

**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, 2011**

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**

(State or other jurisdiction of  
incorporation or organization)

**41-1301878**

(I.R.S. Employer  
Identification No.)

**13859 Progress Blvd., Suite 100 Alachua, FL**

(Address of principal executive offices)

**32615**

(Zip Code)

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

**Securities registered pursuant to Section 12(b) of the Act: None**

**Securities registered pursuant to Section 12(g) of the Act: Common Stock, par value \$0.01 per share**

(Title of class)

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 30, 2011, the value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$8,388,051 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 12, 2012 was 11,062,188 shares.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.



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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**

**The Merger**

On September 30, 2011, AxoGen Corporation (“AC”), a Delaware Corporation, completed its business combination with LecTec Corporation (“LecTec”), a Minnesota corporation, 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 August 9, 2011 and September 30, 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. In October 2011, AxoGen Inc. moved its corporate headquarter facilities (principal executive office) from Texarkana, Texas to 13859 Progress Blvd., Suite 100, Alachua, Florida 32615.

Unless the context otherwise requires, all references herein to “AxoGen,” “the Company,” “we,” “us” and “our” refer to AxoGen Corporation before the Merger and AxoGen, Inc. and its wholly owned subsidiary AC after the Merger, and all references to “LecTec” refer to LecTec Corporation and its business prior to the completion of the Merger and the name change.

In connection with the Merger,

- all outstanding AC convertible securities were converted into shares of AC common stock and exchanged for shares of AxoGen, Inc. common stock;
- all outstanding AC warrants expired unexercised;
- all outstanding shares of AC common stock, including those issued upon conversion of AC convertible securities, were exchanged for shares of AxoGen, Inc. common stock at a ratio of one share of AC common stock for 0.03727336 share of AxoGen, Inc. common stock;
- all outstanding options to purchase shares of AC common stock were exchanged for options to purchase shares of AxoGen, Inc. common stock at a ratio of one option to purchase shares of AC common stock for an option to purchase 0.03727336 share of AxoGen, Inc. common stock.

A total of 6,221,077 shares of the Company’s common stock were issued in share exchange, and an additional 558,267 shares of the Company’s common stock were reserved for issuance upon exercise of AC stock options which were converted into the Company’s stock options. Upon completion of the Merger, all AC securities were cancelled.

Immediately following the completion of the Merger, former AC stockholders owned approximately 56.8% of the outstanding common stock of the Company, LecTec stockholders owned approximately 39.4% of the outstanding common stock of the Company, and certain investors owned the remaining 3.8% of the outstanding common stock of the Company.

For accounting purposes, AC was identified as the acquiring entity and LecTec as the acquired entity. The Merger was accounted for using the purchase method of accounting for financial reporting purposes. The purchase method requires the identification of the acquiring entity, based on the criteria of Accounting Standards Codification 805-10-55-12, *Accounting for Business Combinations*. Under purchase accounting, the assets and liabilities of an acquired company (LecTec) as of the effective date of the acquisition were recorded at their respective estimated fair values and added to those of the acquiring company. Accordingly, the consolidated financial statements and related footnote disclosures presented for periods prior to the Merger are those of AC alone. The consolidated Statement of Operations for the years ended December 31, 2011 and 2010 include the operations and cash flows of AC through September 30, 2011 and the consolidated operations and cash flows of

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the Company subsequent to the Merger. The common stock of AC has been retrospectively adjusted to reflect the exchange ratio of one share of AC common stock for 0.03727336 share of the Company's common shares as established in the Merger Agreement. Historical results for LecTec prior to the Merger are not included in the Company's consolidated financial statements.

LecTec was organized in 1977 as a Minnesota Corporation and went public in December 1986. Prior to the Merger it was an intellectual property ("IP") licensing and holding company. LecTec held multiple domestic and international patents based on its original hydrogel patch technology and filed patent applications on a hand sanitizer patch. LecTec also had a licensing agreement ("Novartis Agreement") with Novartis Consumer Health, Inc., under which the Company continues to receive royalties from time to time based upon a percentage of Novartis' net sales of licensed products. LecTec took legal action to protect its IP and settled all of its litigation prior to the Merger. The Company continues to hold LecTec IP and evaluate its potential future value, however, such value, if any, is not expected to be material.

### **General**

The Company is a regenerative medicine company with a portfolio of proprietary products and technologies for peripheral nerve reconstruction and regeneration. 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 reconstruction and regeneration of peripheral nerves, the Company has developed and licensed technologies which are used in its products. Its product portfolio includes Avance® Nerve Graft, which the Company believes is the first and only commercially available processed allograft nerve for bridging nerve discontinuities (a gap created when the nerve is severed), AxoGuard® Nerve Connector, a coaptation aid allowing for close approximation of severed nerves, and AxoGuard® Nerve Protector, a bioscaffold used to reinforce a coaptation site, wrap a partially severed nerve or isolate and protect nerve tissue.

AxoGen's products are used by surgeons during challenging surgical interventions to repair a wide variety of traumatic nerve injuries ranging from a simple laceration of a finger to a complex brachial plexus case. The Avance® Nerve Graft, unlike hollow-tube conduits, provides surgeons with the essential three-dimensional structure of a natural nerve for bridging nerve discontinuities without the complication, expense and morbidity of autografting a nerve. Additionally, the Avance® Nerve Graft has product and sales synergies with the 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 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.

The primary driver of sustained growth in the regenerative medical product market is continued favorable efficacy as compared to autograft and synthetic medical products, and a wider understanding of this advantage by practitioners. Autografting requires a secondary recovery procedure to remove tissue from another location of the body to repair the injured area and can result in loss of function at the site of donation. Autografting may also be costly and time consuming, as and may result in complications such as infection. Alternatives to autograft include 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 reconstruction.

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Regenerative medicine products typically consist of:

- i. A scaffold or ExtraCellular Matrix (“ECM”) to support the cells and/or provide the architecture of the tissue: and/or
- ii. Cells to regenerate or recellularize the scaffold.

AxoGen provides a simple solution for the reconstruction of peripheral nerves; its 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, resulting in a loss of 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 alleviating compression and tension on the nerve.

### ***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 conducted by the Centers of Disease Control, the Canadian Institute for Health Information and various academic centers, each year in the U.S. more than 700,000 people suffer traumatic injuries to peripheral nerves resulting in approximately 250,000 nerve repair procedures in the U.S. annually.

Beyond traumatic injury to nerves, nerve damage also occurs due to surgical intervention. Some of these nerve cases occur after dental or oral surgery when patients lose sensory and taste function in the mouth, including complications from third molar extractions and dental implants. Also, nerves that support erectile function may be injured or removed following a surgical prostatectomy to remove prostate cancer. 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.

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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 can 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, to repair a severed nerve gap, surgeons have relied on an autotransplantation (autologous grafting or autograft). In 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 – fix the damaged nerve while creating a 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.

Drawbacks of autografts eventually led to the development of hollow-tube conduits, or 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 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. Additionally, hollow-tube conduits do not provide familiar handling characteristics to the surgeon and in some instances are contraindicated for use in infected wound beds. 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. However, with surgeons seeking alternatives to autografts, the annual number of procedures using hollow-tube conduits has grown. AxoGen believes this demand has resulted in hollow-tube conduits being used for gap lengths where their likelihood of effectiveness is greatly diminished.

The growth of hollow-tube conduit use demonstrates there is market demand for products that do not have the drawbacks of autografting. However, as stated above, the shortcomings of 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 complication, expense and morbidity of autografting a nerve. AxoGen believes its product portfolio meets this market need.

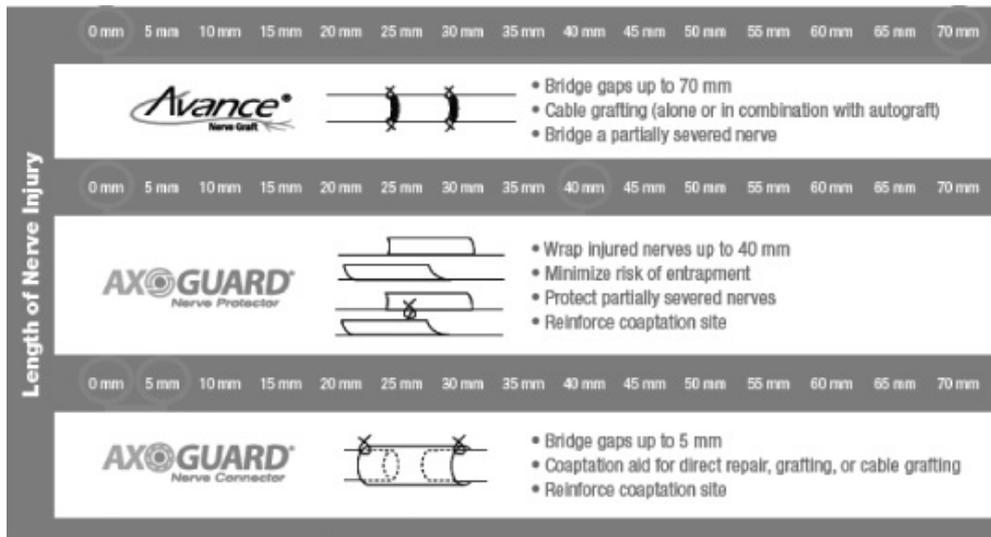
### **AxoGen's Product Portfolio**

#### *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 for nerve gaps up to 70mm in length. AxoGuard® Nerve Connector is the surgical solution for nerve gaps of less than 5mm in length, or where surgeons wish to provide additional protection to suture sites when autograft or Avance Nerve® Graft are used. AxoGuard® Nerve Protector completes the product portfolio by allowing a protective wrap in cases of nerves damaged by compression, or where the surgeon wants to protect and isolate the nerve during the healing process after surgery. This product portfolio, depicted below, provides surgeons off-the-shelf solutions for a wide variety of peripheral nerve injuries.

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The following table provides a summary of certain peripheral nerve injuries for which AxoGen products are used:



**Avance® Nerve Graft**

Avance® Nerve Graft is a processed peripheral nerve allograft intended for the reconstruction of peripheral nerve discontinuities (gaps in a severed nerve) 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 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 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 scaffold, basal lamina tubular structure, 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.

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 only commercially available processed nerve allograft for bridging nerve discontinuities.

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

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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:

- Applies to long and short gap nerve injuries;
- Decellularized and cleansed extracellular matrix that remodels into patient's own tissue;
- Provides a three-dimensional bioscaffold for bridging a nerve gap;
- Structurally supports the body's own regeneration process;
- No donor-nerve surgery, therefore no loss of donor nerve function;
- Handles similar to an autograft, and is flexible and pliable;
- Alleviates tension at the repair site;
- Three year shelf life; and
- Supplied sterile in lengths of up to 70 mm and diameters up to 5 mm.

### ***AxoGuard® Nerve Connector***

AxoGuard® Nerve Connector is coaptation aid that allows for the close approximation of severed nerves. AxoGuard® Nerve Connector is a tubular, multilaminar extracellular matrix with an open lumen where the severed nerve ends are placed. Typically, the AxoGuard® Nerve Connector is used to align and connect nerves 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 to remodel and form a tissue similar to the nerve epineurium. AxoGuard® Nerve Connector is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs.

AxoGuard® Nerve Connector can be used to:

- Bridge gaps up to 5 mm;
- Aid coaptation in direct repair, grafting, or cable grafting repairs; and
- Reinforce the coaptation site.

AxoGuard® Nerve Connector has the following advantages:

- Alleviates tension at the repair site;
- Reduces the number of required sutures (versus direct repair);
- Reduces potential for fascicular mismatch;
- Reduces the risk of neuroma by containing regenerating axons;
- Allows visualization of underlying nerve;
- Strong and flexible, easy to suture; and
- Stored at room temperature with an 18 month shelf life.

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### ***AxoGuard® Nerve Protector***

The AxoGuard® Nerve Protector is a surgical implant that provides protection for peripheral nerves. It is designed to protect and isolate the nerve during the healing process after surgery. AxoGuard® is a multilaminar extracellular matrix that separates and protects the nerve from the surrounding tissues during the healing process. 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 can be used to:

- Wrap injured nerves up to 40 mm;
- 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:

- Isolates and protects the nerve in a traumatized wound bed;
- 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;
- Reduces the risk of neuroma by containing regenerating axons;
- Strong and flexible, plus easy to suture;
- Stored at room temperature with an 18 month shelf life.

### **Tissue Recovery and Processing for Avance® Nerve Graft**

#### ***Avance® Nerve Graft Processing Overview***

Over several years, AxoGen has developed advanced and proprietary techniques to process the Avance® Nerve Graft from donated peripheral nerve tissue. The 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® Nerve Graft processing requires 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.

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### ***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 currently uses LifeNet Health, an FDA registered tissue establishment to process the peripheral nerve tissue and package the Avance® Nerve Graft product. LifeNet processes and engineers many dental, cardiovascular, spinal and orthopedic bio-implants. In March 2012, AxoGen renewed its tissue processing agreement with LifeNet Health for a one-year term. The agreement renews automatically for additional one-year terms unless terminated. Under the agreement, AxoGen pays LifeNet Health a facility fee and tissue processing service fees for each production run, and is not subject to any minimum or maximum service commitments. Either party may terminate the agreement during a renewal term with 180-day advanced written notice. AxoGen leverages the LifeNet Health Quality System and works with LifeNet Health to train and manage AxoGen employed-processors working in LifeNet's facility on the Avance® Nerve Graft. 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, 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 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 service team and product is shipped from the distribution facilities.

### ***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 ("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, suturable, 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 with AxoGen to distribute its product worldwide in the field of peripheral nerve repair, and the parties subsequently amended the agreement in March, 2012. The agreement has a seven-year initial term, renews automatically for an additional seven-year term, subject to pricing agreement, requires

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certain minimum purchases 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*

AxoGen strives to have its products be the premier choice for surgeons who treat peripheral nerve injuries. AxoGen is focused on the developing market of peripheral nerve reconstruction and regeneration and is committed to improving awareness of new peripheral nerve reconstruction options, as well as building additional scientific and clinical data to assist surgeons and patients in making informed choices. AxoGen believes this 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 Bridging Nerve Gaps*

Prior to the introduction of AxoGen's portfolio of products, surgeons had a limited number of options available for the reconstruction 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 reconstruction options based on extracellular matrix tissue. Unlike other off-the-shelf nerve reconstruction 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 its products through the 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. Initially, AxoGen will focus on plastic reconstructive surgeons and orthopedic and plastic surgeons who perform surgeries on patients suffering traumatic nerve injuries and who perform hand reconstructive surgeries. In select hospital accounts, AxoGen is also expanding into the market for the reconstruction of nerve injuries in oral surgery.

#### *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. A multicenter prospective randomized comparative pilot study of hollow tube conduits and Avance® Nerve Graft is in process. A case series in digital nerve repair has already been published and other studies have been completed. Case series in brachial plexus, military trauma, prostate cancer and breast reconstruction 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 for National Coverage*

As of the date of this Form 10-K, AxoGen provides full sales and distribution services through both a direct sales force of 16 representatives and a team of 21 independent distributors. AxoGen provides support and resources for independent distributors and is increasing its direct sales force in selected 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.

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### ***AxoGen Strengths***

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

#### Established Nerve Repair Reconstruction and Regeneration Expertise

AxoGen has made a significant investment in understanding nerve reconstruction and regeneration through interaction with leading academic centers throughout the United States and by building 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 commercial team 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 peripheral nerve reconstruction. 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* contains an article summarizing the RANGER study results to date, reporting over 87% meaningful recovery in sensory, motor and mixed nerve injuries treated with the Avance® Nerve Graft (Published Microsurgery DOI: 10.1002/micr.20975). 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.

### ***International Opportunity for Product Sales***

AxoGen currently focuses on the U.S. market, with additional Avance® Nerve Graft foreign sales in Canada, Italy and Switzerland. The need for reconstruction 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 EU-wide approval for the Avance® Nerve Graft or the AxoGuard® products and is reviewing a regulatory strategy for Europe and other international regions. AxoGen does not anticipate significant penetration beyond its current markets in the near future.

## **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. 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, 2011 and 2010, AxoGen spent approximately \$697,000 and \$436,000, 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

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products may be offered in the future that may compete with AxoGen's products. Currently, AxoGen competes primarily against autograft and hollow-tube conduits based on product features and performance, price, surgical application, ease of use and healthcare provider education. AxoGen's major competitors in hollow-tube conduits are the following companies:

- Integra LifeSciences Holding Corporation (NASDAQ: IART) ("Integra"). Integra offers NeuraGen, a hollow bovine collagen conduit and NeuraWrap, a nerve repair conduit also made from bovine collagen;
- Baxter International, Inc. (NYSE: BAX) ("Baxter"). Baxter acquired Synovis that offered the Neurotube, which is a hollow conduit comprised of polyglycolic acid; and
- Stryker Corporation (NYSE: SYK), ("Stryker"). Stryker offers the NeuroMatrix and Neuroflex products, both of which are hollow conduits derived from bovine collagen.

AxoGen believes that surgeons use Avance® Nerve Graft because, unlike hollow-tube conduits, it provides them with the natural three-dimensional structure of a typical nerve for bridging nerve discontinuities (severed nerves) without the complications, expense and morbidity of autografting a nerve. 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 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®, 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.

## **Intellectual Property**

### *Overview*

AxoGen relies on a combination of patent, trademark, trade secret, and copyright, as well as other 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"), the University of Texas at Austin ("UTA") and Emory University ("Emory"). 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;

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- 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. Regarding the license agreement with Emory, a series of milestone payments are listed within the agreement. Particularly, the agreement includes a schedule of license maintenance fees to be paid in the event that no regulatory-related milestone payments have been paid by certain anniversary dates of the agreement, of which none has yet been met. AxoGen renegotiated the license agreement with Emory prior to any license maintenance fees coming due, but will continue to owe certain fees in the future or risk the loss of such license.

