs, liabilities, damages or expenses arising from the presence of the Generator System and the installation and operation thereof by Tenant.

9. Tenant warrants and represents that it has dealt with no broker in connection with the consummation of this Third Amendment, other than Front Street Commercial Real Estate Group and Coldwell Banker Commercial/M.M. Parrish Realtors (individually and collectively, the "Brokers"), and in the event of any brokerage claims or liens, other than by the Brokers, against Landlord or the Building predicated upon or arising out of prior dealings with Tenant, Tenant agrees to defend the same and indemnify and hold Landlord harmless against any such claim, and to discharge any such lien.

10. As amended hereby, the Lease is hereby ratified and confirmed.

IN WITNESS WHEREOF, the parties hereunto have executed this Third Amendment as of the date first written above.

LANDLORD:

SNH MEDICAL OFFICE PROPERTIES TRUST

By: Reit Management & Research LLC,
its managing agent

By: /s/ David M. Lepore
David M. Lepore
Senior Vice President

TENANT:

AXOGEN CORPORATION

By: /s/ Karen Zaderej
Name: Karen Zaderej
Title: President/CEO

EXHIBIT A

LEASED PREMISES

[See attached.]

EXHIBIT B

TERMINATION FEE SCHEDULE

Axogen Termination Schedule

	Enter values		Amortized Amounts:		Termination Fee:	$0.00	$0.00
Loan amount	$	63,571.56	TIA:	$ 2,500.00			
Annual interest rate		10.000%	Abated Rent:	$ 0.00			
Loan period in years		5.0	Commissions:	$ 61,071.56			
Start date of loan		12/1/2013	Est. Legal Fees:	$ 0.00			
Optional extra payments			Total:	$ 63,571.56			
Scheduled monthly payment	$	1,350.71					
Scheduled number of payments		60					
Actual number of payments		60					
Total of early payments	$	—					
Total interest	$	17,470.91					

No.	Payment Date	Beginning Balance	Scheduled Payment	Extra Payment	Total Payment	Principal	Interest	Ending Balance
1	12/1/2013	$ 63,571.56	$ 1,350.71	$ —	$ 1,350.71	$ 820.94	$ 529.76	$ 62,750.62
2	1/1/2014	$ 62,750.62	$ 1,350.71	$ —	$ 1,350.71	$ 827.79	$ 522.92	$ 61,922.83
3	2/1/2014	$ 61,922.83	$ 1,350.71	$ —	$ 1,350.71	$ 834.68	$ 516.02	$ 61,088.15
4	3/1/2014	$ 61,088.15	$ 1,350.71	$ —	$ 1,350.71	$ 841.64	$ 509.07	$ 60,246.51
5	4/1/2014	$ 60,246.51	$ 1,350.71	$ —	$ 1,350.71	$ 848.65	$ 502.05	$ 59,397.85
6	5/1/2014	$ 59,397.85	$ 1,350.71	$ —	$ 1,350.71	$ 855.73	$ 494.98	$ 58,542.13
7	6/1/2014	$ 58,542.13	$ 1,350.71	$ —	$ 1,350.71	$ 862.86	$ 487.85	$ 57,679.27
8	7/1/2014	$ 57,679.27	$ 1,350.71	$ —	$ 1,350.71	$ 870.05	$ 480.66	$ 56,809.22
9	8/1/2014	$ 56,809.22	$ 1,350.71	$ —	$ 1,350.71	$ 877.30	$ 473.41	$ 55,931.92
10	9/1/2014	$ 55,931.92	$ 1,350.71	$ —	$ 1,350.71	$ 884.61	$ 466.10	$ 55,047.32
11	10/1/2014	$ 55,047.32	$ 1,350.71	$ —	$ 1,350.71	$ 891.98	$ 458.73	$ 54.155.34
12	11/1/2014	$ 54,155.34	$ 1,350.71	$ —	$ 1,350.71	$ 899.41	$ 451.29	$ 53,255.92
13	12/1/2014	$ 53,255.92	$ 1,350.71	$ —	$ 1,350.71	$ 906.91	$ 443.80	$ 52,349.01
14	1/1/2015	$ 52,349.01	$ 1,350.71	$ —	$ 1,350.71	$ 914.47	$ 436.24	$ 51,434.55
15	2/1/2015	$ 51,434.55	$ 1,350.71	$ —	$ 1,350.71	$ 922.09	$ 428.62	$ 50,512.46
16	3/1/2015	$ 50,512.46	$ 1,350.71	$ —	$ 1,350.71	$ 929.77	$ 420.94	$ 49,582.69
17	4/1/2015	$ 49,582.69	$ 1,350.71	$ —	$ 1,350.71	$ 937.52	$ 413.19	$ 48,645.17
18	5/1/2015	$ 48,645.17	$ 1,350.71	$ —	$ 1,350.71	$ 945.33	$ 405.38	$ 47,699.84
19	6/1/2015	$ 47,699.84	$ 1,350.71	$ —	$ 1,350.71	$ 953.21	$ 397.50	$ 46,746.63
20	7/1/2015	$ 46,746.63	$ 1,350.71	$ —	$ 1,350.71	$ 961.15	$ 389.56	$ 45,785.48
21	8/1/2015	$ 45,785.48	$ 1,350.71	$ —	$ 1,350.71	$ 969.16	$ 381.55	$ 44,816.32
22	9/1/2015	$ 44,816.32	$ 1,350.71	$ —	$ 1,350.71	$ 977.24	$ 373.47	$ 43,839.08
23	10/1/2015	$ 43,839.08	$ 1,350.71	$ —	$ 1,350.71	$ 985.38	$ 365.33	$ 42,853.70

24	11/1/2015	$ 42,853.70	$ 1,350.71	$ —	$ 1,350.71	$ 993.59	$ 357.11	$ 41,860.10
25	12/1/2015	$ 41,860.10	$ 1,350.71	$ —	$ 1,350.71	$ 1,001.87	$ 348.83	$ 40,858.23
26	1/1/2016	$ 40,858.23	$ 1,350.71	$ —	$ 1,350.71	$ 1,010.22	$ 340.49	$ 39,848.01
27	2/1/2016	$ 39,848.01	$ 1,350.71	$ —	$ 1,350.71	$ 1,018.64	$ 332.07	$ 38,829.37
28	3/1/2016	$ 38,829.37	$ 1,350.71	$ —	$ 1,350.71	$ 1,027.13	$ 323.58	$ 37,802.24
29	4/1/2016	$ 37,802.24	$ 1,350.71	$ —	$ 1,350.71	$ 1,035.69	$ 315.02	$ 36,766.55
30	5/1/2016	$ 36,766.55	$ 1,350.71	$ —	$ 1,350.71	$ 1,044.32	$ 306.39	$ 35,722.23
31	6/1/2016	$ 35,722.23	$ 1,350.71	$ —	$ 1,350.71	$ 1,053.02	$ 297.69	$ 34,669.20
32	7/1/2016	$ 34,669.20	$ 1,350.71	$ —	$ 1,350.71	$ 1,061.80	$ 288.91	$ 33,607.41
33	8/1/2016	$ 33,607.41	$ 1,350.71	$ —	$ 1,350.71	$ 1,070.65	$ 280.06	$ 32,536.76
34	9/1/2016	$ 32,536.76	$ 1,350.71	$ —	$ 1,350.71	$ 1,079.57	$ 271.14	$ 31,457.19
35	10/1/2016	$ 31,457.19	$ 1,350.71	$ —	$ 1,350.71	$ 1,088.56	$ 262.14	$ 30,368.63
36	11/1/2016	$ 30,368.63	$ 1,350.71	$ —	$ 1,350.71	$ 1,097.64	$ 253.07	$ 29,270.99
37	12/1/2016	$ 29,270.99	$ 1,350.71	$ —	$ 1,350.71	$ 1,106.78	$ 243.92	$ 28,164.21
38	1/1/2017	$ 28,164.21	$ 1,350.71	$ —	$ 1,350.71	$ 1,116.01	$ 234.70	$ 27,048.20
39	2/1/2017	$ 27,048.20	$ 1,350.71	$ —	$ 1,350.71	$ 1,125.31	$ 225.40	$ 25,922.90
40	3/1/2017	$ 25,922.90	$ 1,350.71	$ —	$ 1,350.71	$ 1.134.68	$ 216.02	$ 24,788.21
41	4/1/2017	$ 24,788.21	$ 1,350.71	$ —	$ 1,350.71	$ 1,144.14	$ 206.57	$ 23,644.07
42	5/1/2017	$ 23,644.07	$ 1,350.71	$ —	$ 1,350.71	$ 1,153.67	$ 197.03	$ 22,490.40
43	6/1/2017	$ 22,490.40	$ 1,350.71	$ —	$ 1,350.71	$ 1,163.29	$ 187.42	$ 21,327.11
44	7/1/2017	$ 21,327.11	$ 1,350.71	$ —	$ 1,350.71	$ 1,172.98	$ 177.73	$ 20,154.13
45	8/1/2017	$ 20,154.13	$ 1,350.71	$ —	$ 1,350.71	$ 1,182.76	$ 167.95	$ 18,971.37
46	9/1/2017	$ 18,971.37	$ 1,350.71	$ —	$ 1,350.71	$ 1,192.61	$ 158.09	$ 17.778.76
47	10/1/2017	$ 17,778.76	$ 1,350.71	$ —	$ 1,350.71	$ 1,202.55	$ 148.16	$ 16,576.21
48	11/1/2017	$ 16,576.21	$ 1,350.71	$ —	$ 1,350.71	$ 1,212.57	$ 138.14	$ 15,363.64