### **Patents**

As of the date of this Form 10-K, AxoGen owned or was the exclusive licensee of six issued U.S. patents, five pending U.S. patent applications, three issued international patents and nine pending international patent applications with regard to its peripheral nerve products. In Mexican cases PA/A/2004/001334, 2007/012379, 2007/012380, and 2007/012382, Notices of Allowance have been issued, and the four patents are awaiting issuance. Additionally, the granted European Patent No. EP1425390 is in the process of being validated in France, Germany, Italy, Spain, Sweden, Switzerland, and the United Kingdom. The following table illustrates the issued 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.

<b>Patent No.</b>	<b>Description</b>	<b>Estimated expiration date</b>
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 7,772,185	Materials and Methods for Promotion of Nerve Regeneration	November 18, 2023
Japan No. 4,749,667	Materials and Methods to Promote Repair of Nerve Tissue	August 13, 2022
Europe No. EP1425390	Materials and Methods to Promote Repair of Nerve Tissue	August 12, 2022
Japan No. 4,773,976	Materials and Methods for Promotion of Nerve Regeneration	January 31, 2025

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. 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

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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

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 IP position in the areas that are important to the development of its business.

Finally, the Company continues to hold IP, including patents, related to LecTec's original hydrogel patch technology and hand sanitizer patch. AxoGen continues to evaluate any further value that may be derived from such LecTec IP; it will, however, take all action necessary to maintain the patents licensed to Novartis Consumer Health, Inc. pursuant to the Novartis Agreement.

### ***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 21 CFR § 820 ("Quality System Regulation") and related laws and regulations. Cook Biotech has obtained a 510(k) marketing clearance from the FDA for porcine small intestine submucosa for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. AxoGuard® products represent the product for which 510(k) clearance was obtained.

In 2007, AxoGen began to process and distribute its Avance® Nerve Graft pursuant to section 361 of the Public Health Service Act and 21 CFR § 1271 Human Cell & Tissue Products ("HCT/P") controls. Such action was based on AxoGen's good faith belief that the Avance® Nerve Graft product was a 361 HCT/P tissue product.

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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 (“RFD”) filed by AxoGen, the FDA determined that the Avance® Nerve Graft was a biological product that would be reviewed and regulated by Center for Biologics Evaluation and Research (“CBER”) under the biologics licensing provision of the Public Health Service Act (the “PHS Act”).

AxoGen has been working with CBER on developing the design for a phase 3 clinical trial that would support a premarket submission for Avance® Nerve Graft. AxoGen met with CBER in July 2010 and, in the time period between July 2010 and November 2010, provided information to CBER that resulted in the FDA issuing a letter in November 2010 stating the agency’s intent to exercise enforcement discretion with respect to the introduction or delivery into interstate commerce of the Avance® Nerve Graft provided that:

- 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 conduct a phase 3 clinical trial to demonstrate safety, purity and potency of the Avance® Nerve Graft under a Special Protocol Assessment; and
- AxoGen continues to comply with the regulations and standard for 21 CFR § 1271 and exercises due diligence in executing the transition.

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

The BLA application and commercial distribution of the Avance Nerve Graft, if approved, will requires 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 Chemistry, Manufacturing, and Controls (“CMC”) and continues to move with diligence toward the completion of the BLA. A Special Protocol Assessment has been submitted, reviewed and approved by CBER. The study will be a prospective randomized blinded comparative study of nerve injuries in the hand. The approved study design will include 150 subjects enrolled across 15 centers. In compliance with the transition plan established by the FDA, AxoGen is able to continue to distribute the Avance® Nerve Graft.

### ***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;

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- 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 prior 510(k) clearance or approval of a 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, or devices deemed not substantially equivalent to a previously cleared 510(k) device are generally placed in Class III. Class III devices requiring an approved PMA to be marketed are devices that were regulated as new drugs prior to May 28, 1976 (transitional devices), devices not found substantially equivalent to a predicate device, and Class III pre-amendment devices that by regulation require pre-market approval. 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 Clearance and Approval Requirements—Biologic Products***

#### **Biologics License Application (BLA) Pathway**

In order to be approved as a biologic product, a BLA must demonstrate the safety and efficacy of the product candidate based on results of CMC, preclinical studies and clinical trials. A BLA must also contain extensive manufacturing information, and the applicant must pass an FDA pre-approval inspection or review of the manufacturing facility or facilities at which, or operations by 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 Investigational New Drug Application ("IND"), for human clinical testing, which must become effective before human clinical trials may begin and which must include independent Institutional Review Board (IRB), approval at each clinical site before the trials may be initiated;

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- 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.

### 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 may 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

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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 current products that are currently under development.

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. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND or IDE. In addition, an IRB at each site at which the study is conducted must approve the protocol, subject consent form and any amendments. 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, the Company 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.

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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 usually larger, more time consuming, more complex and more costly than Phase 1 and Phase 2 clinical trials. FDA regulators may accept a single study for the Avance® Nerve Graft on a smaller number of patients than would typically be required for pharmaceutical products in general, provided the data are sufficiently robust. 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 (IND) 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.

### ***AxoGen Clinical Studies***

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. AxoGen intends to continue to enroll patients in RANGER over the next several years. The CHANGE study is being run as a pilot comparative study and enrollment is now completed.

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

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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 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 must be approved by a local ethics committee and, in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

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

#### Educational Grants

The FDA permits a medical product manufacturer to 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 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 nonpromotional, 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;
- 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; and
- 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.

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 an assurance that the FDA or other government authorities would view the programs supported as being independent.

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### Pervasive and Continuing Regulation

There are numerous regulatory requirements that apply after a product is cleared or approved. These include: the FDA's Quality System Regulation (QSR) per 21 CFR § 820 for medical devices, the FDA's Good Tissue Practices (GTP) per 21 CFR §1271 for HCT/P tissue products and the FDA's Good Manufacturing Practices (GMP) per 21 CFR § 210, 211, and 600 for biologic products. 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 use or indication;
- to comply with requirements to obtain clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in 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 good manufacturing practice or an unexpected or unforeseeable event that may affect the safety, purity, or potency of the product must be reported; and (c) for 361 HCT/P 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;
- 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
- 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 or the AxoGuard® products and has not had to submit any Medical Device Reports ("MDRs"), biological deviation reports, or tissue adverse reaction reports to the FDA. Although AxoGen has had no adverse events 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 MDR's, 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 has 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 QSR, GTP 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;

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- 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 premarket approval (PMA or BLA) of new products, new intended uses or modifications to existing products;
- withdrawing premarket approvals that have already been granted; and
- criminal prosecution.

### 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

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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.

### ***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. Depending on the final determination of the FDA on whether the product is a device or biologic product, AxoGen will comply with appropriate regulations when exporting the product.

The primary regulatory body in Europe is that of the European Union (EU), 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 conformity 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 EU 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. Compliance establishes the presumption of conformity with the essential requirements for a CE Marking.

### ***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., Canada, Switzerland and Italy under compliance with the individual country regulations.

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These requirements are dynamic in nature and, as such, are continually changing. New regulations may be promulgated at any time and with limited notice. 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.

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 Matters**

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.

### **Employees**

At December 31, 2011, the Company had 41 full time employees which included 8 in administration, 6 in manufacturing and quality control, 5 in research and development and regulatory and 22 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**

Prior to the Merger, Mr. Gregory Freitag was LecTec's only executive officer serving as CEO and CFO. The following table, except as noted, lists the names and positions of the individuals who have served since the completion of the Merger, and who are, as of March 15, 2012, executive officers the Company:

<u>Name</u>	<u>Title</u>
Karen Zaderej	President, Chief Executive Officer and Director
Gregory G. Freitag	Chief Financial Officer, General Counsel and Director
John P. Engels	Vice President
Jill F. Schiaparelli (1)	Senior Vice President, Business Strategy and Marketing
Brad Hedger	Vice President of Sales
Mark Friedman, Ph.D.	Vice President of Regulatory and Quality
David Hansen	Corporate Controller

(1) Ms. Schiaparelli joined AxoGen as its Senior Vice President, Business Strategy and Marketing on February 27, 2012.

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

*Karen Zaderej, President, Chief Executive Officer and Director (Age 50)*

Ms. Zaderej has served as AxoGen's President, Chief Executive Officer and a member of its board of directors since September 30, 2011. She has served as AC's Chief Executive Officer and a member of its board of directors since May 2010. Ms. Zaderej joined AC 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.

*Gregory G. Freitag, J.D., CPA, Chief Financial Officer, General Counsel and Director (Age 50)*

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. Mr. Freitag also founded and is a principal of EmployRx, Inc., a business that provides services to self-insured employers relating to prescription drug benefits. Prior to founding FreiMc, LLC and EmployRx, Inc., 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 Pressure BioSciences, Inc., a publicly traded life sciences company focused on the development of a novel, enabling technology called Pressure Cycling Technology and of the Foundation Board of HealthEast Care System Foundation, a health care system in Minnesota.

*John P. Engels, Vice President (Age 40)*

Mr. Engels has served as AxoGen's Vice President since September 30, 2011. He is a co-founder of AC and has served as AC's Vice President since November 2002, 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 46)*

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

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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.

### *Brad Hedger, Vice President of Sales (Age 50)*

Mr. Hedger has served as AxoGen's Vice President of Sales since September 30, 2011. He has served as AC's Vice President of Sales since January 2011. From September 2008 to December 2010, Mr. Hedger served as President and Chief Executive Officer of Patient Care, a company founded by Mr. Hedger, which distributed products directly for AxoGen and DePuy Spine, Inc. in the states of Colorado and Wyoming. Mr. Hedger served as Director of Upper Extremity Trauma Sales for the Orthopaedics division of Stryker Corporation from March 2006 to September 2008. Prior to that, Mr. Hedger held direct sales and regional management positions for 13 years at Synthes Inc., an orthopedic trauma company. Mr. Hedger has a BA with a double major in Political Science and Computer Science from Cornell College.

### *Mark Friedman, Ph.D., Vice President of Regulatory and Quality (Age 54)*

Dr. Friedman has served as AxoGen's Vice President of Regulatory and Quality since September 30, 2011. He has served as AC's Vice President of Regulatory and Quality since June 2011 and served as AC'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 51)*

Mr. Hansen has served as AxoGen's Corporate Controller since September 30, 2011. He has served as AC'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.

AxoGen has key-person life insurance policies for \$3,000,000 and \$2,000,000 insuring the lives of Ms. Zaderej and Mr. Freitag, respectively.

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### **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.

***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, 2011, AxoGen had an accumulated deficit of approximately \$48 million. If AxoGen product sales do not increase as anticipated, then it will continue to experience negative cash flows and adverse operating conditions. As a result of AxoGen's continuing capital needs and other factors, it is considering to raise additional funds in the next 12 months 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, 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 Incorporated. Such contract is for a seven year initial term through August 2015, and renews automatically for an additional seven-year term, subject to agreement on future pricing. 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 enforce such minimum purchase provision. 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.

***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

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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 tissue for other allografts (i.e., bones, tendon, etc.) may limit widespread acceptance of AxoGen's Avance® Nerve Graft allograft. 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, families of potential donors from whom AxoGen is required to obtain consent before processing tissue may become 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 its relationship with its processor LifeNet Health 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 of its processor LifeNet Health, could lead to significant costs and disruptions that could reduce its revenues and harm its business reputation and financial results. AxoGen is highly reliant on its relationship with LifeNet. In March 2012, AxoGen renewed its tissue processing agreement with LifeNet Health for a one-year term. The agreement renews automatically for additional one-year terms unless terminated. Either party may terminate the agreement during a renewal term with 180-day advanced written notice. Any natural or man-made event that impacts AxoGen's ability to utilize these facilities could have a significant impact on its operating results, reputation and ability to continue operations. The regulatory process for approval of facilities is time-consuming and AxoGen's ability to rebuild facilities would take a considerable amount of time and expense and cause a significant disruption in service to its customers. Although AxoGen has business interruption insurance which would in these instances, 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 product 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.

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

Although most of the raw materials used in the production of Avance® Nerve Graft are available from more than one supplier, AxoGen currently obtains one of the chemicals it uses in the manufacture of Avance® Nerve Graft from only one supplier. Some of the test results and reagents AxoGen uses in its manufacturing process are also obtained from single suppliers. 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 depend 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

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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.

***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, 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

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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 from the Avance® Nerve Graft in Switzerland, Italy 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, level 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 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, and efficiently meeting product mix and product demand requirements. AxoGen may be unable to manage its inventory efficiently, keep inventory within expected budget goals, keep its work-in-process inventory on hand or efficiently, 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 loan agreement containing covenants that if breached could lead to a default and materially adversely affect its financial condition.***

AxoGen is party to the MidCap Loan (see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Long-Term Debt") which contains 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

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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 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 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. If AxoGen cannot meet any of the covenants, it would be deemed a default under the MidCap Loan, and the loan would become immediately due and payable. Such events would have a material adverse effect on AxoGen. There can be no assurance that AxoGen can meet the required covenants in (iii) above. To maintain minimum cash balance, AxoGen may need to raise additional capital, which could dilute the holdings of AxoGen shareholders and have a negative effect on AxoGen's stock price.

***As a public company, AxoGen incurs costs to comply with relevant securities laws and regulations including, without limitation, the requirements with respect to internal control over financial reporting. Failure to maintain an effective system of internal control over financial reporting could adversely affect AxoGen's ability to report its results of operations and financial condition accurately and in a timely manner, and could cause investors to lose confidence in the reliability of AxoGen's financial statements.***

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.

AxoGen identified a material weakness in its internal control over financial reporting which pertains to inappropriately treating a contract as an expense as opposed to a prepaid asset during the fourth quarter of 2011. See "Item 9A—Controls and Procedures—Management's Report on Internal Control Over Financial Reporting." While AxoGen has implemented remedial measures related to the identified material weakness, and will continue to review its disclosure controls and procedures and its internal control over financial reporting to ensure the quality of its financial reporting, it cannot guarantee that this material weakness has been fully remediated or that no future material weaknesses, significant deficiencies or other errors or omissions will be discovered. If AxoGen does not adequately remedy the material weakness, or if it fails to maintain proper and effective internal control over financial reporting in future periods, including any failure to implement or difficulty in implementing new or improved controls, its ability to provide timely and reliable financial results could suffer, and investors could lose confidence in its reported financial information.

***The price of AxoGen's common stock could be highly volatile due to a number of factors.***

The trading price of AxoGen's common stock may fluctuate widely as a result of a number of factors, including:

- trading of AxoGen common stock on the OTCBB;
- limited daily trading volume resulting in the lack of a liquid market;
- fluctuations in price and volume due to investor speculation, internet message postings, and other factors that may not be tied to the financial performance by AxoGen;
- performance by AxoGen in the execution of its business plan;
- financial viability;
- 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; and

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- period-to-period fluctuations in financial results.

***AxoGen does not meet the criteria to list its common stock on an exchange such as the NYSE—AMEX or NASDAQ Stock Market and its common stock lacks illiquidity and may be difficult to sell.***

Trading of AxoGen's common stock is conducted on the OTCBB. Generally, securities that are quoted on the OTCBB lack liquidity and analyst coverage. This may result in lower prices for its common stock than might otherwise be obtained if it met the criteria to list its securities on a larger or more established exchange, such as the NYSE—AMEX or NASDAQ Capital Market and could also result in a larger spread between the bid and asked prices for its common stock.

In addition, there has been only limited trading activity in AxoGen's common stock. The relatively small trading volume will likely make it difficult for AxoGen shareholders to sell their common stock as, and when, they choose.

### ***Risks Related to the Regulatory Environment in which AxoGen Operates***

***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.***

AxoGen's Avance® Nerve Graft product is currently allowed to be sold pursuant to a transition plan with the FDA. See "Business—Government Regulations—U.S. Government Regulation Review." AxoGen is continuing to communicate with CBER since the acceptance of the transition plan on clinical trial design and CMC for the Avance® Nerve Graft. Until final action on the Avance® Nerve Graft premarket submission, if AxoGen remains in compliance with the transition plan, it is able to continue to provide the Avance® Nerve Graft for sale. In the event that the FDA changed 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 the AxoGen's operations and financial viability. In addition, if AxoGen fails to comply with applicable regulatory requirements or fails to comply with the ongoing requirements of the premarket submission to become a biological product, the FDA could deny approval of the premarket application, or impose civil penalties, including fines, product seizures or product recalls and, in extreme 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 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) marketing clearance from the FDA for porcine small intestine submucosa for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. If AxoGen or Cook Biotech Incorporated fails to comply with applicable regulatory requirements the FDA could deny marketing clearance or approval, withdraw approvals, or impose civil penalties, including fines, product seizures or product recalls and, in extreme cases, criminal sanctions.

***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, distribution, manufacturing, labeling, and record-keeping procedures for human tissue for transplantation such as that of AxoGen's Avance® Nerve Graft product. The FDA also regulates medical devices, such as the AxoGuard® products. The process of obtaining marketing clearance from the FDA for new

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products and new applications for existing products 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 or enhancements will not be subject to a lengthy and expensive approval process with the FDA.

It is possible that if regulatory approvals to market a product are obtained from the FDA, the approvals may contain limitations on the indicated uses of such product. 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 extreme 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 they are deemed to have engaged in off-label promotion. AxoGen is seeking FDA approval for 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 on the promotion of a medical device for an indication that has not been approved or cleared by the FDA, or an off-label use. The FDA does not restrict or regulate a physician's use of a medical device within the practice of medicine, and AxoGen cannot prevent a physician from using its products for an off-label use. However, the FD&C Act and the FDA's regulations restrict the kind of communications that may be made about AxoGen's products and if the FDA determines that its promotional or training materials constitute the unlawful promotion of an off-label use, it could request that AxoGen modify its training or promotional materials or subject it to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, civil money penalties, criminal fines and penalties, and exclusion from participation in federal health programs. 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. 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 or cleared by the FDA may not effectively treat such conditions, 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.