No.	Payment Date	Beginning Balance	Scheduled Payment	Extra Payment	Total Payment	Principal	Interest	Ending Balance
49	12/1/2017	$ 15,363.64	$ 1,350.71	$ —	$ 1,350.71	$ 1,222.68	$ 128.03	$ 14,140.96
50	1/1/2018	$ 14,140.96	$ 1,350.71	$ —	$ 1,350.71	$ 1,232.87	$ 117.84	$ 12,908.09
51	2/1/2018	$ 12,908.09	$ 1,350.71	$ —	$ 1,350.71	$ 1,243.14	$ 107.57	$ 11,664.95
52	3/1/2018	$ 11,664.95	$ 1,350.71	$ —	$ 1,350.71	$ 1,253.50	$ 97.21	$ 10,411.45
53	4/1/2018	$ 10,411.45	$ 1,350.71	$ —	$ 1,350.71	$ 1,263.95	$ 86.76	$ 9,147.51
54	5/1/2018	$ 9,147.51	$ 1,350.71	$ —	$ 1,350.71	$ 1,274.48	$ 76.23	$ 7,873.03
55	6/1/2018	$ 7,873.03	$ 1,350.71	$ —	$ 1,350.71	$ 1,285.10	$ 65.61	$ 6,587.93
56	7/1/2018	$ 6,587.93	$ 1,350.71	$ —	$ 1,350.71	$ 1,295.81	$ 54.90	$ 5,292.12
57	8/1/2018	$ 5,292.12	$ 1,350.71	$ —	$ 1,350.71	$ 1,306.61	$ 44.10	$ 3,985.51
58	9/1/2018	$ 3,985.51	$ 1,350.71	$ —	$ 1,350.71	$ 1,317.50	$ 33.21	$ 2,668.02
59	10/1/2018	$ 2,668.02	$ 1,350.71	$ —	$ 1,350.71	$ 1,328.47	$ 22.23	$ 1,339.54
60	11/1/2018	$ 1,339.54	$ 1,350.71	$ —	$ 1,350.71	$ 1,339.54	$ 11.16	$ (0.00)

TEXAS ASSOCIATION OF REALTORS®

COMMERCIAL LEASE

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ADDENDA & EXHIBITS (check all that apply)

- ☐ Exhibit _____
- ☐ Exhibit _____
- ☐ Commercial Lease Addendum for Broker's Fee (TAR-2102)
- ☐ Commercial Lease Addendum for Expense Reimbursement (TAR-2103)
- ☐ Commercial Lease Addendum for Extension Option (TAR-2104)
- ☐ Commercial Lease Addendum for Percentage Rent (TAR-2106)
- ☐ Commercial Lease Addendum for Parking (TAR-2107)
- ☒ Commercial Landlord's Rules and Regulations (TAR-2108)
- ☐ Commercial Lease Guaranty (TAR-2109)
- ☒ Commercial Lease Addendum for Right of First Refusal (TAR-2105)
- ☐ Commercial Lease Addendum for Optional Space (TAR-2110)
- ☐ Commercial Lease Addendum for Construction (TAR-2111) or (TAR-2112)
- ☐ Commercial Lease Addendum for Contingencies (TAR-2119)
- ☐ _____
- ☐ _____
- ☒ Information About Brokerage Services

Orr 504 Timber Ct. Burleson, TX 76028
Phone: 817.295.2238 Fax: 817.265.0441 Michael Langford

TEXAS ASSOCIATION OF REALTORS®

COMMERCIAL LEASE

1. PARTIES: The parties to this lease are:

Landlord: Ja-Cole _____ ; and

Tenant: AxoGen, ~~Inc.~~ Corporation _____ .

2. LEASED PREMISES:

A. Landlord leases to Tenant the following described real property, known as the "leased premises," along with all its improvements *(Check only one box)*:

☒ (1) Multiple-Tenant Property: Suite or Unit Number A-2&3 containing approximately 5400 square feet of rentable area in Boone Business Park *(project name)* at 300 Boone Rd *(address)* in Burleson *(city)*, Johnson *(county)*, Texas, which is legally described on attached Exhibit _____ or as follows: BOONE BUSINESS PARK BLK 1 LOT 3 _____ .

☐ (2) Single-Tenant Property: The real property at: _____ *(address)* in _____ *(city)*, _____ *(county)*, Texas, which is legally described on attached Exhibit _____ or as follows: _____ .

B. If Paragraph 2A(1) applies:
(1) "Property" means the building or complex in which the leased premises are located, inclusive of any common areas, drives, parking areas, and walks; and
(2) the parties agree that the rentable area of the leased premises may not equal the actual or useable area within the leased premises and may include an allocation of common areas in the Property. The rentable area ☐ will ☒ will not be adjusted if re-measured.

3. TERM:

A. Term: The term of this lease is 37 months and 7 days, commencing on: October 25, 2013 (Commencement Date) and ending on November 30, 2016 (Expiration Date).

B. Delay of Occupancy: If Tenant is unable to occupy the leased premises on the Commencement Date because of construction on the leased premises to be completed by Landlord that is not substantially complete or a prior tenant's holding over of the leased premises, Landlord will not be liable to Tenant for such delay and this lease will remain enforceable. In the event of such a delay, the Commencement Date will automatically be extended to the date Tenant is able to occupy the Property and the Expiration Date will also be extended by a like number of days, so that the length of this lease remains unchanged. If Tenant is unable to occupy the leased premises after the 90th day after the Commencement Date because of construction on the leased premises to be completed by Landlord that is not substantially complete or a prior tenant's holding over of the leased premises, Tenant may terminate this lease by giving written notice to Landlord before the leased premises become available to be occupied by Tenant and Landlord will refund to Tenant any amounts paid to Landlord by Tenant. This Paragraph 3B does not apply to any delay in occupancy caused by cleaning or repairs.

C. Unless the parties agree otherwise, Tenant is responsible for obtaining a certificate of occupancy for the leased premises if required by a governmental body.

4. RENT AND EXPENSES:

A. Base Monthly Rent: On or before the first day of each month during this lease, Tenant will pay Landlord base monthly rent as described on attached Exhibit _____ or as follows:

Dates		Rate per rentable square foot *(optional)*		Base Monthly Rent $
From	To	$ Monthly Rate	$ Annual Rate	
10/25/2013	11/30/2013	/ rsf / month	/ rsf / year	Free
12/01/2013	11/30/2016	8.00 / rsf / month	/ rsf / year	3,600.00
		/ rsf / month	/ rsf / year	
		/ rsf / month	/ rsf / year	
		/ rsf / month	/ rsf / year	

B. Additional Rent: In addition to the base monthly rent, Tenant will pay Landlord all other amounts, as provided by the attached *(Check all that apply.)*:
- ☐ (1) Commercial Lease Addendum for Expense Reimbursement (TAR-2103)
- ☐ (2) Commercial Lease Addendum for Percentage Rent (TAR-2106)
- ☐ (3) Commercial Lease Addendum for Parking (TAR-2107)
- ☐ (4) _____

All amounts payable under the applicable addenda are deemed to be "rent" for the purposes of this lease.

C. First Full Month's Rent: The first full monthly rent is due on or before December 1, 2013.

D. Prorated Rent: If the Commencement Date is on a day other than the first day of a month, Tenant will pay Landlord as prorated rent, an amount equal to the base monthly rent multiplied by the following fraction: the number of days from the Commencement Date to the first day of the following month divided by the number of days in the month in which this lease commences. The prorated rent is due on or before the Commencement Date.

E. Place of Payment: Tenant will remit all amounts due Landlord under this lease to the following person at the place stated or to such other person or place as Landlord may later designate in writing:

Name: JA-COLE
Address: 232 NW Tarrant Ave
Burleson, TX 76028

F. Method of Payment: Tenant must pay all rent timely without demand, deduction, or offset, except as permitted by law or this lease. If Tenant fails to timely pay any amounts due under this lease or if any check of Tenant is returned to Landlord by the institution on which it was drawn, Landlord after providing written notice to Tenant may require Tenant to pay subsequent amounts that become due under this lease in certified funds. This paragraph does not limit Landlord from seeking other remedies under this lease for Tenant's failure to make timely payments with good funds.

G. Late Charges: If Landlord does not actually receive a rent payment at the designated place of payment within 5 days after the date it is due, Tenant will pay Landlord a late charge equal to 10% of the amount due. In this paragraph, the mailbox is not the agent for receipt for Landlord. The late charge is a cost associated with the collection of rent and Landlord's acceptance of a late charge does not waive Landlord's right to exercise remedies under Paragraph 20.

H. Returned Checks: Tenant will pay $ 35.00 for each check Tenant tenders to Landlord which is returned by the institution on which it is drawn for any reason, plus any late charges until Landlord receives payment.

5. SECURITY DEPOSIT:

A. Upon execution of this lease, Tenant will pay $ 3,600.00 to Landlord as a security deposit.

B. Landlord may apply the security deposit to any amounts owed by Tenant under this lease. If Landlord applies any part of the security deposit during any time this lease is in effect to amounts owed by Tenant, Tenant must, within 10 days after receipt of notice from Landlord, restore the security deposit to the amount stated.

C. Within 60 days after Tenant surrenders the leased premises and provides Landlord written notice of Tenant's forwarding address, Landlord will refund the security deposit less any amounts applied toward amounts owed by Tenant or other charges authorized by this lease.

6. TAXES: Unless otherwise agreed by the parties, Landlord will pay all real property ad valorem taxes assessed against the leased premises.

7. UTILITIES:

A. The party designated below will pay for the following utility charges to the leased premises and any connection charges for the utilities. *(Check all that apply.)*

	N/A	Landlord	Tenant
(1) Water	☐	☒	☐
(2) Sewer	☐	☒	☐
(3) Electric	☐	☐	☒
(4) Gas	☐	☐	☒
(5) Telephone	☐	☐	☒
(6) Internet	☐	☐	☒
(7) Cable	☐	☐	☒
(8) Trash	☐	☐	☒
(9) _____	☐	☐	☒
(10) All other utilities	☐	☐	☒

B. The party responsible for the charges under Paragraph 7A will pay the charges directly to the utility service provider. The responsible party may select the utility service provider except that if Tenant selects the provider, any access or alterations to the Property or leased premises necessary for the utilities may be made only with Landlord's prior consent, which Landlord will not unreasonably withhold. If Landlord incurs any liability for utility or connection charges for which Tenant is responsible to pay and Landlord pays such amount, Tenant will immediately upon written notice from Landlord reimburse Landlord such amount.

C. **Notice: Tenant should determine if all necessary utilities are available to the leased premises and are adequate for Tenant's intended use.**

D. After-Hours HVAC Charges: "HVAC services" means heating, ventilating, and air conditioning of the leased premises. *(Check one box only.)*

☐ (1) Landlord is obligated to provide the HVAC services to the leased premises only during the Property's operating hours specified under Paragraph 9C.

☐ (2) Landlord will provide the HVAC services to the leased premises during the operating hours specified under Paragraph 9C for no additional charge and will, at Tenant's request, provide HVAC services to the leased premises during other hours for an additional charge of $ _____ per hour. Tenant will pay Landlord the charges under this paragraph immediately upon receipt of Landlord's invoice. Hourly charges are charged on a half-hour basis. Any partial hour will be rounded up to the next half hour. Tenant will comply with Landlord's procedures to make a request to provide the additional HVAC services under this paragraph.

☒ (3) Tenant will pay for the HVAC services under this lease.

8. INSURANCE:

A. During all times this lease is in effect, Tenant must, at Tenant's expense, maintain in full force and effect from an insurer authorized to operate in Texas:
(1) public liability insurance naming Landlord as an additional insured with policy limits on an occurrence basis in a minimum amount of: *(check only (a) or (b) below)*
☐ (a) $1,000,000; or
☒ (b) $2,000,000.
If neither box is checked the minimum amount will be $1,000,000.
(2) personal property damage insurance for the business operations being conducted in the leased premises and contents in the leased premises in an amount sufficient to replace such contents after a casualty loss; and
☐ (3) business interruption insurance sufficient to pay 12 months of rent payments;

B. Before the Commencement Date, Tenant must provide Landlord with a copy of insurance certificates evidencing the required coverage. If the insurance coverage is renewed or changes in any manner or degree at any time this lease is in effect, Tenant must, not later than 10 days after the renewal or change, provide Landlord a copy of an insurance certificate evidencing the renewal or change.

C. If Tenant fails to maintain the required insurance in full force and effect at all times this lease is in effect, Landlord may:
(1) purchase insurance that will provide Landlord the same coverage as the required insurance and Tenant must immediately reimburse Landlord for such expense; or
(2) exercise Landlord's remedies under Paragraph 20.

D. Unless the parties agree otherwise, Landlord will maintain in full force and effect insurance for: (1) fire and extended coverage in an amount to cover the reasonable replacement cost of the improvements of the Property; and (2) any public liability insurance in an amount that Landlord determines reasonable and appropriate.

E. If there is an increase in Landlord's insurance premiums for the leased premises or Property or its contents that is caused by Tenant, Tenant's use of the leased premises, or any improvements made by or for Tenant, Tenant will, for each year this lease is in effect, pay Landlord the increase immediately after Landlord notifies Tenant of the increase. Any charge to Tenant under this Paragraph 8E will be equal to the actual amount of the increase in Landlord's insurance premium.

9. USE AND HOURS:

A. Tenant may use the leased premises for the following purpose and no other: AxoGen, Inc. Distribution and Storage Services.