### ***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 product in the event that it determines that due to material deficiencies or defects that use of the product poses an unacceptable risk to health. In addition, manufacturers may, on their own initiative, recall a product to remove or correct a deficiency

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or to remedy a violation of the Federal Food, Drug, and Cosmetic Act that may pose a risk to health. A government-mandated or a voluntary recall could occur as a result of an unacceptable risk to health, failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls, corrections or removals of 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 removals 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 relating to 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 processor 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 European Union (the "EU") regulations, if applicable, differ from one EU 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 EU, as well 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 EU 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 EU 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 a biologics license 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.

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AxoGen has continued to communicate with 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 its BLA. If AxoGen is unable to agree, or unable to meet the standards required of it by the FDA, regarding preclinical studies, clinical studies and CMC, 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 supplement, which could further delay the BLA of AxoGen's products. If AxoGen is unable to demonstrate the safety and efficacy of its products through its clinical trials, it will be unable to obtain regulatory approval to market its products and will not be able to continue to sell its Avance® Nerve Graft.

***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 ("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 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.***

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/Ps. 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 enforcement action, which affects the conduct of its business. See "Business — Government Regulations." In addition, these regulations can increase the cost of tissue recovery activities.

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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 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 is 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, including the recently enacted legislation to reform the U.S. healthcare system, 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;
- 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

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ownership interests, with the first of such reports due March 31, 2013 for calendar year 2012 (“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, beginning on or before January 1, 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.

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 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;

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- 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 success depends on its ability to avoid infringing on the intellectual property rights of third parties which could expose it to litigation or commercially unfavorable licensing arrangements.

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. 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 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.

***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

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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 UTA 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 UTA do not perform as purported, are not efficacious, or are not the property of UFRF or UTA, or some similar problem with the license, any of which would have an immediate and negative impact on AxoGen's business.

## **ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

## **ITEM 2. PROPERTIES**

AxoGen's corporate headquarters are currently located in Alachua, Florida, in a facility with a lease for 4,742 square feet of office space until April 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 under a one-year lease until September 2012 and 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 \$169,000 per year. AxoGen believes that these facilities are sufficient to operate its business and that lease arrangements will not significantly change in the future.

## **ITEM 3. LEGAL PROCEEDINGS**

On July 25, 2008, LecTec filed a complaint for patent infringement (the "Complaint") against five companies, including Chattem, Inc. (Ticker: CHTT), Endo Pharmaceuticals, Inc. (Ticker: ENDP), Johnson & Johnson Consumer Company, Inc. (Ticker: JNJ), The Mentholatum Company, Inc. (Division of Rohto Pharmaceuticals, Ticker RPHCF.PK), and Prince of Peace Enterprises, Inc. (Private Company) (collectively, the "Defendants") in the U.S. District Court for the Eastern District of Texas. The Complaint alleged, among other things, that the Defendants infringed two of LecTec's patents (the "Patents-In-Suit"), which related to LecTec's medicated patch technology. LecTec sought to enjoin the Defendants from infringing the Patents-In-Suit and to recover monetary damages related to such infringement, as well as interest and litigation costs.

As of December 31, 2010, LecTec had settlement with Endo Pharmaceuticals, Inc., Johnson & Johnson Consumer Company, Inc. and The Mentholatum Company. On March 23, 2011, LecTec entered into a Confidential Settlement Agreement and Mutual Release (the "Chattem Settlement Agreement") with Chattem to settle LecTec's claims against Chattem that Chattem infringed the Patents-In-Suit. Pursuant to the Chattem Settlement Agreement, Chattem paid a one-time sum of \$3,600,000 to LecTec. and LecTec granted to Chattem a

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fully paid-up, world-wide, non-exclusive and irrevocable license to (a) the Patents-In-Suit, (b) any patent that claims priority, directly or indirectly, from the Patents-In-Suit (the “Family Patents”) and (c) any foreign counterparts of the Family Patents, for use in connection with any product or process sold or used by Chattem, other than products covered by exclusive licenses previously granted to other companies. Such settlement proceeds were before payment of contingent legal fees and any applicable taxes. In addition, under the Chattem Settlement Agreement, LecTec and Chattem entered into mutual releases of all claims.

On April 25, 2011, LecTec entered into a Confidential Settlement Agreement and Mutual Release (the “POP Settlement Agreement”) with Prince of Peace Enterprises, Inc. (“POP”) to settle LecTec’s claims against POP that POP infringed the Patents-In-Suit. Pursuant to the Settlement Agreement, POP paid LecTec a one-time sum of \$225,000 and LecTec granted to POP a fully paid-up, world-wide, non-exclusive and irrevocable license to (a) the Patents-In-Suit, (b) the “Family Patents” and (c) any foreign counterparts of the Family Patents, for use in connection with any product or process sold or used by POP, other than products covered by exclusive licenses previously granted to other companies. Such settlement proceeds were before payment of contingent legal fees and any applicable taxes. In addition, under the POP Settlement Agreement, LecTec and POP entered into mutual releases of all claims.

The Company has completed, through settlement, its previous material legal action against the five defendants. It currently has no active or pending material legal proceedings.

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II**

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

The Company's common stock trades on the Over the Counter ("OTC") Bulletin Board under the symbol AXGN.OB.

The following table sets forth, for each of the calendar periods indicated, the quarterly high and low closing bid prices for the Company's common stock quoted on the OTC Bulletin Board. 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.

	Year Ended December 31, 2011		Year Ended December 31, 2010	
	High	Low	High	Low
First Quarter (1)	\$ 4.00	\$ 2.75	\$ 6.31	\$ 2.90
Second Quarter	\$ 3.37	\$ 2.17	\$ 3.75	\$ 2.70
Third Quarter	\$ 3.00	\$ 2.00	\$ 4.25	\$ 2.90
Fourth Quarter	\$ 3.10	\$ 2.05	\$ 3.50	\$ 3.00

- (1) LecTec Corporation paid a \$1.00 special dividend on February 12, 2010.  
See "— Dividend Policy" below.

**Dividend Policy**

At a Board of Directors meeting held on December 21, 2009, the Board of LecTec Corporation declared a special cash dividend of \$1.00 per share to shareholders of record at January 29, 2010 that was payable on February 12, 2010. LecTec Corporation distributed \$4,298,350 on February 12, 2010 to its shareholders. Although LecTec Corporation had paid out this special dividends in 2010, the Company 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.

**Shareholders**

As of March 12, 2012, the Company had 11,062,188 shares of common stock outstanding, and approximately 250 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 850 individual owners.

**Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

We did not repurchase any of our securities during the fourth quarter of 2011.

**Recent Sales of Unregistered Securities**

We had no sales of unregistered securities during 2011 that have not been previously disclosed in a Current Report on Form 8-K or Quarterly Reports on Form 10-Q, except on October 10, 2011 each non-employee director of AxoGen (in the case of Mr. Joseph Mandato, his designee) was granted 5,455 shares of AxoGen common stock, valued at \$2.75 per share, in lieu of a cash retainer payment for the director's services through December 31, 2012.

**ITEM 6. SELECTED FINANCIAL DATA**

Not applicable.

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

**Overview**

On September 30, 2011, LecTec completed its business combination with AC in accordance with the terms of 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. Immediately following the Merger, LecTec changed its name to AxoGen, Inc. In October 2011, AxoGen, Inc. moved its corporate headquarter facilities (principal executive office) from Texarkana, Texas to 13859 Progress Blvd., Suite 100, Alachua, Florida 32615.

For accounting purposes, AC was identified as the acquiring entity and LecTec as the acquired entity. The Merger was accounted for using the purchase method of accounting for financial reporting purposes. The purchase method requires the identification of the acquiring entity, based on the criteria of Accounting Standards Codification 805-10-55-12, *Accounting for Business Combinations*. Under purchase accounting, the assets and liabilities of an acquired company (LecTec) as of the effective date of the acquisition were recorded at their respective estimated fair values and added to those of the acquiring company. Accordingly, the consolidated financial statements and related footnote disclosures presented for periods prior to the Merger are those of AC alone. The consolidated Statement of Operations for the year ended December 31, 2011 and 2010 include the operations and cash flows of AC through September 30, 2011 and the combined operations and cash flows of the Company subsequent to the Merger. The common stock of AC has been retrospectively adjusted to reflect the exchange ratio of one share of AC common stock for 0.03727336 share of the Company's common shares as established in the Merger Agreement. Historical results for LecTec prior to the Merger are not included in the Company's consolidated financial statements.

AxoGen is a regenerative medicine company with a portfolio of proprietary products and technologies for peripheral nerve reconstruction and regeneration. 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 reconstruction and regeneration of peripheral nerves, AxoGen has developed and licensed technologies, which are used in its products. Its product portfolio includes Avance® Nerve Graft, which AxoGen believes is the first and only commercially available allograft nerve for bridging nerve discontinuities (a gap created when the nerve is severed), AxoGuard® Nerve Connector, a coaptation aid allowing for close approximation of severed nerves, and AxoGuard® Nerve Protector, an implant that protects nerves during the body's healing process after surgery.

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 the fourth quarter and the twelve months of 2011 compared to the fourth quarter and the twelve months of 2010, respectively, as a result of increased penetration into key accounts and establishing new accounts through both its direct sales force and independent distributors. 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, even though in the near term revenue growth may lag behind expense increase.

From May 2009 to December 2010, AxoGen temporarily stopped the manufacturing of Avance Nerve Graft due to adequate inventory. In January 2011, AxoGen resumed the manufacturing of Avance Nerve Graft, and as a result has incurred higher processing and testing fees, travel costs and temporary labor costs compared to the same periods last year. In addition, to adequately reflect the amount of inventory, AxoGen reviewed and adjusted inventories and established reserves. In reviewing inventory expiration AxoGen wrote off inventory for products manufactured in early 2009. AxoGen believes that it has the necessary inventories and manufacturing capabilities for its anticipated sales growth.

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### Results of Operations

#### *Comparison of the Years Ended December 31, 2011 and 2010*

##### Revenues

Revenues for the year ended December 31, 2011 increased 61.4% to approximately \$4,849,000 as compared to approximately \$3,004,000 for the year ended December 31, 2010 principally due to increased sales penetration into key accounts.

##### Gross Profit

Gross profit for the year ended December 31, 2011 increased 49.0% to approximately \$2,423,000 as compared to approximately \$1,626,000 for the year ended December 31, 2010, primarily attributable to the increased revenues in 2011, partially offset by a \$614,000 inventory write-off for expiring inventory and a \$214,000 write-off for raw material obsolescence in 2011, and higher processing and testing fees, travel costs and temporary labor costs due to the resumption of the manufacturing of Avance® Nerve Graft since January 2011.

##### Costs and Expenses

Total cost and expenses increased 53.8% to approximately \$9,392,000 for the year ended December 31, 2011 as compared to approximately \$6,107,000 for the year ended December 31, 2010. These increases were primarily due to increasing sales and marketing activities, increases in salaries as AxoGen hires to meet growth needs and increased general and administrative costs associated with securing additional funding prior to the Merger and in connection with the Merger. As a percentage of revenues, total operating expenses were 193.7% for the year ended December 31, 2011 compared to 203.3% for the year ended December 31, 2010. Such lower total costs and expenses a percentage of revenue were a result of such increased expenses being absorbed by increased revenues.

Sales and marketing expenses increased 45.6% to approximately \$4,379,000 for the year ended December 31, 2011 as compared to approximately \$3,007,000 for the year ended December 31, 2010. This increase was primarily due to expansion of the direct sales force and increased support for both its direct sales force and independent distributors. As a percentage of revenues, sales and marketing expenses were 90.3% for the year ended December 31, 2011 compared to 100.1% for the year ended December 31, 2010. Such lower sales and marketing expenses as a percentage of revenue were a result of such increase in expenses being outpaced by the increase in revenues.

General and administrative expenses increased 62.0% to approximately \$4,316,000 for the year ended December 31, 2011 as compared to approximately \$2,664,000 for the year ended December 31, 2010. As a percentage of revenues, general and administrative expenses were 89.0% for the year ended December 31, 2011 compared to 88.7% the year ended December 31, 2010. These increases were principally a result of an increase in consulting, accounting and legal services and other expenses associated with securing additional funding and the Merger.

Research and development expenses increased approximately 60% to approximately \$697,000 in the year ended December 31, 2011 as compared to approximately \$436,000 for the year ended December 31, 2010. Development includes AxoGen's clinical efforts and substantially all of the increase in research and development expenses from 2010 to 2011 related to expenditures for such clinical activity. 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.

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### Other Income and Expenses

Interest expense increased 34.3% to approximately \$1,095,000 in 2011 as compared to approximately \$815,000 for the year ended December 31, 2010. This increase was primarily due to the interest accrued related to the [2010 Convertible Debt (see Note 7 to the Consolidated Financial Statements included in this Form 10-K)] and the increase in the stated interest rate during 2011 pursuant to the amendment to AxoGen's Loan and Security Agreement originally entered into in April 2008 (see "—Liquidity and Capital Resources—Long-Term Debt").

Interest expense—deferred financing costs decreased 7.5% to approximately \$1,223,000 for the year ended December 31, 2011 as compared to approximately \$1,322,000 for the year ended December 31, 2010. This decrease is primarily due to certain deferred financing costs associated with warrants issued as consideration for several amendments executed during 2010 related to the Loan and Security agreement originally entered into in April 2008 becoming fully amortized by March 31, 2011.

Gain from the termination of the distribution agreement was \$1,119,000 in 2010. AxoGen had entered into a long-term agreement to supply nerve grafts to a single national distributor. The distributor paid an up-front deposit of \$1,500,000 to AxoGen, as consideration for exclusive distribution servicing of AxoGen's products, which was initially recorded as deferred revenue. The repayment of the up-front deposit was to be subsequently released and recognized as revenue through discounts of future service fees, until AxoGen had granted discounts aggregating the full amount of the deposit. During the second quarter of 2009, all activities associated with the distribution agreement ceased and negotiations began between AxoGen and the distributor to terminate the agreement. On February 26, 2010, AxoGen and the distributor formally executed a Settlement and Mutual Release Agreement releasing AxoGen from the repayment of the remaining portion of the obligation. AxoGen recorded the gain on termination during the first quarter of 2010 when the settlement was reached.

Gain in fair value of warrant liability decreased 20.5% to approximately \$62,000 in the year ended December 31, 2011 as compared to approximately \$78,000 for the year ended December 31, 2010. This decrease is principally due to the decline in the fair value of AxoGen's warrant liability during the year ended December 31, 2011 as compared to the year ended December 31, 2010.

### Income Taxes

The Company had no income tax expenses or income tax benefit for each of the years ended December 31, 2011 and 2010 due to incurrence of net operating loss in each of these years.

### **Effect of Inflation**

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

### **Liquidity and Capital Resources**

#### *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 MidCap Loan has a principal amount of \$5.0 million and a term of 42 months, and is subject to prepayment penalties. Under this agreement, AxoGen is 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 is 9.9% per annum, and interest is computed on the basis of a 360-day year and the actual number of days elapsed during which such interest accrues.

The MidCap Loan contains customary affirmative and negative covenants, including, without limitation, (i) covenants requiring AxoGen to comply with applicable laws, provide to MidCap copies of AxoGen's

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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 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 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 is 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.

On April 21, 2008, AxoGen entered into a Loan and Security Agreement with Oxford Finance Corporation and ATEL Ventures, Inc., as subsequently amended (the "2008 Loan and Security Agreement"), which provided for a loan with an aggregate principal amount of \$7.5 million. The loan's maturity date was October 1, 2011. The loan bore interest at a rate of 18% per month and was secured by all of AxoGen's assets. On September 30, 2011, AxoGen paid in full the entire outstanding balance of the 2008 Loan and Security Agreement, using the proceeds from the MidCap Loan.

On June 11, 2010, AxoGen entered into Convertible Debt Agreements for an aggregate principal amount of \$3.7 million with 8% interest and principal and interest payable in full on June 30, 2013, as amended. The Convertible Debt Agreements were collateralized by a third lien on certain property and were subordinated to the 2008 Loan and Security Agreement. Immediately prior to the closing of the Merger, the Convertible Debt Agreements pursuant to their terms automatically converted into AC common stock which was then exchanged for Company common stock pursuant to the terms of the Merger Agreement.

On May 3, 2011, AxoGen issued an 8% Convertible Note Payable to LecTec Corporation for \$500,000. On May 31, 2011, AxoGen issued additional convertible notes payable under the same terms of which \$2,000,000 was issued to LecTec and \$500,000 was issued to certain AC shareholders. On August 29, 2011, AxoGen issued an additional subordinated secured convertible promissory note in the principal amount of \$2,000,000 to LecTec and \$500,000 to certain AC shareholders. These notes were collateralized by all of AxoGen's assets and subordinated to the 2008 Loan and Security Agreement. Immediately prior to the closing of the Merger, the notes held by investors other than LecTec automatically convert into AC's common stock which was then exchanged for LecTec common stock pursuant to the terms of the Merger Agreement. Immediately after to the closing of the Merger, the notes held by LecTec were retired.

The Company had no material commitments for capital expenditures at December 31, 2011 or 2010.

### ***Cash Flow Information***

AxoGen had working capital of approximately \$8.8 million and a current ratio of 5.4 at December 31, 2011, compared to a working capital deficit of \$4,120,000 and a current ratio of (0.56) at December 31, 2010. The increase in working capital and the current ratio at December 31, 2011, compared to December 31, 2010, was primarily due to the Merger.

The Company 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, cost of products and acquisition and/or development of new products. As described in — "Long-Term Debt" above, AxoGen must also comply with the covenants in the MidCap Loan agreement to meet certain minimum Net Invoiced Revenue or maintain a cash balance of 80% of the loan principal amount. As a result of AxoGen's continuing capital needs and other factors, it is considering to raise additional funds in the next 12 months 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. Should additional capital

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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 2011, the Company had a net increase in cash and cash equivalents of \$6,392,000 as compared to a net increase of cash and cash equivalents of \$1,516,000 in 2010. The Company's principal sources and uses of funds are explained below:

### Cash used in operating activities

The Company used approximately \$7,079,000 of cash for operating activities in 2011, as compared to using approximately \$3,943,000 of cash for operating activities in 2010. This increase in cash used in operating activities is primarily attributed to the increase in net loss in 2011, offset by an increase in our accounts payable and accrued expenses and no gain on termination of a distribution agreement that was present in 2010.