B. Unless otherwise specified in this lease, Tenant will operate and conduct its business in the leased premises during business hours that are typical of the industry in which Tenant represents it operates.

C. The Property maintains operating hours of *(specify hours, days of week, and if inclusive or exclusive of weekends and holidays):* 24 X 7 including Holidays and Weekends.

10. LEGAL COMPLIANCE:

A. Tenant may not use or permit any part of the leased premises or the Property to be used for:
(1) any activity which is a nuisance or is offensive, noisy, or dangerous;
(2) any activity that interferes with any other tenant's normal business operations or Landlord's management of the Property;
(3) any activity that violates any applicable law, regulation, zoning ordinance, restrictive covenant, governmental order, owners' association rules, tenants' association rules, Landlord's rules or regulations, or this lease;
(4) any hazardous activity that would require any insurance premium on the Property or leased premises to increase or that would void any such insurance;
(5) any activity that violates any applicable federal, state, or local law, including but not limited to those laws related to air quality, water quality, hazardous materials, wastewater, waste disposal, air emissions, or other environmental matters;
(6) the permanent or temporary storage of any hazardous material; or
(7) _____

B. "Hazardous material" means any pollutant, toxic substance, hazardous waste, hazardous material, hazardous substance, solvent, or oil as defined by any federal, state, or local environmental law, regulation, ordinance, or rule existing as of the date of this lease or later enacted.

C. Landlord does not represent or warrant that the leased premises or Property conform to applicable restrictions, zoning ordinances, setback lines, parking requirements, impervious ground cover ratio requirements, and other matters that may relate to Tenant's intended use. Tenant must satisfy itself that the leased premises may be used as Tenant intends by independently investigating all matters related to the use of the leased premises or Property. Tenant agrees that it is not relying on any warranty or representation made by Landlord, Landlord's agent, or any broker concerning the use of the leased premises or Property.

11. SIGNS:

A. Tenant may not post or paint any signs or place any decoration outside the leased premises or on the Property without Landlord's written consent. Landlord may remove any unauthorized sign or decorations, and Tenant will promptly reimburse Landlord for its cost to remove any unauthorized sign or decorations.

B. Any authorized sign must comply with all laws, restrictions, zoning ordinances, and any governmental order relating to signs on the leased premises or Property. Landlord may temporarily remove any authorized sign to complete repairs or alterations to the leased premises or the Property.

C. By providing written notice to Tenant before this lease ends, Landlord may require Tenant, upon move-out and at Tenant's expense, to remove, without damage to the Property or leased premises, any or all signs that were placed on the Property or leased premises by or at the request of Tenant. Any signs that Landlord does not require Tenant to remove and that are fixtures, become the property of the Landlord and must be surrendered to Landlord at the time this lease ends.

12. ACCESS BY LANDLORD:

A. During Tenant's normal business hours Landlord may enter the leased premises for any reasonable purpose, including but not limited to purposes for repairs, maintenance, alterations, and showing the leased premises to prospective tenants or purchasers. Landlord may access the leased premises after Tenant's normal business hours if: (1) entry is made with Tenant's permission; or (2) entry is necessary to complete emergency repairs. Landlord will not unreasonably interfere with Tenant's business operations when accessing the leased premises.

B. During the last 90 days of this lease, Landlord may place a "For Lease" or similarly worded sign in the leased premises.

13. MOVE-IN CONDITION: Tenant has inspected the leased premises and accepts it in its present (as-is) condition unless expressly noted otherwise in this lease or in an addendum. Landlord and any agent have made no express or implied warranties as to the condition or permitted use of the leased premises or Property.

14. MOVE-OUT CONDITION AND FORFEITURE OF TENANT'S PERSONAL PROPERTY:

A. At the time this lease ends, Tenant will surrender the leased premises in the same condition as when received, except for normal wear and tear. Tenant will leave the leased premises in a clean condition free of all trash, debris, personal property, hazardous materials, and environmental contaminants.

B. If Tenant leaves any personal property in the leased premises after Tenant surrenders possession of the leased premises, Landlord may: (1) require Tenant, at Tenant's expense, to remove the personal property by providing written notice to Tenant; or (2) retain such personal property as forfeited property to Landlord.

C. "Surrender" means vacating the leased premises and returning all keys and access devices to Landlord. "Normal wear and tear" means deterioration that occurs without negligence, carelessness, accident, or abuse.

D. By providing written notice to Tenant before this lease ends, Landlord may require Tenant, upon move-out and at Tenant's expense, to remove, without damage to the Property or leased premises, any or all fixtures that were placed on the Property or leased premises by or at the request of Tenant. Any fixtures that Landlord does not require Tenant to remove become the property of the Landlord and must be surrendered to Landlord at the time this lease ends.

15. MAINTENANCE AND REPAIRS:

A. Cleaning: Tenant must keep the leased premises clean and sanitary and promptly dispose of all garbage in appropriate receptacles. ☐ Landlord ☒ Tenant will provide, at its expense, janitorial services to the leased premises that are customary and ordinary for the property type. Tenant will maintain any grease trap on the Property which Tenant uses, including but not limited to periodic emptying and cleaning, as well as making any modification to the grease trap that may be necessary to comply with any applicable law.

B. Repairs of Conditions Caused by a Party: Each party must promptly repair a condition in need of repair that is caused, either intentionally or negligently, by that party or that party's guests, patrons, invitees, contractors or permitted subtenants.

C. Repair and Maintenance Responsibility: Except as otherwise provided by this Paragraph 15, the party designated below, at its expense, is responsible to maintain and repair the following specified items in the leased premises (if any). The specified items must be maintained in clean and good operable condition. If a governmental regulation or order requires a modification to any of the specified items, the party designated to maintain the item must complete and pay the expense of the modification. The specified items include and relate only to real property in the leased premises. Tenant is responsible for the repair and maintenance of its personal property. *(Check all that apply.)*

	N/A	Landlord	Tenant
(1) Foundation, exterior walls, roof, and other structural components	☐	☒	☐
(2) Glass and windows	☐	☐	☒
(3) Fire protection equipment and fire sprinkler systems	☐	☐	☒
(4) Exterior & overhead doors, including closure devices, molding, locks, and hardware	☐	☐	☒
(5) Grounds maintenance, including landscaping and irrigation systems	☐	☒	☐
(6) Interior doors, including closure devices, frames, molding, locks, and hardware	☐	☐	☒
(7) Parking areas and walks	☐	☒	☐
(8) Plumbing systems, drainage systems and sump pumps	☐	☐	☒
(9) Electrical systems, mechanical systems	☐	☐	☒
(10) Ballast and lamp replacement	☐	☐	☒
(11) Heating, Ventilation and Air Conditioning (HVAC) systems	☐	☐	☒
(12) Signs and lighting:			
(a) Pylon	☒	☐	☐
(b) Facia	☐	☐	☒
(c) Monument	☐	☒	☐
(d) Door/Suite	☐	☐	☒
(e) Other: _____	☒	☐	☐
(13) Extermination and pest control, excluding wood-destroying insects	☐	☐	☒
(14) Fences and Gates	☒	☐	☐
(15) Storage yards and storage buildings	☒	☐	☐
(16) Wood-destroying insect treatment and repairs	☐	☒	☐
(17) Cranes and related systems	☒	☐	☐
(18) _____		☐	☐
(19) _____		☐	☐
(20) All other items and systems		☐	☒

D. Repair Persons: Repairs must be completed by trained, qualified, and insured repair persons.

E. HVAC Service Contract: If Tenant maintains the HVAC system under Paragraph 15C(11), Tenant ☐ is ☒ is not required to maintain, at its expense, a regularly scheduled maintenance and service contract for the HVAC system. The maintenance and service contract must be purchased from a HVAC maintenance company that regularly provides such contracts to similar properties. If Tenant fails to maintain a required HVAC maintenance and service contract in effect at all times during this lease, Landlord may do so and Tenant will reimburse Landlord for the expense of such maintenance and service contract or Landlord may exercise Landlord's remedies under Paragraph 20.

F. Common Areas: Landlord will maintain any common areas in the Property in a manner as Landlord determines to be in the best interest of the Property. Landlord will maintain any elevator and signs in the common area. Landlord may change the size, dimension, and location of any common areas, provided that such change does not materially impair Tenant's use and access to the leased premises. Tenant has the non-exclusive license to use the common areas in compliance with Landlord's rules and regulations. Tenant may not solicit any business in the common areas or interfere with any other person's right to use the common areas. This paragraph does not apply if Paragraph 2A(2) applies.

G. Notice of Repairs: Tenant must promptly notify Landlord of any item that is in need of repair and that is Landlord's responsibility to repair. All requests for repairs to Landlord must be in writing.

H. Failure to Repair: Landlord must make a repair for which Landlord is responsible within a reasonable period of time after Tenant provides Landlord written notice of the needed repair. If Tenant fails to repair or maintain an item for which Tenant is responsible within 10 days after Landlord provides Tenant written notice of the needed repair or maintenance, Landlord may: (1) repair or maintain the item, without liability for any damage or loss to Tenant, and Tenant must immediately reimburse Landlord for the cost to repair or maintain; or (2) exercise Landlord's remedies under Paragraph 20.

16. ALTERATIONS:

A. Tenant may not alter (including making any penetrations to the roof, exterior walls or foundation), improve, or add to the Property or the leased premises without Landlord's written consent. Landlord will not unreasonably withhold consent for the Tenant to make reasonable non-structural alterations, modifications, or improvements to the leased premises.

B. Tenant may not alter any locks or any security devices on the Property or the leased premises without Landlord's consent. If Landlord authorizes the changing, addition, or rekeying of any locks or other security devices, Tenant must immediately deliver the new keys and access devices to Landlord.

C. If a governmental order requires alteration or modification to the leased premises, the party obligated to maintain and repair the item to be modified or altered as designated in Paragraph 15 will, at its expense, modify or alter the item in compliance with the order and in compliance with Paragraphs 16A and 17.

D. Any alterations, improvements, fixtures or additions to the Property or leased premises installed by either party during the term of this lease will become Landlord's property and must be surrendered to Landlord at the time this lease ends, except for those fixtures Landlord requires Tenant to remove under Paragraph 11 or 14 or if the parties agree otherwise in writing.

17. LIENS: Tenant may not do anything that will cause the title of the Property or leased premises to be encumbered in any way. If Tenant causes a lien to be filed against the Property or leased premises, Tenant will within 20 days after receipt of Landlord's demand: (1) pay the lien and have the lien released of record; or (2) take action to discharge the lien. Tenant will provide Landlord a copy of any release Tenant obtains pursuant to this paragraph.

18. LIABILITY: To the extent permitted by law, Landlord is NOT responsible to Tenant or Tenant's employees, patrons, guests, or invitees for any damages, injuries, or losses to person or property caused by:

A. an act, omission, or neglect of: Tenant; Tenant's agent; Tenant's guest; Tenant's employees; Tenant's patrons; Tenant's invitees; or any other tenant on the Property;

B. fire, flood, water leaks, ice, snow, hail, winds, explosion, smoke, riot, strike, interruption of utilities, theft, burglary, robbery, assault, vandalism, other persons, environmental contaminants, or other occurrences or casualty losses.

19. **INDEMNITY:** Each party will indemnify and hold the other party harmless from any property damage, personal injury, suits, actions, liabilities, damages, cost of repairs or service to the leased premises or Property, or any other loss caused, negligently or otherwise, by that party or that party's employees, patrons, guests, or invitees.

20. **DEFAULT:**

A. If Landlord fails to comply with this lease within 30 days after Tenant notifies Landlord of Landlord's failure to comply, Landlord will be in default and Tenant may seek any remedy provided by law. If, however, Landlord's non-compliance reasonably requires more than 30 days to cure, Landlord will not be in default if the cure is commenced within the 30-day period and is diligently pursued.

B. If Landlord does not actually receive at the place designated for payment any rent due under this lease within 5 days after it is due, Tenant will be in default. If Tenant fails to comply with this lease for any other reason within 10 days after Landlord notifies Tenant of its failure to comply, Tenant will be in default.

C. If Tenant is in default, Landlord may, with at least 3 days written notice to Tenant: (i) terminate this lease, or (ii) terminate Tenant's right to occupy the leased premises without terminating this lease and may accelerate all rents which are payable during the remainder of this lease or any renewal period. Landlord will attempt to mitigate any damage or loss caused by Tenant's breach by using commercially reasonable means. If Tenant is in default, Tenant will be liable for:
(1) any lost rent;
(2) Landlord's cost of reletting the leased premises, including brokerage fees, advertising fees, and other fees necessary to relet the leased premises;
(3) repairs to the leased premises for use beyond normal wear and tear;
(4) all Landlord's costs associated with eviction of Tenant, such as attorney's fees, court costs, and prejudgment interest;
(5) all Landlord's costs associated with collection of rent such as collection fees, late charges, and returned check charges;
(6) cost of removing any of Tenant's equipment or fixtures left on the leased premises or Property;
(7) cost to remove any trash, debris, personal property, hazardous materials, or environmental contaminants left by Tenant or Tenant's employees, patrons, guests, or invitees in the leased premises or Property;
(8) cost to replace any unreturned keys or access devices to the leased premises, parking areas, or Property;
(9) any other recovery to which Landlord may be entitled under this lease or under law.

21. **ABANDONMENT, INTERRUPTION OF UTILITIES, REMOVAL OF PROPERTY, AND LOCKOUT:** Chapter 93 of the Texas Property Code governs the rights and obligations of the parties with regard to: (a) abandonment of the leased premises; (b) interruption of utilities; (c) removal of Tenant's property; and (d) "lock-out" of Tenant.

22. **HOLDOVER:** If Tenant fails to vacate the leased premises at the time this lease ends, Tenant will become a tenant-at-will and must vacate the leased premises immediately upon receipt of demand from Landlord. No holding over by Tenant, with or without the consent of Landlord, will extend this lease. Tenant will indemnify Landlord ~~and any prospective tenants~~ for any and all damages caused by the holdover. Rent for any holdover period will be 150% of the base monthly rent plus any additional rent calculated on a daily basis and will be immediately due and payable daily without notice or demand.

23. LANDLORD'S LIEN AND SECURITY INTEREST: To secure Tenant's performance under this lease, Tenant grants to Landlord a lien and security interest against all of Tenant's nonexempt personal property that is in the leased premises or on the Property. This lease is a security agreement for the purposes of the Uniform Commercial Code. Landlord may file a financing statement to perfect Landlord's security interest under the Uniform Commercial Code.

24. ASSIGNMENT AND SUBLETTING: Landlord may assign this lease to any subsequent owner of the Property. Tenant may not assign this lease or sublet any part of the leased premises without Landlord's written consent. An assignment of this lease or subletting of the leased premises without Landlord's written consent is voidable by Landlord. If Tenant assigns this lease or sublets any part of the leased premises, Tenant will remain liable for all of Tenant's obligations under this lease regardless if the assignment or sublease is made with or without the consent of Landlord.

25. RELOCATION:

☐ A. By providing Tenant with not less than 90 days advanced written notice, Landlord may require Tenant to relocate to another location in the Property, provided that the other location is equal in size or larger than the leased premises then occupied by Tenant and contains similar leasehold improvements. Landlord will pay Tenant's reasonable out-of-pocket moving expenses for moving to the other location. "Moving expenses" means reasonable expenses payable to professional movers, utility companies for connection and disconnection fees, wiring companies for connecting and disconnecting Tenant's office equipment required by the relocation, and printing companies for reprinting Tenant's stationary and business cards. A relocation of Tenant will not change or affect any other provision of this lease that is then in effect, including rent and reimbursement amounts, except that the description of the suite or unit number will automatically be amended.