### Cash provided by (used) for investing activities

Investing activities for 2011 provided approximately \$7,112,000 of cash as compared to using \$72,000 of cash in 2010. This increase in cash is principally attributable to the cash acquired in the Merger.

### Cash provided by financing activities

Financing activities in 2011 provided approximately \$6,359,000 of cash as compared to approximately \$5,532,000 of cash in 2010. This increase in cash used is primarily attributed to issuance of \$10,500,000 of additional debt, partially offset by the repayment of approximately \$4,733,000 of debt during 2011.

## **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 sheet of AxoGen, Inc. as of December 31, 2011, and the related consolidated statements of operations, shareholders' equity, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit 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 audit 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 audit provide a reasonable basis for our opinion.

In our opinion, the 2011 consolidated financial statements referred to above present fairly, in all material respects, the financial position of AxoGen, Inc. as of December 31, 2011, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ LURIE BESIKOF LAPIDUS & COMPANY, LLP

Minneapolis, Minnesota  
March 15, 2012

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
AxoGen Corporation

We have audited the accompanying balance sheets of AxoGen Corporation as of December 31, 2010 and the related statements of operations, stockholders' deficit, and cash flows for the year then ended. These 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 auditing 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 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 audit 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of AxoGen Corporation at December 31, 2010, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Cross, Fernandez & Riley, LLP.

Certified Public Accountants

May 25, 2011  
Orlando, Florida

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**AXOGEN, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**December 31, 2011 and 2010**

	December 31, 2011	December 31, 2010
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 8,190,781	\$ 1,799,048
Accounts receivable	797,654	407,350
Inventory	1,760,540	1,902,789
Prepaid expenses and other	133,500	74,437
Deferred financing costs	—	1,083,630
<b>Total current assets</b>	<b>10,882,475</b>	<b>5,267,254</b>
<b>Property and equipment, net</b>	<b>247,824</b>	<b>500,742</b>
<b>Goodwill</b>	<b>169,987</b>	<b>—</b>
<b>Intangible assets</b>	<b>899,480</b>	<b>637,771</b>
<b>Deferred financing costs</b>	<b>295,276</b>	<b>—</b>
	<b><u>\$ 12,495,042</u></b>	<b><u>\$ 6,405,767</u></b>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 1,585,100	\$ 967,896
Current portion of long-term debt, related party	—	1,338,455
Current portion of long-term debt	434,734	7,080,512
<b>Total current liabilities</b>	<b>2,019,834</b>	<b>9,386,863</b>
<b>Long-term debt</b>	<b>4,403,737</b>	<b>—</b>
<b>Preferred stock dividends payable</b>	<b>—</b>	<b>6,048,378</b>
<b>Warrant liability</b>	<b>—</b>	<b>2,669,815</b>
<b>Total liabilities</b>	<b><u>6,423,571</u></b>	<b><u>18,105,056</u></b>
<b>Commitments and contingencies</b>		
<b>Temporary equity:</b>		
Series B convertible preferred stock, \$.00001 par value; 17,065,217 shares authorized; 9,782,609 shares issued and outstanding at December 31, 2010	—	4,243,948
Series C convertible preferred stock, \$.00001 par value; 16,798,924 shares authorized; 11,072,239 shares issued and outstanding at December 31, 2010	—	8,092,568
Series D convertible preferred stock, \$.00001 par value; 67,000,000 shares authorized; 30,156,259 shares issued and outstanding at December 31, 2010	—	3,075,523
<b>Total temporary equity</b>	<b><u>—</u></b>	<b><u>15,412,039</u></b>
<b>Stockholders' equity (deficit):</b>		
Common stock, \$.01 par value; 50,000,000 shares authorized; 11,062,188 and 1,205,624 shares issued and outstanding	110,622	12,056
Series A convertible preferred stock, \$.00001 par value; 2,544,750 shares authorized, issued and outstanding at December 31, 2010	—	1,125,000
Additional paid-in capital	54,391,784	9,934,980
Accumulated deficit	(48,430,935)	(38,183,364)
<b>Total stockholders' equity (deficit)</b>	<b><u>6,071,471</u></b>	<b><u>(27,111,328)</u></b>
	<b><u>\$ 12,495,042</u></b>	<b><u>\$ 6,405,767</u></b>

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, 2011 and 2010**

	2011	2010
<b>Revenues</b>	\$ 4,849,470	\$ 3,004,445
<b>Cost of goods sold</b>	<u>2,426,544</u>	<u>1,378,936</u>
<b>Gross profit</b>	2,422,926	1,625,509
<b>Costs and expenses:</b>		
Sales and marketing	4,378,694	3,007,163
Research and development	697,355	436,008
General and administrative	<u>4,315,604</u>	<u>2,663,908</u>
<b>Total costs and expenses</b>	<u>9,391,653</u>	<u>6,107,079</u>
<b>Loss from operations</b>	<u>(6,968,727)</u>	<u>(4,481,570)</u>
<b>Other income (expense):</b>		
Interest expense	(1,094,657)	(814,994)
Interest expense – deferred financing costs	(1,223,126)	(1,322,413)
Gain from termination of distribution agreement	—	1,119,094
Change in fair value of warrant liability	62,305	78,306
Other income (expense)	<u>4,985</u>	<u>(1,584)</u>
<b>Total other income (expense)</b>	<u>(2,250,493)</u>	<u>(941,591)</u>
<b>Net loss</b>	(9,219,220)	(5,423,161)
Preferred Stock dividends (assumes all paid)	(1,028,351)	(1,566,361)
<b>Net loss available to common shareholders</b>	<u>\$(10,247,571)</u>	<u>\$(6,989,522)</u>
Weighted Average Common Shares outstanding – basic and diluted	<u>3,697,390</u>	<u>836,645</u>
<b>Loss Per Common share – basic and diluted</b>	<u>\$ (2.77)</u>	<u>\$ (8.35)</u>

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

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**AXOGEN, INC.**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
**Years ended December 31, 2011 and 2010**

	<i>Series A Convertible Preferred Stock</i>		<i>Common Stock</i>		<i>Additional</i>	<i>Accumulated</i>	<i>Total</i>
	<i>Shares</i>	<i>Amount</i>	<i>Shares</i>	<i>Amount</i>	<i>Paid-in Capital</i>	<i>Deficit</i>	<i>Stockholders' Deficit</i>
<b>Balance, December 31, 2009</b>	2,544,750	\$ 1,125,000	389,186	\$ 3,892	\$ 1,423,489	\$(31,193,841)	\$(28,641,460)
Stock-based compensation	—	—	—	—	187,458	—	187,458
Exercise of stock options	—	—	14,625	146	3,777	—	3,923
Conversion of Series B preferred stock	—	—	263,344	2,633	3,247,367	—	3,250,000
Conversion of Series C preferred stock	—	—	202,986	2,030	3,997,970	—	4,000,000
Conversion of Series D preferred stock	—	—	335,483	3,355	1,074,919	—	1,078,274
Series B preferred stock dividends	—	—	—	—	—	(483,725)	(483,725)
Series C preferred stock dividends	—	—	—	—	—	(784,655)	(784,655)
Series D preferred stock dividends	—	—	—	—	—	(297,982)	(297,982)
Net loss	—	—	—	—	—	(5,423,161)	(5,423,161)
<b>Balance, December 31, 2010</b>	2,544,750	1,125,000	1,205,624	12,056	9,934,980	(38,183,364)	(27,111,328)
Stock-based compensation	—	—	—	—	250,044	—	250,044
Exercise of stock options	—	—	98,700	987	25,493	—	26,480
Directors stock compensation	—	—	27,275	273	74,727	—	75,000
Conversion of preferred stock, debt, and accrued interest into Common Stock and shares exchange in Merger	(2,544,750)	(1,125,000)	(5,001,854)	50,019	21,447,936	—	20,372,955
Series B preferred stock dividends	—	—	—	—	—	(292,330)	(292,330)
Series C preferred stock dividends	—	—	—	—	—	(515,577)	(515,577)
Series D preferred stock dividends	—	—	—	—	—	(220,444)	(220,444)
Preferred Stock dividend payable forfeited	—	—	—	—	7,076,729	—	7,076,729
Warrant Liability forfeited	—	—	—	—	2,607,510	—	2,607,510
LecTec shares in connection with Merger	—	—	4,305,026	43,050	11,804,866	—	11,847,916
Issuance of common stock	—	—	423,709	4,237	995,763	—	1,000,000
Issuance of warrants — MidCap loan	—	—	—	—	173,736	—	173,736
Net loss	—	—	—	—	—	(9,219,220)	(9,219,220)
<b>Balance, December 31, 2011</b>	—	\$ —	11,062,188	\$110,622	\$54,391,784	\$(48,430,935)	\$ 6,071,471

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, 2011 and 2010**

	2011	2010
<b>Cash flows from operating activities:</b>		
Net loss	\$ (9,219,220)	\$ (5,423,161)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	273,528	306,319
Amortization of intangible assets	67,147	46,828
Amortization of deferred financing costs	1,223,126	1,322,413
Amortization of debt discount	23,643	108,580
Stock-based compensation	250,044	187,458
Directors stock compensation	15,000	—
Gain on termination of distribution agreement	—	(1,119,094)
Change in fair value of warrant liability	(62,305)	(78,306)
Interest added to note payable	55,562	—
Change in assets and liabilities:		
Accounts receivable	(368,954)	(114,242)
Inventory	142,249	671,822
Prepaid expenses and other	20,070	37,732
Accounts payable and accrued expenses	500,820	110,152
<b>Net cash used for operating activities</b>	<b>(7,079,290)</b>	<b>(3,943,499)</b>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(20,610)	—
Acquisition of intangible assets	(68,856)	(72,005)
Cash acquired with Merger	7,201,638	—
<b>Net cash provided by (used for) investing activities</b>	<b>7,112,172</b>	<b>(72,005)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of Series D preferred stock and warrants, net	—	1,980,332
Proceeds from issuance of long-term debt	10,500,000	3,697,547
Proceeds from issuance of common stock	1,000,000	—
Repayments of long-term debt	(4,732,857)	—
Debt issuance costs	(434,772)	(150,051)
Proceeds from exercise of stock options	26,480	3,923
<b>Net cash provided by financing activities</b>	<b>6,358,851</b>	<b>5,531,751</b>
Net increase in cash and cash equivalents	6,391,733	1,516,247
<b>Cash and cash equivalents, beginning of year</b>	<b>1,799,048</b>	<b>282,801</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 8,190,781</b>	<b>\$ 1,799,048</b>
<b>Supplemental disclosures of cash flow activity:</b>		
Cash paid for interest	\$ 1,029,753	\$ 812,104
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Conversion of convertible debt into Series D preferred stock	\$ —	\$ 2,690,994
Conversion of preferred stock, convertible debt and accrued interest into common stock	21,497,955	8,328,274
Accretion of dividends of Series B preferred stock	292,330	483,725
Accretion of dividends of Series C preferred stock	515,577	784,654
Accretion of dividends of Series D preferred stock	220,444	297,982
Warrants issued with Series D preferred stock	—	517,529
Deferred financing costs related to warrants issued with debt	—	2,160,879
Preferred stock dividend payable forfeited with the Merger	7,076,729	—
Warrant Liability forfeited with the Merger	2,607,510	—
Debt discount related to warrants issued with debt	173,736	—
Net assets acquired on Merger	11,847,916	—
Note and accrued interest retired with the Merger	4,555,562	—
Directors stock compensation included in prepaid expenses	60,000	—

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

**AXOGEN, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2011 and 2010**

**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, 2011 and December 31, 2010 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**

On September 30, 2011, LecTec Corporation ("LecTec") completed its business combination with 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. In October 2011, the Company moved its corporate headquarter facilities (principal executive office) from Texarkana, Texas to 13859 Progress Blvd., Suite 100, Alachua, Florida 32615.

In connection with the Merger,

- all outstanding AC convertible securities were converted into shares of AC common stock and exchanged for shares of AxoGen, Inc. common stock;
- all outstanding AC warrants expired unexercised;
- all outstanding shares of AC common stock, including those issued upon conversion of AC convertible securities, were exchanged for shares of AxoGen, Inc. common stock at a ratio of one share of AC common stock for 0.03727336 share of AxoGen, Inc. common stock;
- all outstanding options to purchase shares of AC common stock were exchanged for options to purchase shares of AxoGen, Inc. common stock at a ratio of one option to purchase shares of AC common stock for an option to purchase 0.03727336 share of AxoGen, Inc. common stock.

A total of 6,221,077 shares of the Company's common stock were issued in share exchange, and an additional 558,267 shares of the Company's common stock were reserved for issuance upon exercise of AC stock options which were converted into the Company's stock options. Upon completion of the Merger, all AC securities were cancelled.

Immediately following the completion of the Merger, former AC stockholders owned approximately 56.8% of the outstanding common stock of the Company, LecTec stockholders owned approximately 39.4% of the outstanding common stock of the Company, and certain investors owned the remaining 3.8% of the outstanding common stock of the Company.

For accounting purposes, AC was identified as the acquiring entity and LecTec as the acquired entity. The merger was accounted for using the purchase method of accounting for financial reporting purposes. The purchase method requires the identification of the acquiring entity, based on the criteria of Accounting Standards Codification 805-10-55-12, Accounting for Business Combinations. Under purchase accounting, the assets and

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liabilities of an acquired company (LecTec) as of the effective date of the acquisition were recorded at their respective estimated fair values and added to those of the acquiring company. Accordingly, the consolidated financial statements and related footnote disclosures presented for periods prior to the Merger are those of AC alone. The consolidated Statement of Operations for the years ended December 31, 2011 and 2010 include the operations and cash flows of AC through September 30, 2011 and the combined operations and cash flows of AC and LecTec subsequent to the Merger.

The common stock of AC has been retrospectively adjusted to reflect the exchange ratio of one share of AC common stock for 0.03727336 share of the Company's common shares as established in the Merger Agreement.

The Company is a regenerative medicine company with a portfolio of proprietary products and technologies for peripheral nerve reconstruction and regeneration. 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 reconstruction and regeneration of peripheral nerves, the Company has developed and licensed technologies which are used in its products. Its product portfolio includes Avance® Nerve Graft, which the Company believes is the first and only commercially available allograft nerve for bridging nerve discontinuities (a gap created when the nerve is severed), AxoGuard® Nerve Connector, a coaptation aid allowing for close approximation of severed nerves, and AxoGuard® Nerve Protector that protects nerves during the body's healing process after surgery.

The Company's future capital requirements depend on a number of factors, including, without limitation, revenue increases consistent with its business plan, cost of products and acquisition and/or development of new products. As described in Note 7, the Company must also comply with the covenants in the MidCap Loan agreement. As a result of the Company's continuing capital needs and other factors, it is considering to raise additional funds through public or private equity offerings, debt financings or from other sources. There is no assurance that the Company will be able to secure funding on terms acceptable to it, or at all. Should additional capital not become available the Company may be required to take certain action, such as, slowing sales and marketing expansion, delaying regulatory approvals or reducing headcount.

### **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 products are recognized when the tissue is delivered to the customer, at which time title passes to the customer. Once 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 storage and shipping of products are recognized as revenues when processed tissue is shipped to the customer 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 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

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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. As of December 31, 2011 and 2010, there were no amounts deemed uncollectible and there was no allowance for doubtful accounts recorded.

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, AxoGuard® Nerve Connector, AxoGuard® Nerve Protector, and supplies that are valued at the lower of cost (first-in, first-out) or market and consist of the following:

	December 31, 2011	December 31, 2010
Finished goods	\$1,374,817	\$1,081,489
Work in process	145,300	319,293
Raw materials	240,423	502,007
	<u>\$1,760,540</u>	<u>\$1,902,789</u>

Inventories was net of reserve of \$433,706 and \$641,474 at December 31, 2011 and 2010, 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

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 6 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.

### Goodwill

Goodwill represents the excess of the purchase price over the fair value of net assets acquired. No impairment has been recognized during 2011.

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### **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. No impairment has been recognized for 2011 or 2010.

### **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 approximately \$17,000 and \$6,000 for 2011 and 2010, 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.

### **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.

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 an asset or 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, 2008 through 2011.

### **Preferred Stock**

The Company accounted for its preferred stock under the provisions of Accounting Standards Codification on *Distinguishing Liabilities from Equity*, which sets forth the standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. This standard requires an issuer to classify a financial instrument that is within the scope of the standard as a liability or temporary equity if such financial instrument embodies an unconditional obligation to redeem the instrument at a specified date and/or upon an event certain to occur.

Prior to conversion in connection with the Merger, all or any number of the Series B, Series C, and Series D preferred stock was originally redeemable by a majority of preferred shareholder approval at any time after

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January 7, 2015 at a redemption price determined in accordance with the Company's Certificate of Incorporation, plus accrued and unpaid dividends. The Company has determined that its Series B, Series C, and Series D preferred stock required temporary equity classification as its obligation to redeem these instruments were outside the control of the Company. Permanent equity classification was not currently applicable as the preferred stock was not currently redeemable but may become so in the future.

### Derivative Financial Instruments

The Company accounts for derivative instruments in accordance with Accounting Standards Codification on *Derivatives and Hedging*, which requires additional disclosures about the Company's objectives and strategies for using derivative instruments, how the derivative instruments and related hedging items are accounted for, and how the derivative instruments and related hedging items affect the financial statements. The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risk. Terms of convertible debt and equity instruments are reviewed to determine whether or not they contain embedded derivative instruments that are required to be accounted for separately from the host contract, and recorded on the balance sheet at fair value. The fair value of derivative liabilities, including freestanding warrants, is revalued at each reporting date, with corresponding changes in fair value recorded in current period operating results.