☒ B. Landlord may not require Tenant to relocate to another location in the Property without Tenant's prior consent.

26. SUBORDINATION:

A. This lease and Tenant's leasehold interest are and will be subject, subordinate, and inferior to:
(1) any lien, encumbrance, or ground lease now or hereafter placed on the leased premises or the Property that Landlord authorizes;
(2) all advances made under any such lien, encumbrance, or ground lease;
(3) the interest payable on any such lien or encumbrance;
(4) any and all renewals and extensions of any such lien, encumbrance, or ground lease;
(5) any restrictive covenant affecting the leased premises or the Property; and
(6) the rights of any owners' association affecting the leased premises or Property.

B. Tenant must, on demand, execute a subordination, attornment, and non-disturbance agreement that Landlord may request that Tenant execute, provided that such agreement is made on the condition that this lease and Tenant's rights under this lease are recognized by the lien-holder.

27. ESTOPPEL CERTIFICATES & FINANCIAL INFORMATION:

A. Within 10 days after receipt of a written request from Landlord, Tenant will execute and deliver to Landlord an estoppel certificate that identifies the terms and conditions of this lease.

B. Within 30 days after receipt of a written request from Landlord, Tenant will provide to Landlord Tenant's current financial information (balance sheet and income statement). Landlord may request the financial information no more frequently than once every 12 months.

28. CASUALTY LOSS:

A. Tenant must immediately notify Landlord of any casualty loss in the leased premises. Within 20 days after receipt of Tenant's notice of a casualty loss, Landlord will notify Tenant if the leased premises are less than or more than 50% unusable, on a per square foot basis, and if Landlord can substantially restore the leased premises within 120 days after Tenant notifies Landlord of the casualty loss.

B. If the leased premises are less than 50% unusable and Landlord can substantially restore the leased premises within 120 days after Tenant notifies Landlord of the casualty, Landlord will restore the leased premises to substantially the same condition as before the casualty. If Landlord fails to substantially restore within the time required, Tenant may terminate this lease.

C. If the leased premises are more than 50% unusable and Landlord can substantially restore the leased premises within 120 days after Tenant notifies Landlord of the casualty, Landlord may: (1) terminate this lease; or (2) restore the leased premises to substantially the same condition as before the casualty. If Landlord chooses to restore and does not substantially restore the leased premises within the time required, Tenant may terminate this lease.

D. If Landlord notifies Tenant that Landlord cannot substantially restore the leased premises within 120 days after Tenant notifies Landlord of the casualty loss, Landlord may: (1) choose not to restore and terminate this lease; or (2) choose to restore, notify Tenant of the estimated time to restore, and give Tenant the option to terminate this lease by notifying Landlord within 10 days.

E. If this lease does not terminate because of a casualty loss, rent will be reduced from the date Tenant notifies Landlord of the casualty loss to the date the leased premises are substantially restored by an amount proportionate to the extent the leased premises are unusable.

29. CONDEMNATION: If after a condemnation or purchase in lieu of condemnation the leased premises are totally unusable for the purposes stated in this lease, this lease will terminate. If after a condemnation or purchase in lieu of condemnation the leased premises or Property are partially unusable for the purposes of this lease, this lease will continue and rent will be reduced in an amount proportionate to the extent the leased premises are unusable. Any condemnation award or proceeds in lieu of condemnation are the property of Landlord and Tenant has no claim to such proceeds or award. Tenant may seek compensation from the condemning authority for its moving expenses and damages to Tenant's personal property.

30. ATTORNEY'S FEES: Any person who is a prevailing party in any legal proceeding brought under or related to the transaction described in this lease is entitled to recover prejudgment interest, reasonable attorney's fees, and all other costs of litigation from the nonprevailing party.

31. REPRESENTATIONS:

A. Tenant's statements in this lease and any application for rental are material representations relied upon by Landlord. Each party signing this lease represents that he or she is of legal age to enter into a binding contract and is authorized to sign the lease. If Tenant makes any misrepresentation in this lease or in any application for rental, Tenant is in default.

B. Landlord is not aware of any material defect on the Property that would affect the health and safety of an ordinary person or any environmental hazard on or affecting the Property that would affect the health or safety of an ordinary person, except: Landlord is not aware of any material defects to the best of his knowledge. Landlord has fee simple ownership of the property.

C. Each party and each signatory to this lease represents that: (1) it is not a person named as a Specially Designated National and Blocked Person as defined in Presidential Executive Order 13224; (2) it is not acting, directly or indirectly, for or on behalf of a Specially Designated and Blocked Person; and (3) is not arranging or facilitating this lease or any transaction related to this lease for a Specially Designated and Blocked Person. Any party or any signatory to this lease who is a Specially Designated and Blocked person will indemnify and hold harmless any other person who relies on this representation and who suffers any claim, damage, loss, liability or expense as a result of this representation.

32. BROKERS:

A. The brokers to this lease are:

Orr & Associates Real Estate			
Principal Broker	0205161 License No.	Cooperating Broker	License No.
Michael Langford			
Agent		Agent	
232 NW Tarrant Ave			
Address		Address	
Burleson, TX 76028			
(817)295-5291	(817)295-0441		
Phone	Fax	Phone	Fax
michael@orrrealestate.net			
E-Mail	0574473 License No.	E-Mail	License No.

Principal Broker: *(Check only one box)*
- [x] represents Landlord only.
- [ ] representsTenant only.
- [ ] is an intermediary between Landlord and Tenant.

Cooperating Broker represents Tenant.

B. Fees:

[x] (1) Principal Broker's fee will be paid according to: *(Check only one box).*
- [x] (a) a separate written commission agreement between Principal Broker and: [x] Landlord [ ] Tenant.
- [ ] (b) the attached Addendum for Broker's Fee.

[ ] (2) Cooperating Broker's fee will be paid according to: *(Check only one box).*
- [ ] (a) a separate written commission agreement between Cooperating Broker and: [ ] Principal Broker [ ] Landlord [ ] Tenant.
- [ ] (b) the attached Addendum for Broker's Fee.

33. ADDENDA: Incorporated into this lease are the addenda, exhibits and other information marked in the Addenda and Exhibit section of the Table of Contents. If Landlord's Rules and Regulations are made part of this lease, Tenant agrees to comply with the Rules and Regulations as Landlord may, at its discretion, amend from time to time.

34. NOTICES: All notices under this lease must be in writing and are effective when hand-delivered, sent by mail, or sent by facsimile transmission to:

Landlord at: JA-COLE
Address: PO Box 1088, Burleson, TX 76097
Phone: (817)295-5291 Fax: (817)295-0441
and a copy to: _____
Address: _____
Phone: _____ Fax: _____
[ ] Landlord also consents to receive notices by e-mail at: _____

Tenant at the leased premises,
and a copy to: AxoGen, ~~Inc.~~ Corporation 3631 Progress Blvd, Suite 400
Address: ~~13859 Progress Blvd., Suite 100,~~ Alachua, FL 32615
Phone: (352) 262-0773 Fax: _____
☐ Tenant also consents to receive notices by e-mail at: _____

35. SPECIAL PROVISIONS:

Principal Broker has part ownership in Ja-Cole the Landlord

Landlord agrees to have all Doors, Lighting and ceiling titles in good working order prior to tenants move in.

Landlord agrees to Guarantee HVAC system for 6 months for direct damage only as long as HVAC problem is not caused by tenant, Landlord to assign to tenant the benefit of any manufacturer warranty on systems and equipment located within or serving the leased premises.

Landlord agrees to work with Tenant to obtain Certificate of Occupancy.

Landlord agrees to give Tenant $7,500 for Tenant Finish Out.

36. AGREEMENT OF PARTIES:

A. Entire Agreement: This lease contains the entire agreement between Landlord and Tenant and may not be changed except by written agreement.

B. Binding Effect: This lease is binding upon and inures to the benefit of the parties and their respective heirs, executors, administrators, successors, and permitted assigns.

C. Joint and Several: All Tenants are jointly and severally liable for all provisions of this lease. Any act or notice to, or refund to, or signature of, any one or more of the Tenants regarding any term of this lease, its renewal, or its termination is binding on all Tenants.

D. Controlling Law: The laws of the State of Texas govern the interpretation, performance, and enforcement of this lease.

E. Severable Clauses: If any clause in this lease is found invalid or unenforceable by a court of law, the remainder of this lease will not be affected and all other provisions of this lease will remain valid and enforceable.

F. Waiver: Landlord's delay, waiver, or non-enforcement of acceleration, contractual or statutory lien, rental due date, or any other right will not be deemed a waiver of any other or subsequent breach by Tenant or any other term in this lease.

G. Quiet Enjoyment: Provided that Tenant is not in default of this lease, Landlord covenants that Tenant will enjoy possession and use of the leased premises free from material interference.

H. Force Majeure: If Landlord's performance of a term in this lease is delayed by strike, lock-out, shortage of material, governmental restriction, riot, flood, or any cause outside Landlord's control, the time for Landlord's performance will be abated until after the delay.

I. Time: Time is of the essence. The parties require strict compliance with the times for performance.

Brokers are not qualified to render legal advice, property inspections, surveys, engineering studies, environmental assessments, tax advice, or compliance inspections. The parties should seek experts to render such services. READ THIS LEASE CAREFULLY. If you do not understand the effect of this Lease, consult your attorney BEFORE signing.

Landlord: Ja-Cole

By: _____

By (signature): _____
Printed Name: Rob Cole
Title: President

By: _____

By (signature): _____
Printed Name: _____
Title: _____

Tenant: AxoGen, ~~Inc.~~ Corporation

By: _____

By (signature): _____
Printed Name: Karen Zaderej
Title: CEO

By: _____

By (signature): _____
Printed Name: _____
Title: _____

TEXAS ASSOCIATION OF REALTORS®

COMMERCIAL LEASE ADDENDUM FOR RIGHT OF FIRST REFUSAL

ADDENDUM TO THE COMMERCIAL LEASE BETWEEN THE UNDERSIGNED PARTIES CONCERNING THE LEASED PREMISES AT 300 Boone Rd, Burleson, TX 76028

A. "Additional space" means all or part of the following areas along with all its improvements:

☐ (1) the following floors in the Property: _____.

☒ (2) the following suites in the Property, presently identified, as: 300 Boone Rd. Suite A-1.

☐ (3) _____.

The parties agree that the rentable area of the additional space may not equal the actual or useable area within the additional space and may include an allocation of common areas in the Property.

B. If Landlord receives an acceptable written offer from another person to lease the additional space at a time when the above-referenced lease is in effect, Landlord will notify Tenant of the offer. Not later than 7 days after Tenant receives Landlord's notice of the offer, Tenant may notify Landlord that Tenant will lease the additional space identified in the offer under the same terms and conditions in the offer. If Tenant notifies Landlord that Tenant will lease the additional space identified in the offer, Tenant must execute a written lease for the additional space identified in the offer or amend the above-referenced lease, as Landlord may require, not later than 7 days after Tenant receives Landlord's notice. If Tenant fails to timely comply with this paragraph, Landlord may lease the additional space identified in the offer to the person who made the offer. If Tenant does not exercise its right to lease the additional space identified in the offer and Landlord does not lease the additional space identified in the offer to the person who made the offer, Tenant ☐ does ☒ does not retain the right of refusal under this addendum for any subsequent offers Landlord receives for the additional space identified in the offer.

C. An offer for part of the additional space affects the parties' rights and obligations only to the part of the additional space identified in the offer. Rights and obligations to parts of the additional space not identified in the offer are not affected. An offer to renew a lease for the additional space from a tenant occupying the additional space is not an offer to lease the additional space for the purposes of this addendum.

D. Special Provisions:

Orr 504 Timber Ct. Burleson, TX 76028
Phone: 817.295.2238 Fax: 817.265.0441 Michael Langford Brent Huskins

Commercial Lease Addendum for Right of Refusal concerning 300 Boone Rd, Burleson, TX 76028

Landlord: JaCole

By: _____

By (signature): _____
Printed Name: Rob Orr
Title: President

By: _____

By (signature): _____
Printed Name: _____
Title: _____

Tenant: ~~AxoGen, Inc.~~ Corporation

By: _____

By (signature): _____
Printed Name: Karen Laderej
Title: CEO

By: _____

By (signature): _____
Printed Name: _____
Title: _____

Brent Huskins

AMENDMENT NO. 1 TO BOONE BUSINESS PARK COMMERCIAL LEASE

This Amendment No. 1 to the Commercial Lease (this "Amendment"), effective as of November 12, 2013 (the "Amendment Date"), is entered into by and between JA-COLE ("***JA-COLE***") having a place of business at 232 NW Tarrant Avenue, Burleson, TX 76028, and AxoGen Corporation, a Delaware corporation having a place of business at 13859 Progress Blvd, Alachua, FL, 32615 ("***AxoGen***"). Capitalized terms used herein and not otherwise defined shall have the meanings given to such terms in the Lease Agreement (as defined below).

WITNESSETH

WHEREAS, the Parties have heretofore entered into the Commercial Lease Agreement of even date herewith (the "Lease Agreement"); and

WHEREAS, the Parties wish to amend the Lease Agreement in certain respects as described herein.

NOW, THEREFORE, the Parties hereby agree as follows:

1. **Amendments.**

   (a) The last sentence of Section 8 (B) of the Lease Agreement will be replaced in its entirety with the following:

   "If the insurance coverage is renewed or changes as to any material financial terms at any time this lease is in effect, Tenant must, not later than 30 days after the renewal or material change, provide Landlord a copy of an insurance certificate evidencing the renewal or material change."

   (b) The wording "Tenants use of the leased premises" in the first sentence of Section 8 (E) of the Lease Agreement will be replaced in its entirety with "Tenant's specific method and manner of use of the leased premises".

   (c) After the wording "Landlord's rules or regulations" in Section 10 (A)(3) of the Lease Agreement the following will be added "as provided to Tenant with this Lease Agreement and published from time to time from, and as applied in a uniform and nondiscriminatory manner as among all tenants of Property".

   (d) The second sentence of Section 15 (H) of the Lease Agreement will be replaced in its entirety with the following:

   "If Tenant fails to repair or maintain an item for which Tenant is responsible within 30 days after Landlord provides Tenant written notice of the needed repair or maintenance, or, if such condition reasonably requires more than 30 days to cure, Tenant will not be in default if the cure is commenced within the 30-day period and is diligently pursued.

2. **Assignment and Subletting.** Notwithstanding anything to the contrary contained in the Lease Agreement, including Section 24 thereof, Tenant may, without Landlord's consent,

assign the lease or sublet any part of the leased premises to an entity controlling, controlled by, under common control with, or acquiring all or substantially all the assets of Tenant.

3. **Counterparts.** This Amendment may be executed in counterparts with the same effect as if both Parties had signed the same documents. All such counterparts shall be deemed an original, shall be construed together, and shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be duly executed as of the day and year first above written.

AXOGEN CORPORATION.