### 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. 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:

<u>Years ended December 31,</u>	<u>2011</u>	<u>2010</u>
Expected term (in years)	4.0	5.0
Expected volatility	90.9%	55.0%
Risk free rate	1.27%	0.75% - 1.59%
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

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its unvested options outstanding during the years ended December 31, 2011 and 2010 as they were deemed insignificant.

### 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

In September 2011, the Financial Accounting Standards Board (FASB) issued *Accounting Standards Update (ASU) No. 2011-08, Intangibles — Goodwill and Other (Topic 350)—Testing Goodwill for Impairment*. ASU 2011-8 is intended to simplify the testing of goodwill for impairment by permitting an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in Topic 350. ASU 2011-08 will become effective for fiscal years beginning after December 15, 2011, with early adoption permitted in limited circumstances. The Company is assessing the impact of ASU 2011-08 on its goodwill impairment test but do not expect an impact on its financial condition or results of operations.

### Reclassification

Certain reclassifications were made to the 2010 financial statements in order to conform to the presenting of the 2011 consolidated financial statements. The reclassifications did not have any effect on previously reported stockholders deficit, net loss or net cash flows.

## **4. Merger**

On September 30, 2011, LecTec completed its business combination with AC pursuant to the terms of the Merger Agreement (see Note 2). Such merger was conducted because it was believed that the merger would result in greater growth prospects and increased shareholder value as compared to each organization operating alone.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the date of acquisition. The total acquisition price of \$11,847,916 has been allocated as follows:

Cash and cash equivalents	\$ 7,201,638
Other current assets	40,483
Notes and accrued interest receivable	4,555,562
Goodwill	169,987
Intangible assets	260,000
Accounts payable and accrued expenses	<u>(379,754)</u>
Total purchase price	\$11,847,916

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The following table sets forth the unaudited pro forma results of the Company as if the Merger had taken place on the first day of the period presented. These combined results are not necessarily indicative of the results that may have been achieved had the companies always been combined.

	Years Ended December 31,	
	2011	2010
Revenues	\$ 4,914,938	\$ 3,095,717
Net Loss	(\$ 8,610,775)	(\$ 8,293,300)
Basic and diluted net loss per common share	\$ (0.79)	\$ (0.76)
Weighted average shares – basic and diluted	10,957,705	10,932,427

## 5. Property and Equipment

Property and equipment consist of the following:

	December 31, 2011	December 31, 2010
Furniture and equipment	\$ 535,183	\$ 514,573
Leasehold improvements	42,564	42,564
Processing equipment	988,716	988,716
Less: accumulated depreciation	(1,318,639)	(1,045,111)
Property and equipment	<u>\$ 247,824</u>	<u>\$ 500,742</u>

## 6. Intangible Assets

The Company's intangible assets consist of the following:

	December 31, 2011	December 31, 2010
License agreements	\$ 899,231	\$ 833,481
Patents	291,907	28,801
Less: accumulated amortization	(291,658)	(224,511)
Intangible assets, net	<u>\$ 899,480</u>	<u>\$ 637,771</u>

License agreements are being amortized over periods ranging from 17-20 years. Patent costs are being amortized over three years. Pending patent costs are not amortizable. Amortization expense for 2011 and 2010 was approximately \$67,000 and \$47,000, respectively. As of December 31, 2011, future amortization of license agreements is expected to be \$133,000 for 2012 and 2013, \$112,000 for 2014 and \$47,000 for 2015 and 2016.

### License Agreements

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

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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 owe 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;
- 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 sublicensee 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.

Regarding the license agreement with Emory, a series of milestone payments are listed within the agreement. Particularly, the agreement includes a schedule of license maintenance fees to be paid in the event that no regulatory-related milestone payments have been paid by certain anniversary dates of the agreement, of which none has yet been met. AxoGen renegotiated the License Agreement with Emory prior to any license maintenance fees coming due, but will continue to owe certain fees in the future or risk the loss of such License.

Royalty fees were approximately \$115,000 and \$81,000 during 2011 and 2010 and are included in sales and marketing expense on the accompanying consolidated statements of operations.

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### 7. Long-Term Debt

Long-term debt consists of the following:

	December 31, 2011	December 31, 2010
Loan and Security Agreement with financial institutions for aggregate of \$5,000,000 with 9.9% interest payable monthly through September 2012; principal and interest payable monthly for the 30 months thereafter maturing on April 1, 2015, collateralized by all the assets of the Company and subject to certain financial covenant restrictions including minimum revenue requirements	\$5,000,000	—
The 2008 Loan and Security Agreement (defined later) with financial institutions for \$7,500,000 with 18% interest, payable monthly; principal payable in full on October 1, 2011 (as amended), collateralized by all the assets of the Company and subject to no financial covenant restrictions. Loan was fully paid on September 30, 2011	—	\$ 4,732,857
2010 Related Party Convertible Debt with 8.0% interest; principal and interest payable in full on June 30, 2013, as amended; subordinated to the Loan and Security Agreement; collateralized by a third lien on certain property, converted into common stock on September 30, 2011	—	1,338,455
2010 Convertible Debt with 8.0% interest; principal and interest payable in full on June 30, 2013, as amended; subordinated to the Loan and Security Agreement; collateralized by a third lien on certain property, converted into common stock on September 30, 2011	—	2,359,091
<b>Total debt</b>	<b>5,000,000</b>	<b>8,430,403</b>
Less unamortized debt discount	(161,529)	(11,436)
Less current portion	(434,734)	(8,418,967)
<b>Long-term portion</b>	<b>\$4,403,737</b>	<b>\$ —</b>

Future principal payments on long-term debt are \$241,935 for 2012, \$967,742 for each of 2013 and 2014, and \$322,581 for 2015.

#### **Loan and Security Agreements and Warrants**

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 has a principal amount of \$5.0 million and a term of 42 months, and is subject to prepayment penalties. Under the MidCap Loan, AxoGen is 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 is 9.9% per annum, and interest is computed on the basis of a 360-day year and the actual number of days elapsed during which such interest accrues.

The agreement contains 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 is 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

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was recorded as debt discount and is 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 is being amortized over the term of the loan. Amortization of the deferred financing cost was \$22,714 for 2011.

On April 21, 2008, the Company entered into a Loan and Security Agreement with two different lenders, as subsequently amended (the “2008 Loan and Security Agreement”), which provided for a loan with an aggregate principal amount of \$7.5 million. The loan’s maturity date was October 1, 2011. The loan bore interest at a rate of 18% per month, as amended, and was secured by all of the Company’s assets. Upon the execution of the 2008 Loan and Security Agreement, the Company recorded \$155,556 in deferred financing costs which were being amortized through interest expense on the accompanying consolidated statements of operations over the life of the term note. Amortization of the deferred financing costs was \$12,963 and \$61,531 for 2011 and 2010, respectively.

In conjunction with the 2008 Loan and Security Agreement, the Company also issued warrants to purchase a combined 280,803 shares of the Company’s Series C Preferred Stock, immediately exercisable at \$0.7345 per share, expiring on May 1, 2018. The fair value of the warrants 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 this debt discount was \$11,436 and \$34,308 during 2011 and 2010, respectively.

During 2010, the Company executed six amendments to the 2008 Loan and Security Agreement, resulting in the issuance of a total of 28,561,272 additional warrants for the purchase of the Company’s Series D preferred stock, immediately exercisable at \$0.1198 per share, expiring on varying dates during the year 2020. The total fair value of the warrants of \$2,160,879 was recorded as deferred financing costs during 2010 and was being amortized through interest expense—deferred financing costs on the accompanying consolidated statement of operations. The Company recognized \$990,792 and \$1,170,087 in amortization of these costs for 2011 and 2010, respectively. See additional discussion related to the accounting for the warrants at Note 9.

On April 11, 2011, the Company entered into a waiver and seventh amendment (the “Amendment”) to the 2008 Loan and Security Agreement. The Amendment waived the event of default resulting from the failure to pay the balance due under the 2008 Loan and Security Agreement by March 31, 2011, increased the annual interest rate to 18% beginning April 1, 2011, and extended the maturity to the earlier of an acquisition event (including the Merger discussed in Note 4), or October 1, 2011. In connection with the Amendment, an event of default would occur if the Company fails to receive proceeds from equity and/or convertible subordinated debt financings of at least \$2.5 million by May 31, 2011 and an additional \$2.5 million by August 31, 2011.

On September 30, 2011, the Company paid the entire outstanding loan balance under the 2008 Loan and Security Agreement. The Company also paid a loan pay off fee of \$109,436 which is included in the amortization of deferred financing costs for 2011. The warrants issued to the holders of the 2008 Loan and Security Agreement (see Note 9) expired upon the effective date of the Merger.

### **2009 Convertible Debt and Warrants**

The 2009 Convertible Debt was initially convertible automatically into shares of conversion stock, defined in the agreement as a future “qualified next equity financing,” or its Series C preferred stock. The debt was also convertible at the option of the Company in the event of a future equity financing which was not considered a “qualified next equity financing”. The conversion price was defined as the per share purchase price of the applicable equity financing which results in the conversion of the debt, or \$0.734 per share if converted into Series C preferred stock.

Upon issuance of the 2009 Convertible Debt, the Company recorded a total of \$49,639 in debt issuance costs. These costs were included in deferred financing costs in the accompanying consolidated balance sheet and were

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being amortized through interest expense on the accompanying consolidated statements of operations over the debt term. Amortization of the debt issuance costs was \$45,203 as a result of the conversion of the debt in full into Series D preferred stock during January 2010.

In conjunction with the issuance of the 2009 Convertible Debt, the Company also issued warrants, initially for the purchase of 4,368,948 shares of the Company's Series C Preferred Stock, immediately exercisable at \$0.7345 per share, expiring on August 31, 2014. The fair value of the warrants of \$74,272 was recorded as debt discount and was being amortized through interest expense using the effective interest method over the term of the debt. This debt discount was expensed in full through interest expense in 2010 as a result of the conversion of the associated debt, as noted below. The lenders paid additional consideration totaling \$5,234 for the purchase of the warrants. As a result of the Company's subsequent issuance of its Series D preferred stock on January 7, 2010, the warrants became exercisable for the purchase of Series D preferred stock at \$0.1198 per share. All other terms of the warrants remained unchanged. See additional discussion related to the accounting for the warrants at Note 9.

As a result of the Company's closing on the sale of its Series D preferred stock on January 7, 2010, all of the \$2,617,000 in principal under the 2009 Convertible Debt, along with \$73,994 in accrued and unpaid interest, was converted into 22,462,387 shares of the Series D preferred stock at a rate of \$0.1198 per share.

### **2010 Convertible Debt and Warrants**

The 2010 Convertible Debt is convertible automatically into shares of conversion stock, defined in the agreement as a future "qualified next equity financing", or its Series C preferred stock. The debt is also convertible at the option of the Company in the event of a future equity financing which is not considered a "qualified next equity financing". The conversion price is 65% of the price per share paid at the next equity financing, as defined in the agreement.

Upon issuance of the 2010 Convertible Debt, the Company recorded a total of \$122,900 in deferred financing costs which were being amortized through interest expense on the accompanying consolidated statements of operations over the debt term. Amortization of the deferred financing costs was \$87,221 and \$35,679 for 2011 and 2010, respectively.

In conjunction with the issuance of the 2010 Convertible Debt, the Company also issued warrants, for the purchase of shares of the Company. The warrants expired upon the effective date of the Merger.

In connection with the Merger on September 30, 2011, the 2010 convertible debt of \$1,338,455 and \$2,359,091 and accrued interest of \$263,371 were converted into 2,581,963 shares of AxoGen, Inc. common stock using a conversion price of \$0.0572 (65% of price per share paid at the next equity financing or \$0.088) and the 0.03727336 exchange ratio.

### **2011 Convertible Debt**

On May 3, 2011, the Company issued an 8% convertible note payable for \$500,000 to LecTec related to the Merger. On May 31, 2011, the Company issued additional convertible notes payable under the same terms of which \$2,000,000 was issued to LecTec and \$500,000 was issued to certain AC shareholders. The notes were collateralized by all assets of the Company and subordinated to the Company's 2008 Loan and Security Agreement. Principal and interest accrued under the note is due upon the earlier of June 30, 2013 or a change in control other than in connection with the Merger.

On August 29, 2011, the Company issued an additional subordinated secured convertible promissory note in the principal amount of \$2,000,000 to LecTec and \$500,000 to certain AC shareholders on the same terms as the \$3,000,000 notes issued by the Company in May 2011.

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The \$4,500,000 notes to LecTec were retired after the closing of the Merger. The \$1,000,000 notes to certain AC shareholders were converted into 423,709 shares of AxoGen, Inc.'s common stock using the \$0.088 conversion price and the 0.03727336 exchange ratio.

### **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.

In connection with the Merger, AC common stock were converted into 1,219,199 shares of AxoGen, Inc.'s common stock using the 0.03727336 exchange ratio.

On September 30, 2011, AxoGen sold to certain investors in a private placement 423,709 shares of common stock at \$2.36 per share.

On October 10, 2011, each non-employee director of AxoGen was granted 5,455 shares of AxoGen common stock, valued at \$2.75 per share, in lieu of a cash retainer payment for the director's services through December 31, 2012. The Company recorded \$15,000 of directors fee included in general and administrative expenses and \$60,000 in prepaid expenses related to issuance of 27,275 shares of common stock to five directors.

#### **AC Classes of Stock**

##### *General*

AC had authorized 133,000,000 shares of common stock with a \$.00001 par value.

AC had authorized 103,408,891 shares of preferred stock with a \$.00001 par value which the Board of Directors is empowered to designate and issue in different series. At December 31, 2010, the Board of Directors had designated and issued 2,544,750 shares of Series A Preferred Stock; 17,065,217 shares of Series B Preferred Stock; 16,798,924 shares of Series C Preferred Stock and 67,000,000 shares of Series D Preferred Stock.

In connection with the Merger, on September 30, 2011 each share of Series A, B, C and D convertible preferred stock, for a total of 53,555,857 shares, were converted into shares of AC common stock and exchanged for 1,996,206 shares of AxoGen, Inc. common stock using the 0.03727336 exchange ratio.

##### *Series A Convertible Preferred Stock*

In 2004, AC issued 2,544,750 shares of Series A Convertible Preferred Stock ("Series A") at \$0.4421 per share for an aggregate price of \$1,125,000. No dividends accrued or were payable on the Series A, except upon the declaration of dividends on AC's common stock, payable at a rate per share of Series A equal to the amount the holder would be entitled to receive had all of the Series A been converted to AC common stock. Upon liquidation, Series A holders have preference to any distribution of any of the assets of AC to the holders of AC Common Stock after Series B, Series C, and Series D preferences have been paid. Series A has no redemption option. Each share of Series A is convertible into AC common stock at any time at the option of the holder by dividing the Preferred Original Issue Price by the Conversion Price at the time of conversion, which as of December 31, 2010 is equal to the purchase price of \$0.4421. The conversion price is subject to adjustment, as defined. The only election right for Series A is to vote along with AC common stockholders to elect two directors to the Board. Each share of Series A has voting rights equal to the number of AC common shares as if converted.

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### ***Series B Convertible Preferred Stock***

In 2006, AC issued 16,847,826 shares of Series B Convertible Preferred Stock ("Series B") at \$0.46 per share for an aggregate price of \$7,750,000. The holders of the Series B are entitled to receive a cash dividend in preference over shares of AC common stock and Series A stockholders of AC at a rate of 8% of the issued price, per annum. Upon liquidation, the Series B holders have preference to any distributions of any of AC's assets equal to the Preferred Original Issue Price plus any unpaid dividends after Series C and Series D preferences have been paid. At any time on or after January 7, 2015, the Series B stockholders have the right to redeem shares equal to the redemption price upon written request of at least 55% of the holders of Series B. Each share of Series B is convertible into AC common stock at any time at the option of the holder by dividing the Preferred Original Issue Price by the Conversion Price at the time of conversion, which as of December 31, 2010 is equal to the purchase price of \$0.46. The conversion price is subject to adjustment, as defined. The holders of a majority of the Series B, C and D Preferred Stock have the right to elect three directors to the Board. Also, Series B, C and D will vote together with Series A and AC common stockholders to elect two directors to the Board. Each share of Series B, C and D has voting rights equal to the number of AC common shares as if converted.

AC is accreting dividends on the Series B, based on the stated dividend rate of 8% per annum. The Series B dividends accreted for the years ended December 31, 2011 and 2010 was \$292,329 and \$483,725, respectively. A total of \$3,152,603 in Series B dividends have been accreted as of September 30, 2011 and were forfeited in accordance with the Merger.

On June 11, 2010, 7,065,217 shares of Series B, representing \$3,250,000, were converted into 263,344 shares of AC's common stock at the election of the stockholder.

### ***Series C Convertible Preferred Stock***

In 2007, AC issued 16,518,121 shares of Series C Convertible Preferred Stock ("Series C") at \$0.7345 per share for an aggregate purchase price of \$12,132,559. The holders of the Series C are entitled to receive a cash dividend in preference over shares of AC common stock, Series A and Series B stockholders of AC at a rate of 8% of the issued price, per annum. Upon liquidation, the Series C holders have preference to any distributions of any of AC's assets equal to the Preferred Original Issue Price plus any unpaid dividends after Series D preferences have been paid. At any time on or after January 7, 2015, the Series C shareholders have the right to redeem shares equal to the redemption price upon written request of at least 60% of the holders of Series C. Each share of Series C is convertible into AC common stock at any time at the option of the holder by dividing the Preferred Original Issue Price by the Conversion Price at the time of conversion, which as of December 31, 2010 is equal to the purchase price of \$0.7345. The conversion price is subject to adjustment, as defined. The holders of a majority of the Series B, C and D have the right to elect three directors to the Board. Also, Series B, C and D will vote together with Series A and AC common stockholders to elect two directors to the Board. Each share of Series B, C and D has voting rights equal to the number of AC common shares as if converted.

AC is accreting dividends on the Series C, based on the stated dividend rate of 8% per annum. The dividends accreted for the years ended December 31, 2011 and 2010 was \$515,577 and \$784,654, respectively. A total of \$3,403,651 in Series C dividends have been accreted as of September 30, 2011 and were forfeited in accordance with the Merger.

On June 11, 2010, 5,445,882 shares of Series C, representing \$4,000,000, were converted into 202,986 shares of AC's common stock at the election of the stockholder.

### ***Series D Convertible Preferred Stock and Warrants***

On January 7, 2010, AC issued 39,156,876 shares of Series D Preferred Stock ("Series D") at \$0.1198 per share for an aggregate price of \$4,661,326, net of issuance costs of \$29,667. Of the total shares issued, 16,694,489 shares were issued for \$2,000,000 in cash. The remaining 22,462,387 shares were issued in conjunction with the

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conversion of \$2,617,000 of principal and \$73,994 of accrued and unpaid interest under the 2009 Convertible Debt (see Note 7). The holders of the Series D are entitled to receive a cash dividend in preference over all other stockholders of AC at a rate of 8% of the issued price, per annum. Upon liquidation, the Series D holders have preference to any distributions of any of AC's assets equal to the Preferred Original Issue Price plus any unpaid dividends. At any time on or after January 7, 2015, the Series D shareholders have the right to redeem shares equal to the redemption price upon written request of at least 66 2/3% of the holders of Series D. Each share of Series D is convertible into AC common stock at any time at the option of the holder by dividing the Preferred Original Issue Price by the Conversion Price at the time of conversion, which as of December 31, 2010 is equal to the purchase price of \$0.1198. The conversion price is subject to adjustment, as defined. The holders of a majority of the Series B, C and D have the right to elect three directors to the Board. Also, Series B, C and D will vote together with Series A and AC common stockholders to elect two directors to the Board. Each share of Series B, C and D has voting rights equal to the number of AC common shares as if converted.

AC is accreting dividends on the Series D, based on the stated dividend rate of 8% per annum. Dividends accreted during the years ended December 31, 2011 and 2010 were \$220,444 and \$297,982, respectively. A total of \$518,426 in Series D dividends have been accreted as of September 30, 2011 and were forfeited in accordance with the Merger.

On September 11, 2010, 9,000,617 shares of Series D, representing \$1,078,274, were converted into 335,483 of AC's common stock at the election of the stockholder.

In conjunction with the issuance of the Series D, AC also issued warrants for the purchase of 8,347,236 shares of AC's Series D Preferred Stock, immediately exercisable at \$0.1198 per share, expiring on January 7, 2015. The investors paid additional consideration totaling \$10,000 for the purchase of the warrants. The warrants are considered offering costs related to the Series D issuance and their fair value of \$517,529 was recorded net against proceeds on the issuance of the stock during 2010.

## **9. Preferred Stock Warrants and Warrant Liability**

### **Preferred Stock Warrants**

At September 30, 2011, the outstanding warrants to purchase the Company's Series C and Series D preferred stock which were issued in connection with certain financing arrangements and amendments to existing financing arrangements were expired unexercised in connection with the Merger. Information relating to these warrants at December 31, 2010 is summarized as follows:

<u>Warrants</u>	<u>Remaining Number Outstanding</u>	<u>Exercise Price</u>
Series C Warrants-2008 Loan and Security Agreement	280,803	\$ 0.7345
Series D Warrants-2009 Convertible Debt	4,368,948	\$ 0.1198
Series D Warrants-Series D Preferred Stock Issuance	8,347,236	\$ 0.1198
*Series D Warrants-1 <sup>st</sup> Amendment	6,243,362	\$ 0.1198
*Series D Warrants-2 <sup>nd</sup> Amendment	8,694,558	\$ 0.1198
*Series D Warrants-3 <sup>rd</sup> Amendment	4,462,227	\$ 0.1198
*Series D Warrants-5 <sup>th</sup> Amendment	2,260,440	\$ 0.1198
*Series D Warrants-6 <sup>th</sup> Amendment	6,900,685	\$ 0.1198
<b>Total</b>	<b>41,558,259</b>	

\* Warrants issued to lenders in conjunction with amendments to 2008 Loan and Security Agreement (see Note 7).

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### **Warrant Liability**

The warrants issued in conjunction with the 2008 Loan and Security Agreement (see Note 7) are issuable for Series C preferred stock. The warrants issued in connection with the 2009 Convertible Debt (see Note 7) and the Series D Preferred Stock (see Note 8) are issuable for Series D preferred stock. Both the Series C and Series D preferred stock are considered contingently redeemable based on the stockholders' right to redeem the shares on or after January 7, 2015. In accordance with Accounting Standards Codification on *Distinguishing Liabilities from Equity*, since the warrants are indexed to contingently redeemable securities of the Company, they are classified as liabilities upon issuance. As liability classified derivative financial instruments, the warrants are initially and subsequently required to be measured at their fair values as defined in Accounting Standards Codification on *Fair Value Measurement*.

The change in fair value of the warrants between each reporting period is recorded in the consolidated statements of operations and was estimated by the Company using a binomial lattice valuation model. The following assumptions were incorporated into the valuations for 2011 and 2010:

	2011	2010
Exercise price	\$ 0.1198 – \$0.7345	\$ 0.1198 – \$0.7345
Market value of stock at end of period	\$0.01	\$0.01
Expected dividend rate	N/A	N/A
Expected volatility	33.47% – 62.86%	39.46% – 75.57%
Risk-free interest rate	0.03% – 3.18%	0.12% – 3.39%
Expected life in years	3.40 – 9.90	7.33 – 10.00
Shares underlying warrants outstanding classified as liabilities	41,558,259	41,558,259

The Company recorded income of \$62,305 and \$78,306 for 2011 and 2010, respectively, as a result of the change in the fair value of warrant liability between reporting periods which was recorded in other income (expense) on the consolidated statements of operations. The total balance of the warrant liability as of September 30, 2011 of \$2,607,510 was forfeited in accordance with the Merger.

### **10. 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 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

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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 \$250,044 and \$187,458 for 2011 and 2010, respectively.

The following is a summary of stock option activity:

	Common Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term(Years)
Outstanding at December 31, 2009:	173,965	\$ 2.68	
Granted	331,383	0.27	
Forfeited	(43,065)	2.68	
Exercised	(14,624)	2.41	
Outstanding at December 31, 2010:	447,659	0.27	8.62
Granted	1,141,952	2.61	
LecTec stock option from Merger	464,000	3.48	
Forfeited	(9,223)	(0.06)	
Exercised	(98,700)	(0.27)	
Outstanding at December 31, 2011	<u>1,945,688</u>	<u>\$ 2.41</u>	<u>7.35</u>
Exercisable at December 31, 2011	<u>682,481</u>	<u>\$ 2.88</u>	<u>7.17</u>

The average fair value of options granted at market during 2011 and 2010 was \$0.42 and \$0.04 per option, respectively.

The intrinsic value of options exercised during the years ended December 31, 2011 and 2010 was approximately \$190,000 and \$0, respectively. The intrinsic value of options outstanding at December 31, 2011 was approximately \$1,126,000. The intrinsic value of options exercisable at December 31, 2011 was approximately \$391,000.

During 2010, the Board of Directors approved the repricing of all outstanding options, effectively reducing the exercise price to \$0.01 per share. As a result of the repricing, the Company recorded approximately \$1,800 and \$15,000 in stock-based compensation expense for the year ended December 31, 2011 and 2010, respectively.

In connection with the Merger, all outstanding options to purchase shares of AC Common Stock were exchanged for options to purchase shares of AxoGen, Inc. common stock at a ratio of one to 0.03727336. The Company recorded \$38,521 incremental cost in 2011 related to this modification.

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Total future compensation expense related to nonvested awards is expected to be approximately \$1,904,000 at December 31, 2011, which is expected to be recognized over a weighted – average period of 3.65 years. The following table represents non-vested share-based payment activity with employees for the year ended December 31, 2011 and 2010:

	Number of Options	Weighted Average Grant Date Fair Value
Nonvested options - December 31, 2009:	85,269	\$ 2.68
Granted	331,383	0.27
Vested	(81,897)	(2.41)
Forfeited	(9,180)	(2.68)
Nonvested options - December 31, 2010:	325,575	0.27
Granted	1,141,952	0.42
Vested	(195,099)	0.87
Forfeited	(9,223)	0.004
Nonvested options - December 31, 2011	1,263,205	1.41

Subsequent to year end, the Company granted additional 201,326 shares of stock option to employees.

## 11. 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	2011	2010
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 15,065,000	\$ 11,785,000
Charitable contributions	3,000	3,000
Inventory reserves	163,000	—
Accruals	—	50,000
Stock-based compensation	361,000	267,000
Total deferred tax assets	<u>15,592,000</u>	<u>12,105,000</u>
<b>Deferred tax liabilities:</b>		
Depreciation	(160,000)	(189,000)
Amortization	(51,000)	(47,000)
Total deferred tax liabilities	<u>(211,000)</u>	<u>(236,000)</u>
Net deferred tax assets	15,381,000	11,869,000
Valuation allowance	<u>(15,381,000)</u>	<u>(11,869,000)</u>
	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2011, the Company had net operating loss carryforwards of approximately \$31.6 million to offset future taxable income which expire in various years through 2030. 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, 2011 and 2010. 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. The valuation allowance increased by \$3,512,000 and \$2,402,000 during 2011 and 2010, respectively. The difference between the expected federal income tax rate and actual tax rate is primarily due to the valuation of deferred tax assets.

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**12. 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 2011 and 2010, the Company match was 3% of the participating employee's annual salary. The Company contributed \$66,687 and \$54,363 in matching funds during 2011 and 2010, respectively.

**13. Commitments and Contingencies Operating Leases**

**Operating Leases**

The Company leases its lab space under one-year lease agreements, currently expiring in September 2012.

Its corporate office space lease agreement expires in April 2013. The Company also leases equipment and storage facilities. Estimated future minimum rental payments on the leases are as follows:

<u>Year ending December 31</u>	
2012 .....	\$153,000
2013 .....	<u>34,000</u>
TOTAL .....	<u>\$187,000</u>

Total rent expense for the years ended December 31, 2011 and 2010 was approximately \$171,000 and \$178,000, respectively.

**Service Agreements**

In February 2008, the Company entered into a two-year tissue processing agreement with a vendor. This Agreement was renewed and amended in March 2012. Tissue processing fees are based on a per donor batch rate. The Company is also required to pay processing room fees. The agreement is for a one year term, automatically renewing for one year terms unless terminated. Either party can terminate a renewal term with 180 days notice.

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 a seven-year initial term, renews automatically for an additional seven-year term, subject to pricing agreement, requires certain minimum purchases, and establishes a formula for the transfer cost of the AxoGuard® products.

In January 2011, the Company entered into a one year biostorage and services agreement with a vendor. The agreement specifies monthly administration fees, storage, receiving and shipping fees based on volume. The agreement automatically renews for one year periods and can be terminated with 30 days written notice.

The Company currently uses one vendor for its biostorage and tissue processing and purchases AxoGuard product from one supplier. Although there are a limited number of vendors available for biostorage and processing, management believes that other vendors could provide similar services on comparable terms, or the Company would be able to do the processing and storage in-house. Loss of the AxoGuard supplier would be difficult to replace and have a material adverse effect.

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In December 2011, the Company also entered into a Master Services Agreement for Clinical Research and Related Services. The Company is 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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**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, 2011 and concluded that our disclosure controls and procedures were ineffective as of December 31, 2011.

**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. 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.

Management has excluded AC from its assessment of internal control over financial reporting as of December 31, 2011 because it was acquired in a business combination that was accounted for as a reverse merger at the end of the third quarter of 2011. AC’s total assets and total revenues represents 34% and 99%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2011. The Company is currently determining the extent of testing needed to comply with Sarbanes-Oxley Act of 2002, and we expect to complete our review and testing before the first anniversary of the Merger.

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.

Subsequent to December 31, 2011, we became aware of an instance in which the accounting for a contract was inappropriately treated as an expense as opposed to a prepaid asset. Specifically, an effective control was not operating to ensure that accounting for the contract was completely and accurately recorded during the fourth quarter of 2011. This control deficiency could have resulted in misstatement of net loss that would not have been prevented or detected. Accordingly, we have determined that this control deficiency constitutes a material weakness.

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A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Because of this material weakness, management concluded that the Company did not maintain effective internal control over financial reporting as of December 31, 2011, based on criteria issued by the COSO.

During the first quarter of 2012, in response to the conclusion reached by our Chief Executive and Chief Financial Officers that, as of December 31, 2011, our disclosure controls and procedures were not effective, we have implemented a control procedure whereby all significant contracts will be reviewed by the Chief Financial Officer at the end of each quarter and the Chief Financial Officer will then review the accounting with the Company's corporate controller prior to the recording of all such contracts.

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 quarter ended December 31, 2011, 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**

After the Merger, on October 1, 2011, Mr. Gregory G. Freitag resigned as CEO of LecTec and was appointed as CFO of AxoGen, Inc. and AC. Mr. Freitag did not have any employment agreement with the Company before the Merger. In January 2012, Mr. Freitag entered into an employment agreement with AC, retroactively effective on October 1, 2011. A description of Mr. Freitag's employment agreement under "Item 11. Executive Compensation – Employment Agreements" is incorporated herein by reference.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.**

**Executive Officers and Directors**

Prior to the Merger, Gregory Freitag was LecTec’s only executive officer, serving as CEO and CFO; and LecTec’s Board of Directors consisted of the following five directors: Gregory G. Freitag, Timothy M. Heaney, Lowell Hellervik, Ph. D., Robert J. Rudelius and Elmer Salovich, M.D. At the Company’s 2011 annual meeting of shareholders (the “Annual Meeting”), Messrs. Freitag and Rudelius were nominated for re-election, while Mr. Heaney and Drs. Hellervik and Salovich did not stand for re-election. At the Annual Meeting, LecTec shareholders approved, among other things, an increase of the size of the Company’s board of directors to seven members, and elected the following directors (i) Messrs. Freitag and Rudelius, and (ii) Mark Gold, M.D., Jamie M. Grooms, John Harper, Joe Mandato and Karen Zaderej, each of whom was then a director of AC, subject to completion of the Merger. Each elected director was to hold office for a term of one year and until their successors are duly elected and qualified (except in the case of earlier death, resignation or removal). The following table lists the names, age and positions of the individuals who serve on the Board of Directors of the Company as of March 15, 2012,

<u>Name</u>	<u>Age</u>	<u>Title</u>
Karen Zaderej	50	Chief Executive Officer and Director
Gregory Freitag	50	Chief Financial Officer, General Counsel and Director
Jamie M. Grooms	52	Director, Chairman of the Board of Directors
Mark Gold, M.D.	62	Director
John Harper	61	Director
Joe Mandato	67	Director
Robert Rudelius	56	Director

*Karen Zaderej, President, Chief Executive Officer and Director (Age 50)*

Ms. Zaderej’s biographical information is provided above under “Business — Executive Officers of the Registrant.”

*Gregory G. Freitag, Chief Financial Officer and Director (Age 50)*

Mr. Freitag’s biographical information is provided above under “Business — Executive Officers of the Registrant.”

*Jamie M. Grooms, Chairman and Director (Age 52)*

Mr. Grooms has served as Chairman of the Company’s board of directors since September 30, 2011 and AC’s board of directors since 2002. Mr. Grooms is a co-founder of AC and from 2002 to May 2010 served as AC’s Chief Executive Officer. Since leaving AC in May 2010, Mr. Grooms has provided consulting services to start-up companies and serves on the board of directors of several companies. From 1998 to 2002, Mr. Grooms served as the founding Chief Executive Officer and Chairman of the Board of Regeneration Technologies, Inc. a publicly-traded company involved in processing human tissue for allogenic grafts used in orthopedic, oral maxillofacial, urinary and cardiovascular surgeries. Mr. Grooms has extensive experience in all areas of operations of the allograft business and has worked at the Virginia Tissue Bank (now LifeNet Health), Osteotech, Inc., and CryoLife, Inc. in various positions of leadership. In addition, Mr. Grooms has served as Director of the University of Florida Tissue Bank from 1992 to 1995. Mr. Grooms holds a Bachelor’s degree in biology from Old Dominion University.

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### *Mark Gold, MD, Director (Age 62)*

Dr. Gold has served as a member of the Company's board of directors since September 30, 2011 and AC's board of directors since July 2007. Since 1999, Dr. Gold has been a Professor at the University of Florida College of Medicine's McKnight Brain Institute. Dr. Gold has taught medical neuroscience for four decades and has been a pioneer in translational neuroscience research for over three decades. Dr. Gold was also a Founder of Somerset Valley Bank and served on its board of directors from its formation through its initial public offering to its acquisition by Fulton Financial Corporation, a publicly-traded financial holding company. Dr. Gold has consulted for many major global pharmaceutical companies as well as firms such as the Carlyle Group and Cressey & Company. Dr. Gold has authored hundreds of scientific research articles, chapters, and abstracts on a wide variety of research subjects and is frequently interviewed for comment by the Wall Street Journal, CNN and other major business and national publications concerned with the strengths and limitations of new technology and treatments.

### *John Harper, Director (Age 61)*

Mr. Harper has served as a member of the Company's board of directors since September 30, 2011 and AC's board of directors since June 2006. From June 2005 to January 2006, Mr. Harper was the Entrepreneur-in-Residence at The Innovation Factory, a medical device incubator. From August 2000 to October 2001, Mr. Harper served as President and Chief Executive Officer of ATI Medical, Inc. and from February 1998 to May 1999, he served as Executive Chairman of Meretek Diagnostics, Inc., which was acquired by American Standard Companies. From November 1995 to March 1997, Mr. Harper served as President and Chief Executive Officer of Indigo Medical, Inc., which merged with Johnson & Johnson. Mr. Harper also served as Vice President of Sales and Marketing, and then President and Chief Executive Officer, of Menlo Care, Inc. from June 1989 to June 1995. Menlo Care, Inc. merged with Johnson & Johnson in 1995. Mr. Harper has served on the board of directors for a number of medical device and biotechnology companies since 1999. He received his BA in Economics from Davidson College in 1971.