By: _____
Name: Karen Zaderej
Title: Chief Executive Officer

JA-COLE

By: _____
Name:
Title:

TEXAS ASSOCIATION OF REALTORS®

COMMERCIAL LANDLORD'S RULES AND REGULATIONS

REGARDING THE COMMERCIAL LEASE CONCERNING THE LEASED PREMISES AT 300 Boone Rd, Burleson, TX 76028

NOTICE: These rules and regulations are adopted to maintain and enhance the safety and appearance of the Property. From time to time Landlord, at its discretion, may amend these rules and regulations for the purposes for which they were adopted. Under the above-referenced lease, Tenant agrees to comply with these rules and regulations as they may be amended. Exceptions or waivers must be authorized by Landlord in writing. "Property" means the building or complex in which the leased premises are located, inclusive of any common areas, drives, parking areas, and walks, and landscaped areas.

A. Goods, merchandise, equipment, or any personal property may not be stored on the Property, except for inventory within the leased premises necessary for Tenant's normal business operations.

B. Food is not permitted on the Property, except as inventory for sale and for a small amount of food for Tenant's personal consumption.

C. Other than those provided by Landlord or specifically authorized by Landlord, no vending machines are permitted on the Property.

D. The Property may not be used for lodging or sleeping quarters in any manner.

E. Unless authorized by law or the lease, no animals may be brought or kept on the Property.

F. No obstruction or interference that impedes use of the common areas, walks, drives, loading areas, parking areas, corridors, hallways, vestibules, and stairs is permitted on the Property.

G. Persons parking on the Property must comply with all posted signs and directions regulating the parking areas.

H. No flammable, toxic, noxious, or hazardous materials may be kept on the Property except for over-the-counter cleaning materials kept in enclosed storage closets or cabinets.

I. Tenants moving in or out of the Property must use only the service entrances and service elevators during the move. All moves must be made at times that do not cause inconvenience in the normal use of the Property.

J. Deliveries and shipping of goods and merchandise in or out of the Property must be made only through the service entrances, service elevators, loading docks, or other designated shipping and receiving areas. Shipments and deliveries must be made at times that do not cause inconvenience to tenants or patrons on the Property.

K. Leased premises must be kept clean and free of debris. Trash must be deposited into appropriate receptacles. Trash receptacles controlled by Tenant must not be allowed to overflow, attract rodents or vermin, or emit odors.

Orr 504 Timber Ct. Burleson, TX 76028
Phone: 817.295.2238 Fax: 817.265.0441 Michael Langford Brent Huskins

L. Repair requests must be submitted to Landlord in writing in compliance with the lease.

M. No modification to the Property and leased premises may be made unless authorized by Landlord, in writing, or permitted by the lease.

N. No illegal or offensive activity is permitted on the Property nor is any activity that constitutes a nuisance or interferes with the rights of other tenants.

O. Unless specifically authorized by Landlord, no solicitation or business operations are permitted in the common areas.

P. Other:

TEXAS ASSOCIATION OF REALTORS®

COMMERCIAL LEASE AMENDMENT

AMENDMENT TO THE COMMERCIAL LEASE BETWEEN THE UNDERSIGNED PARTIES CONCERNING THE LEASED PREMISES AT 300 Boone Rd, Burleson, TX 76028

Effective on December 10, 2013, Landlord and Tenant amend the above-referenced lease as follows:

❑ A. Leased Premises: The suite or unit number identified in Paragraph 2A(1) is:

❑ (1) changed to _____.

❑ (2) contains approximately _____ square feet.

❑ B. Term:

❑ (1) The length of the term stated in Paragraph 3A is changed to _____ months and _____ days.

❑ (2) The Commencement Date stated in Paragraph 3A is changed to _____.

❑ (3) The Expiration Date stated in Paragraph 3A is changed to _____.

❑ C. Rent: The amount of the base monthly rent specified in Paragraph 4A is changed to:

$ _____ from _____ to _____;
$ _____ from _____ to _____;
$ _____ from _____ to _____;
$ _____ from _____ to _____;
$ _____ from _____ to _____;
$ _____ from _____ to _____.

❑ D. Security Deposit: The amount of the security deposit in Paragraph 5 is changed to $ _____.

❑ E. Maintenance and Repairs: The following item(s) specified in the identified subparagraph of Paragraph 15C will be maintained by the party designated below:

Para. No.	Description	Responsible Party
_____	_____	❑ N/A ❑ Landlord ❑ Tenant
_____	_____	❑ N/A ❑ Landlord ❑ Tenant
_____	_____	❑ N/A ❑ Landlord ❑ Tenant
_____	_____	❑ N/A ❑ Landlord ❑ Tenant

❑ F. Parking:

❑ (1) Common Parking: The number of vehicles identified in Paragraph A(1) of the Commercial Lease Parking Addendum is changed to _____ vehicles.

❑ (2) Restricted Common Parking for Tenants: The number of vehicles identified in Paragraph A(2) of the Commercial Lease Parking Addendum is changed to _____ vehicles.

Orr 504 Timber Ct. Burleson, TX 76028
Phone: 817.295.2238 Fax: 817.265.0441 Michael Langford

Boone Rd A2 & A3

Amendment to Commercial Lease concerning 300 Boone Rd, Burleson, TX 76028

☐ (3) Assigned Parking: Tenant's assigned parking areas identified in Paragraph A(3) of the Commercial Lease Parking Addendum is changed to _____.

☐ (4) Parking Rental: The amount of rent identified in Paragraph B of the Commercial Lease Parking Addendum is changed to $ _____.

☒ G. Other: Paragraph(s) _____ are changed to read *(cite specific paragraphs and copy the applicable paragraphs verbatim, making any necessary changes)*:

Landlord and Tenant agree that Tenant will put in a concrete Pad in back for generator size of ~~164'L x 65'W x 6'H~~. And that tenant is responsible at tenants expense to remove concrete pad upon move out and fix any damage to property. / reasonable

16'L x 8'W x 6'H

DT BBF

1/30/2014 January 30, 2014

Landlord: Ja-Cole

By: _____

By (signature): _____
Printed Name: _____
Title: PRESIDENT Date: 1-16-2014

By: _____

By (signature): _____
Printed Name: _____
Title: _____ Date: _____

Tenant: AxoGen Corporation

By: _____

By (signature): _____
Printed Name: Greg Freitag
Title: CFO & General Counsel Date: January 16, 2014

By: _____

By (signature): _____
Printed Name: _____
Title: _____ Date: _____

EXHIBIT 21.1

SUBSIDIARY OF AXOGEN, INC.

As of December 31, 2013, AxoGen Inc.'s sole subsidiary was AxoGen Corporation, a Delaware corporation.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of AxoGen, Inc. on Form S-8 (File No. 333-177980, effective November 14, 2011) of our report dated March 6, 2014, appearing in this annual report on form 10-K of AxoGen, Inc. as of and for the years ended December 31, 2013 and 2012.

/s/ LURIE BESIKOF LAPIDUS & COMPANY, LLP

Minneapolis, Minnesota
March 6, 2014

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Karen Zaderej, certify that:

1. I have reviewed this annual report on Form 10-K of AxoGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have;

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 6, 2014

/s/ Karen Zaderej
Karen Zaderej
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gregory G. Freitag, certify that:

1. I have reviewed this annual report on Form 10-K of AxoGen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have;

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 6, 2014

/s/ Gregory G. Freitag
Gregory G. Freitag
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES —OXLEY ACT OF 2002

In connection with the Annual Report of AxoGen, Inc. (the "Company") on Form 10-K for the year ended December 31, 2013 as filed with the Securities and Exchange Commission (the "Report"), I, Karen Zaderej, Chief Executive Officer and Gregory G. Freitag, Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Karen Zaderej
Karen Zaderej
Chief Executive Officer
March 6, 2014

/s/ Gregory G. Freitag
Gregory G. Freitag
Chief Financial Officer
March 6, 2014