### *Joe Mandato, Director (Age 67)*

Mr. Mandato has served as a member of the Company's board of directors since September 30, 2011 and AC's board of directors since February 2006. From March 2003 to the present, Mr. Mandato has served as a Managing Director of DeNovo Ventures, a venture capital firm and a stockholder of AxoGen. From February 1999 to September 2000, Mr. Mandato served as Chairman of Confer Software, Inc., a developer of enterprise software used to automate healthcare business processes. From September 1995 to February 1999, Mr. Mandato served as Confer Software's Chief Executive Officer. From September 1994 to May 1995, Mr. Mandato served as a Vice President, member of founding management committee and Chief Executive Officer of two of Guidant Corporation's five operating units, Origin Medsystems and Heart Rhythm Technology. He also served as President and Chief Executive Officer of Origin Medsystems from May 1991 to May 1995. In March 1994, Mr. Mandato co-founded Gynecare, Inc., a developer of devices used in gynecology, which was spun out of Guidant Corporation., and served as its Chief Executive Officer until April 1995. From July 1986 to November 1990, Mr. Mandato was Chief Executive Officer of Ioptex Research Inc., an ophthalmic device company. Mr. Mandato serves on the board of directors of several companies and non-profit organizations.

### *Robert J. Rudelius, Director (Age 56)*

Mr. Rudelius has served as a member of the Board of Directors since September 2010. Since 2003, Mr. Rudelius has been the Managing Director and Chief Executive Officer of Noble Ventures, LLC, a company he founded that provides advisory and consulting services to early-stage companies in the information technology, renewable energy and loyalty marketing fields. From April 1999 through May 2001, when it was acquired by StarNet L.P., Mr. Rudelius was the founder and Chief Executive Officer of Media DVX, Inc., a start-up business that provided a satellite-based, IP-multicasting alternative to transmitting television commercials via analog videotapes to television stations, networks and cable television operators throughout

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North America. Mr. Rudelius assisted StarNet L.P. with the transition and integration of the Media DVX, Inc. business through January 2002. From April 1998 to April 1999, Mr. Rudelius was the President and Chief Operating Officer of Control Data Systems, Inc., during which time Mr. Rudelius reorganized and repositioned the software company as a professional services company, which resulted in the successful sale of Control Data Systems, Inc. to Syntegra, British Telecom's systems integration subsidiary. From October 1995 through April 1998, Mr. Rudelius was the founding Managing Partner of AT&T Solution's Media, Entertainment & Communications industry group. From January 1990 through September 1995, Mr. Rudelius was a partner in McKinsey & Company's Information, Technology and Systems practice group, during which time he headed the practice group in Tokyo and co-lead the practice group in London. Mr. Rudelius is currently a member of the Board of Directors of ProUroCare Medical, Inc., a publicly-held medical device company that develops and markets prostate imaging systems.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934 requires our executive officers and directors and persons who beneficially own more than 10% of our common stock to file initial reports of ownership and reports of changes in ownership with the Securities and Exchange Commission. Such executive officers, directors, and greater than 10% beneficial owners are required by the regulations of the Securities and Exchange Commission to furnish us with copies of all Section 16(a) reports they file.

Based solely on a review of the copies of such reports furnished to us and representations from the executive officers and directors, we believe that all Section 16(a) filing requirements applicable to our executive officers, directors and greater than 10% beneficial owners during 2011 have been satisfied, except that one report on Form 4 was inadvertently filed late for Robert Rudelius, a director, reporting purchase transactions, and one report on Form 4 was inadvertently filed for each of Mark Friedman, Vice President of Regulatory and Quality and David Hansen, Corporate Controller reporting an option exercise.

### **Code of Ethics**

We have adopted a Code of Business Ethics applicable to all of our employees, including our principal executive officer, principal financial officer, and principal accounting officer. Our Code of Business Ethics is required to be read and signed upon the commencement of employment with the Company. A copy of our Code of Business Ethics is available to any person free of charge upon request sent to Investor Relations of the Company. Requests can be made by e-mail to [InvestorRelations@AxoGenInc.com](mailto:InvestorRelations@AxoGenInc.com) or by calling customer relations at 888-296-4361. The Code of Business Ethics is also available at the Company's website.

### **Director Independence**

The Company is not a listed issuer and so is not subject to the director independence requirements of any exchange or inter-dealer quotation system. Nevertheless, in determining whether its directors and director nominees are independent, the Company uses the definition of independence provided in Rule 4200(a) (15) of the NASDAQ Stock Market's Marketplace Rules. Under this definition of independence, Messrs. Gold, Harper, Mandato and Rudelius would be considered independent directors.

### **Board Committees**

The standing committees of AxoGen's Board of Directors include an Audit Committee, a Compensation Committee and a Governance and Nominating Committees. Messrs. Rudelius (Chairman) and Harper are the members of the Audit Committee. Messrs. Harper (Chairman), Rudelius and Mandato and Dr. Gold are members of the Compensation Committee. Dr. Gold (Chairman) and Messrs. Grooms and Harper are members of the Nominating and Governance Committees. The Charters of each of the Audit Committee, the Compensation, and

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Governance and Nominating Committee can be found on our website under “About AxoGen – Investors – Corporate Governance.”

### ***Audit Committee***

The Audit Committee is responsible for review of audits, financial reporting and compliance, and accounting and internal controls policy. For audit services, the Audit Committee is responsible for the engagement and compensation of independent auditors, oversight of their activities and evaluation of their independence. The Audit Committee has instituted procedures for receiving reports of improper record keeping, accounting or disclosure. In the opinion of the AxoGen Board of Directors, each of the members of the Audit Committee has both business experience and an understanding of generally accepted accounting principles and financial statements enabling them to effectively discharge their responsibilities as members of that Committee. Moreover, the AxoGen Board of Directors has determined that each of Messrs. Rudelius and Harper is an “audit committee financial expert” as such term is defined in Item 407(d)(5) of Regulation S-K promulgated by the SEC.

### ***Compensation Committee***

The Compensation Committee is responsible for establishing executive compensation and administering AxoGen’s Incentive Compensation Plan.

### ***Governance and Nominating Committee***

The Governance and Nominating Committee is responsible to provide oversight in relation to the corporate governance of AxoGen and also identifies director nominees for election to fill vacancies on the AxoGen Board of Directors. Nominees are approved by the AxoGen Board of Directors on recommendation of the Governance and Nominating Committee. In evaluating nominees, the Governance and Nominating Committee particularly seeks candidates of high ethical character with significant business experience at the senior management level who have the time and energy to attend to board responsibilities. Candidates should also satisfy such other particular requirements that the Governance and Nominating Committee may consider important to AxoGen’s business at the time. When a vacancy occurs on the AxoGen Board of Directors, the Governance and Nominating Committee will consider nominees from all sources, including shareholders, nominees recommended by other parties, and candidates known to the directors or AxoGen’s management. The best candidate from all evaluated will be recommended to the AxoGen Board of Directors to consider for nomination.

Shareholders who wish to recommend candidates for consideration as nominees should on or before January 1 of each year furnish in writing detailed biographical information concerning the candidate to the Governance and Nominating Committee addressed to the Corporate Secretary of AxoGen at 13859 Progress Blvd., Suite 100, Alachua, FL 32615. No material changes have been made to the procedures by which security holders may recommend nominees to AxoGen’s Board of Directors.

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**ITEM 11. EXECUTIVE COMPENSATION.**

**Executive Compensation**

The following table sets forth the cash and non-cash compensation for the fiscal years 2011 and 2010 for: (i) each individual serving as the Company's Chief Executive Officer ("CEO") or acting in a similar capacity during any part of such fiscal years; and (ii) the other two most highly paid executive officers who were serving as executive officers during such periods (our "named executive officers").

**Summary Compensation Table**

Name and Principal Position	Year	Salary(\$)	Bonus(\$)	Stock Awards(\$)(1)	Option Awards(#)(1)(2)	All Other Compensation(\$)	Total
Judd A. Berlin(3)	2011	—	—	—	—	—	—
Former CEO and CFO	2010	165,000	—	—	—	80,500	245,500
Gregory G. Freitag(4)	2011	254,808	100,000	—	172,859	—	527,667
Former CEO and CFO and General Counsel	2010	87,500	—	—	393,060	6,000	486,560
Dr. Daniel C. Sigg(5)	2011	—	—	—	—	—	—
Former Chief Scientific Officer	2010	87,083	—	—	—	15,000	102,083
Karen Zaderej	2011	252,403	23,254	—	516,697	7,537	799,891
CEO(6)(7)	2010	196,492	8,090	—	19,426	6,151	230,159
Jamie M. Grooms	2011	—	—	—	—	—	—
Former CEO(6)(8)	2010	82,327	—	—	14,407	39	96,773
John P. Engels	2011	171,138	16,833	—	121,998	5,453	315,422
Vice President(6)(9)	2010	157,194	7,742	—	5,902	4,905	175,743

- (1) The amounts in this column are calculated based on the aggregate grant date fair value computed in accordance with Accounting Standards Codification ("ASC") Topic 718 as of December 31 of the year indicated.
- (2) The amounts shown for option awards relate to option awards granted under the AxoGen Corporation 2002 Stock Incentive Plan, as amended. These amounts are equal to the aggregate grant date fair value of the options computed in accordance with FASB ASC Topic 718 using the assumptions set forth in Note to AxoGen's audited consolidated financial statements included elsewhere in this Form 10-K. In March 2010, the AxoGen Board of Directors approved the repricing of all outstanding options, effectively reducing the exercise price to \$0.01 per share. As a result of the repricing, AxoGen recorded approximately \$15,000 in stock-based compensation expense for the year ended December 31, 2010, \$2,521 of which was the incremental fair value of Ms. Zaderej's outstanding options as of the repricing date, \$1,642 of which was the incremental fair value of Mr. Grooms' outstanding options as of the repricing date and \$555 of which was the incremental fair value of Mr. Engels' outstanding options as of the repricing date.
- (3) Mr. Berlin served as AxoGen's CEO and CFO through June 1, 2010, at which time Mr. Berlin stepped down as our CEO and CFO, but continued as an advisor to AxoGen. The Summary Compensation Table reflects \$165,000 in compensation received by Mr. Berlin in his capacity as our CEO and CFO in 2010 and \$80,500 in compensation received by Mr. Berlin in his capacity as an advisor to LecTec in 2010.
- (4) Mr. Gregory G. Freitag is our current CFO and General Counsel and has been serving in such capacity since June 1, 2010, and, prior to such time, served as a consultant to the Company in 2010. Mr. Freitag stepped down as CEO on September 30, 2011 in conjunction with the Merger. The Summary Compensation Table reflects \$87,500 in compensation received by Mr. Freitag in his capacity as our CEO and CFO in 2010 and \$6,000 in compensation received by Mr. Freitag in his capacity as a consultant to the Company in 2010. On September 30, 2011, Mr. Freitag received a one-time bonus as a result of completing the Merger.

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- (5) Dr. Sigg served as our Chief Scientific Officer until October 1, 2010, at which time Dr. Sigg stepped down as our Chief Scientific Officer, but continued as an advisor to the Company. The Summary Compensation Table reflects \$87,083 in compensation received by Dr. Sigg in his capacity as our Chief Scientific Officer in 2010 and \$15,000 in compensation received by Dr. Sigg in his capacity as an advisor to the Company in 2010.
- (6) Ms. Zaderej voluntarily accepted reduced salaries in 2010 and for a portion of 2011.
- (7) Ms. Zaderej has been CEO of the Company since September 30, 2011 as a result of the Merger, CEO of AC since May 2010 and was Chief Operating Officer of AC from 2007 through May 2010. The amounts include life insurance premiums paid by AxoGen on behalf of Zaderej in 2010 of \$256 and \$365 in 2011 and also includes amounts contributed by the Company to the SIMPLE IRA plan on her behalf for 2010 of \$5,895 and 2011 of \$7,172.
- (8) The amounts include life insurance premiums paid by AxoGen on behalf of Mr. Grooms in 2010 of \$39.
- (9) The amounts include life insurance premiums paid by AxoGen on behalf of Mr. Engels in 2010 of \$189 and \$319 in 2011 and also includes amounts contributed by the Company to the SIMPLE IRA plan on his behalf for 2010 of \$4,716 and 2011 of \$5,134.

### *Outstanding Equity Awards at Fiscal Year End*

The following table summarizes the equity awards granted to our named executive officers that remain outstanding as of December 31, 2011.

Option Awards					
Name	Option Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Judd A. Berlin(1)	9/26/ 2008	66,000	—	\$ 4.00	9/26/ 2018
Gregory G. Freitag	6/1/ 2010	125,000(2)	—	\$ 3.50	6/1/ 2020
	12/26/ 2011	—	92,000(3)	\$ 2.74	12/26/ 2018
Dr. Daniel C. Sigg(4)	9/20/2007	25,000	—	\$ 2.60	9/20/2017
	9/20/2007	25,000	—	\$ 5.20	9/20/2017
	9/26/ 2008	16,000	—	\$ 4.00	9/26/ 2018
Karen Zaderej	11/18/2008	—	126(5)	\$ 0.27	11/18/2018
	6/9/2010	—	90,278(5)	\$ 0.27	6/9/2020
	12/26/2011	—	275,000(6)	\$ 2.74	12/26/2018
	12/26/2011	—	100,000(7)	\$ 2.74	12/26/2018
Jamie M. Grooms	12/5/2007	11,182(8)	—	\$ 0.27	12/5/2017
	12/6/2007	3,197(8)	—	\$ 0.27	12/6/2017
	11/18/2008	371(8)	123(8)	\$ 0.27	11/18/2018
	6/9/2010	27,247(8)	81,742(8)	\$ 0.27	6/9/2020
	10/10/2011	12,000(9)	—	\$ 2.75	10/10/2018
John P. Engels	6/7/2006	3,727(10)	—	\$ 0.27	6/7/2016
	12/6/2007	719(10)	—	\$ 0.27	12/6/2017
	11/18/2008	305(10)	101(10)	\$ 0.27	11/18/2018
	6/9/2010	11,421(10)	34,264(10)	\$ 0.27	6/9/2020
	12/16/2011	—	65,000(11)	\$ 2.74	12/16/2018

- (1) Mr. Berlin received this option which is fully vested and exercisable. The option was granted under plans previously approved by the Company's shareholders and the exercise price for the option was issued at a price equal to the fair market value of the Company's common stock on the date of grant.

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- (2) Mr. Freitag received this option which became fully vested and exercisable on August 29, 2011 pursuant to the vesting terms of the option. The option was granted outside of plans previously approved by the Company's shareholders and the exercise price for the option was issued at a price equal to the fair market value of the Company's common stock on the date of grant.
- (3) Mr. Freitag received this option to purchase 92,000 shares of the Company's common stock. All shares pursuant to the option will be fully vested on December 26, 2015 (4 years from the option grant date) based upon a vesting schedule whereby 25% of the aggregate shares vest on December 26, 2012 (12 months from the option grant date) and an additional 12.5% of aggregate shares each 6 months thereafter and will expire December 26, 2018. The option was granted under plans previously approved by the Company's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the Company's common stock on the date of grant.
- (4) Dr. Sigg was awarded these options which are fully vested and exercisable. The options were granted under plans previously approved by the Company's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the Company's common stock on the date of grant.
- (5) Ms. Zaderej received these options to purchase shares of AC common stock, which options pursuant to the Merger have been adjusted and provide for the right to purchase Company Common Stock. The options vest semi-annually and become fully vested and exercisable four years from the grant date. The options were granted under plans previously approved by AxoGen's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the AxoGen's common stock on the date of grant.
- (6) Ms. Zaderej received this option to purchase 275,000 shares of the Company's common stock. All shares pursuant to the option will be fully vested on December 26, 2015 (4 years from the option grant date) based upon a vesting schedule whereby 25% of the aggregate shares vest on December 26, 2012 (12 months from the option grant date) and an additional 12.5% of aggregate shares each 6 months thereafter and will expire December 26, 2018. The option was granted under plans previously approved by the Company's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the Company's common stock on the date of grant.
- (7) Ms. Zaderej received this option to purchase 100,000 shares of the Company's common stock. The shares under the Option are subject to a performance vesting provision (the "Performance Shares") whereby all, none or a portion of the Performance Shares, to the extent to which the performance standards established by the Board of Directors are met, will vest as to 25% of the Performance Shares on March 31, 2013, and an additional 12.5% of the Performance Shares each six months thereafter, with all Performance Shares being fully vested on December 26, 2015 (4 years from the Option grant date) and will expire December 26, 2018. The option was granted under plans previously approved by the Company's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the Company's common stock on the date of grant.
- (8) Mr. Grooms received these options to purchase shares of AC common stock, which options pursuant to the Merger have been adjusted and provide for the right to purchase Company Common Stock. The options vest semi-annually and become fully vested and exercisable four years from the grant date. The options were granted under plans previously approved by AxoGen's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the AxoGen's common stock on the date of grant.
- (9) Mr. Grooms received this option as part of his compensation as a member of the Company's Board of Directors, which option is fully vested and exercisable. The option was granted under plans previously approved by the Company's shareholders and the exercise price for the option was issued at a price equal to the fair market value of the Company's common stock on the date of grant.
- (10) Mr. Engels received these options to purchase shares of AC common stock, which options pursuant to the Merger have been adjusted and provide for the right to purchase Company Common Stock. The options vest semi-annually and become fully vested and exercisable four years from the grant date. The options were granted under plans previously approved by AxoGen's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the AxoGen's common stock on the date of grant.

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(11) Mr. Engels received this option to purchase 65,000 shares of the Company's common stock. All shares pursuant to the option will be fully vested on December 16, 2015 (4 years from the option grant date) based upon a vesting schedule whereby 25% of the aggregate shares vest on December 26, 2012 (12 months from the option grant date) and an additional 12.5% of aggregate shares each 6 months thereafter and will expire December 16, 2018. The option was granted under plans previously approved by the Company's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the Company's common stock on the date of grant.

### *Employment Agreements*

AC is a party to employment agreements with each of Karen Zaderej, effective October 15, 2007 and as amended September 29, 2011, John P. Engels, effective May 6, 2003 and as amended September 29, 2011, Gregory Freitag, effective October 1, 2011 and Jill Schiaparelli, effective February 27, 2012. Ms. Zaderej and Mr. Engels employment agreements renew for one year periods on each anniversary of the effective date and provide for severance benefits upon termination of the executive officer's employment: (1) by AxoGen for any reason other than "substantial cause" (as defined below), permanent disability, or death, (2) by the executive officer due to AxoGen's breach of the employment agreement and AxoGen's failure to cure such breach within ten days following notice by the executive officer of such breach; or (3) by the executive officer within six months of a "change of control" (as defined below) of AxoGen.

Upon a termination of Ms. Zaderej's employment for any of the reasons set forth above, Ms. Zaderej is entitled to base salary in an amount equal to the base salary that she would have been paid for the remainder of the then current employment period had the executive officer's employment not been terminated or the one-year non-competition period, whichever is longer. Upon a termination of Mr. Engels' employment for any of the reasons set forth above, Mr. Engels is entitled to base salary in an amount equal to the base salary that he would have been paid for the remainder of the then current employment period had the executive officer's employment not been terminated. Both Ms. Zaderej and Mr. Engels are entitled to continued medical and dental benefits (in the form of a reimbursement for the COBRA premiums) and continued bonus payments to which the executive officer would have been entitled for the remainder of the then current employment period had the executive officer's employment not been terminated.

Under their respective employment agreement, Mr. Freitag and Ms. Schiaparelli employment are at will. In the event Mr. Freitag or Ms. Schiaparelli is terminated without substantial cause either prior to a change of control or 180 days following a change in control the person is entitled to a severance payment consisting of (A) twelve months of base salary; and (B) an amount equal to any bonuses paid during the twelve month period prior to termination of employment. Mr. Freitag and Ms. Schiaparelli are also entitled to severance of twelve months of base salary if the person leaves AxoGen for "good reason" (as defined below) within 180 days following a change of control.

In addition, Ms. Zaderej is entitled to full vesting of her outstanding stock options that were granted prior to the Merger upon a change of control, regardless of whether her employment terminates on or following the change of control. With respect to Ms. Zaderej's, Ms. Schiaparelli's and Messrs. Freitag's and Engle's post-Merger stock options, if a change of control occurs, such options shall automatically accelerate and become fully exercisable in the event that within twelve months following the change of control they are terminated without cause or leave for good reason.

For purposes of the executive officer's employment agreements, "change of control" means the occurrence of any of the following events:

- any person who holds less than 20% of the combined voting power of the securities of AC or AxoGen, Inc., becomes the beneficial owner, directly or indirectly, of securities of AC or AxoGen, Inc., representing 50% or more of the combined voting power of the securities of AC or AxoGen, Inc. then outstanding;

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- during any period of 24 consecutive months, individuals who at the beginning of such period constitute all members of the AxoGen, Inc.'s Board of Directors cease, for any reason, to constitute at least a majority of the board of directors, unless the election of each director who was not a director at the beginning of the period was either nominated for election by, or was approved by a vote of, at least two-thirds of the directors then still in office who were directors at the beginning of the period;
- AC or AxoGen, Inc. consolidates or merges with another company and AC or AxoGen, Inc. is not the continuing or surviving corporation, provided, however, that any consolidation or merger whereby AxoGen, Inc. continues as the majority holder of AC securities or a merger or consolidation of AC and AxoGen, Inc. will not constitute a change in control;
- shares of AC's or AxoGen, Inc.'s common stock are converted into cash, securities, or other property (other than by a merger set forth in (iii) above) in which the holders of the AC's or AxoGen, Inc.'s common stock immediately prior to the merger have the same proportionate ownership of common stock of the surviving corporation as immediately after the merger;
- AC or AxoGen, Inc. sells, leases, exchanges, or otherwise transfers all or substantially all of its assets (in one transaction or in a series of related transactions); or
- the holders of AxoGen's stock approve a plan or proposal for the liquidation or dissolution of AC or AxoGen, Inc.

For purposes of Ms. Zaderej's, Ms. Schiaparelli's and Mr. Freitag's employment agreements, "substantial cause" means:

- commission of any act of fraud, theft, or embezzlement;
- material breach of the employment agreement, provided that AC shall have first delivered to the executive officer written notice of the alleged breach, specifying the exact nature of the breach in detail, and provided, further, that the executive officer shall have failed to cure or substantially mitigate such breach within ten days after receiving such written notice;
- commission or conviction of any felony, or of any misdemeanor involving moral turpitude, or entry of a plea of guilty or nolo contendere to any felony or misdemeanor;
- material failure to adhere to AC's corporate codes, policies or procedures which have been adopted in good faith for a valid business purpose as in effect from time to time; or
- failure to meet reasonable performance standards as determined by AC.

For purposes of Mr. Engels' employment agreement, "substantial cause" means the commission by Mr. Engels of any act of fraud, theft or embezzlement.

For purposes of Mr. Freitag's and Ms. Schiaparelli's employment agreements, "good reason" means the occurrence of any one or more of the following:

- the assignment of any duties inconsistent in any respect with the person's position (including status, offices, titles, and reporting requirements), authorities, duties, or other responsibilities as in effect immediately prior to a change of control or any other action by AxoGen which results in a diminishment in such position, authority, duties, or responsibilities, other than an insubstantial and inadvertent action which is remedied by AxoGen;
- a reduction by AC in the person's base salary; or
- the failure by AC to (A) continue in effect any material compensation or benefit plan, program, policy or practice in which the person was participating at the time of the change of control of AxoGen or (B) provide the person with compensation and benefits at least equal (in terms of benefit levels and/or reward opportunities) to those provided for under each employee benefit plan, program, policy and practice as in effect immediately prior to the change in control (or as in effect following the Change in Control of the Company), if greater.

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### *Pension Benefits*

AxoGen adopted the AxoGen SIMPLE IRA plan in 2007. The AxoGen named executive officers participate in the SIMPLE IRA 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 AxoGen to make matching contributions of between 1% and 3% of the employee's annual salary as long as the employee participates in the SIMPLE IRA plan. Additionally, the matching contribution has to be at least 3% for three of the first five years of the SIMPLE IRA. Both employee contributions and AxoGen contributions are fully vested at all times. In 2011, AxoGen's matching contribution was 3% of the AxoGen named executive officers' annual base salary. AxoGen contributed approximately \$12,000 in matching funds for the AxoGen named executive officers during 2011.

### *Director Compensation*

Upon election to the Board of Directors, each non-employee director receives a cash retainer payment of \$12,000 for annual services to AxoGen, which cash payment is paid in advance. Non-employee directors are also paid \$1,500 per in-person Board of Directors meeting and \$750 per telephone Board of Directors meeting attended. Non-employee directors are paid \$1,000 per committee meeting attended in-person and \$500 for each committee meeting attended by telephone. The total board and committee member fees cannot exceed \$2,500 per day. There is a limit, however, that the total number of paid board meetings will not exceed four per year and the total number of paid telephone meetings will not exceed three per quarter.

In addition, all non-employee directors receive an annual non-qualified stock option grant equal to 0.1% of the fully diluted stock of AxoGen, rounded down to a 250 share increment, at an exercise price equal to the fair market value of our common stock on the date of grant. Such stock options are for a term of seven years and are fully vested upon grant.

The following table shows the compensation earned by all persons serving as members of our Board of Directors during 2011.

**Director Compensation Table**

<u>Name</u>	<u>Fees Earned or Paid in Cash(\$)</u>	<u>Stock Awards(\$)</u>	<u>Option Awards\$(3)</u>	<u>Total(\$)</u>
Lowell Hellervik, Ph.D.(1)	8,137	—	58,700	66,837
Elmer Salovich, M.D.(1)	7,381	—	58,701	66,082
Timothy M. Heaney(1)	9,000	—	—	9,000
Robert J. Rudelius	17,400	15,000	22,534	54,934
Gregory G. Freitag	—	—	—	—
Karen Zaderej(2)	—	—	—	—
Jamie M. Grooms(2)	3,000	15,000	22,534	40,534
Mark Gold, M.D.(2)	5,000	15,000	22,534	42,534
John Harper(2)	5,000	15,000	22,534	42,534
Joe Mandato(2)	—	15,000	22,534	37,534

- (1) Service through September 30, 2011, at which time the Merger was completed and directors elected at the Company's 2010 Annual Meeting of Shareholders assumed office.
- (2) Service as a member of our Board of Directors began on September 30, 2011 when their election at the Company's 2010 Annual Meeting of Shareholders took effect as a result of the closing of the Merger. Stock awards for Joe Mandato are issued to DeNovo Ventures II, LP, as designee.
- (3) The amounts in this column are calculated based on the aggregate grant date fair value computed in accordance with Accounting Standards Codification (ASC) Topic 718 as of December 31, 2011.

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

*Securities Authorized for Issuance Under Equity Compensation Plans*

The following table summarizes, with respect to the Company's equity compensation plans, the number of shares of the Company's common stock to be issued upon exercise of outstanding options, warrants and other rights to acquire shares, the weighted-average exercise price of these outstanding options, warrants and rights and the number of shares remaining available for future issuance under the Company's equity compensation plans as of December 31, 2011.

<u>Plan Category</u>	<u>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (\$)</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column)</u>
Equity compensation plans approved by security holders	2,035,368	2.41	719,215
Equity compensation plans not approved by security holders	—	—	—
<b>Total</b>	<b>2,035,368</b>	<b>2.41</b>	<b>719,215</b>

*AxoGen, Inc. 2010 Stock Incentive Plan*

In September 2010 AxoGen's shareholders approved, the AxoGen, Inc. 2010 Stock Incentive Plan, which was Amended and Restated in September 2011 by shareholder approval (the "Stock Incentive Plan"). The purpose of the Stock Incentive Plan is to promote the interests of AxoGen's and its shareholders by aiding AxoGen in attracting and retaining employees, officers, consultants, advisors and non-employee directors who the Company expects will contribute to its success and to enable these individuals to participate in the Company's long-term success and growth by giving them a proprietary interest in LecTec. The aggregate number of shares of AxoGen common stock that may be issued under all stock-based awards made under the Stock Incentive Plan is 2,750,000.

The Compensation Committee of our Board of Directors (the "Compensation Committee") administers the Stock Incentive Plan and has full power and authority, along with the Board, to determine when and to whom awards will be granted, and the type, amount, form of payment and other terms and conditions of each award, consistent with the provisions of the Stock Incentive Plan. In addition, the Compensation Committee can specify whether, and under what circumstances, awards to be received under the Stock Incentive Plan or amounts payable under such awards may be deferred automatically or at the election of either the holder of the award or the Compensation Committee. Subject to the provisions of the Stock Incentive Plan, the Compensation Committee may amend or waive the terms and conditions, or accelerate the exercisability, of an outstanding award. The Compensation Committee has authority to interpret the Stock Incentive Plan and establish rules and regulations for the administration of the Stock Incentive Plan.

Any employee, officer, consultant, advisor or non-employee director providing services to AxoGen or any of its affiliates, who is selected by the Compensation Committee, is eligible to receive an award under the Stock Incentive Plan, provided that, in the case of consultants and advisors, such services are not in connection with the offer or sale of securities in a capital-raising transaction and do not directly or indirectly promote or maintain a market for our securities.

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The Stock Incentive Plan permits grants of:

- stock options (including both incentive and non-qualified stock options);
- stock appreciation rights (“SARs”);
- restricted stock and restricted stock units;
- dividend equivalents;
- performance awards of cash, stock or property;
- stock awards; and
- other stock-based awards.

Awards may be granted alone, in addition to, in combination with or in substitution for, any other award granted under the Stock Incentive Plan or any other compensation plan. Awards can be granted for no cash consideration or for any cash or other consideration as may be determined by the Compensation Committee or as required by applicable law. Awards may provide that upon the grant or exercise thereof, the holder will receive cash, shares of AxoGen common stock, other securities or property or any combination of these in a single payment, installments or on a deferred basis. The exercise price per share under any stock option and the grant price of any SAR may not be less than the fair market value of the Company’s common stock on the date of grant of such option or SAR except to satisfy legal requirements of foreign jurisdictions or if the award is in substitution for an award previously granted by an entity acquired by us. Determinations of fair market value under the Stock Incentive Plan will be made in accordance with methods and procedures established by the Compensation Committee. The term of awards may not be longer than ten years from the date of grant. Awards will be adjusted by the Compensation Committee in the case of a stock dividend or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase or exchange of shares, issuance of warrants or other rights or other similar corporate transaction or event that affects shares of our common stock in order to prevent dilution or enlargement of the benefits or potential benefits intended to be provided under the Stock Incentive Plan.

If an award entitles the holder to receive or purchase shares of Company common stock, the shares covered by such award or to which the award relates will be counted against the aggregate number of shares available for awards under the Stock Incentive Plan. For SARs settled in shares upon exercise, the aggregate number of shares with respect to which the SAR is exercised, rather than the number of shares actually issued upon exercise, will be counted against the number of shares available for awards under the Stock Incentive Plan. Awards that do not entitle the holder to receive or purchase shares and awards that are settled in cash will not be counted against the aggregate number of shares available for awards under the Stock Incentive Plan.

The Stock Incentive Plan provides that shares covered by an award made under the Stock Incentive Plan (or to which such an award relates) that are not purchased, that are forfeited or are reacquired by AxoGen (including shares of restricted stock, whether or not dividends have been paid on such shares), or that are subject to an award that otherwise terminates or is cancelled without delivery of such shares, shall be available for award again under the Stock Incentive Plan to the extent of any such forfeiture, reacquisition, termination or cancellation. Shares that are withheld in full or partial payment of the purchase or exercise price of any award or in connection with the satisfaction of tax obligations relating to an award will not be available again for grant awards under the Stock Incentive Plan.

Unless terminated by the Board of Directors, the Stock Incentive Plan will expire on September 27, 2021. No awards may be made after that date. However, unless otherwise expressly provided in an applicable award agreement, any award granted under the Stock Incentive Plan prior to expiration may extend beyond the expiration of the Stock Incentive Plan through the award’s normal expiration date. The Board of Directors may

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amend, alter, suspend, discontinue or terminate the Stock Incentive Plan at any time, although shareholder approval must be obtained for any amendment to the Stock Incentive Plan that would: (1) increase the number of shares of our common stock available under the Stock Incentive Plan, (2) increase the award limits under the Stock Incentive Plan, (3) permit awards of options or SARs at a price less than fair market value, (4) permit repricing of options or SARs or (5) cause Section 162(m) of the Internal Revenue Code to become unavailable with respect to the Stock Incentive Plan. Shareholder approval is also required for any action that requires shareholder approval under the rules and regulations of the Securities and Exchange Commission or any other securities exchange that are applicable to us.

No option or SAR may be amended to reduce its initial exercise or grant price, and no option or SAR may be cancelled and replaced with awards having a lower exercise or grant price. However, the Compensation Committee may adjust the exercise or grant price of, and the number of shares subject to, any outstanding option or SAR in connection with a stock dividend or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase or exchange of shares, issuance of warrants or other rights or other similar corporate transaction or event that affects shares of our common stock, in order to prevent dilution or enlargement of the benefits, or potential benefits intended to be provided under the Stock Incentive Plan.

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**Table of Security Ownership of Certain Beneficial Owners and Management**

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 12, 2012, by each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock, each of our directors, each of our executive officers named in the Summary Compensation Table above and all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock under options held by that person that are currently exercisable or exercisable within 60 days of, March 12, 2012 are considered outstanding. Each shareholder named in the table has sole voting and investment power for the shares shown as beneficially owned by them, and such shares are not subject to any pledge. Percentage of ownership is based on 11,062,304 shares of common stock outstanding on March 12, 2012.

<u>Name of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned</u>	<u>Number of Shares Underlying Options Beneficially Owned</u>	<u>Percent of Shares Outstanding (%)</u>
DeNovo Ventures II, LP(1) 2180 Sand Hill Rd. Suite 200 Menlo Park, CA 94025	1,431,847		12.9%
JAM Mark 3:1, LP 16 Boardwalk Plaza Saint Simons Island, GA 31522	1,114,613		10.1%
CHP II, L.P. 230 Nassau St. Princeton, NJ 08542 Attn: John Park	886,556		8.0%
AMV Partners I, L.P. 2750 Premier Parkway Suite 200 Duluth, GA 30097	1,017,904		9.2%
Springboard Capital II, LLC 11512 Lake Mead Ave Bldg. 100 Jacksonville, FL 32256	664,261		6.0%
Karen Zaderej	119,790	0	1.1%
Jamie M. Grooms(2)	351,417	67,620	3.8%
John P. Engels	90,698	21,883	1.0%
Mark Gold, M.D.(3)	381,891	25,740	3.7%
John Harper	60,871	15,976	0.7%
Joe Mandato(1)	—	12,000	0.1%
Robert Rudelius	23,273	32,000	0.5%
Greg Freitag	24,318	125,000	1.3%
All directors and executive officers as a group (12 persons) (1)(2)(3)(4)	1,057,713	325,096	12.1%

(1) Mr. Mandato is the Managing Director of this venture capital fund. Mr. Mandato disclaims beneficial ownership of the shares owned by the fund.

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- (2) These shares include 218,534 shares of record held by Mr. Grooms, and 132,883 shares held by the Jamie Grooms Trust, of which Mr. Grooms is the trustee.
- (3) These shares include 107,690 shares held by Dr. Gold's wife, 143,013 held by Dr. Gold's son and 125,523 shares held by MJSK, Ltd., an investment trust held by Dr. Gold's family.
- (4) Includes 5,665 shares held by Mark Friedman and a number of shares underlying options equal to 15,622, and 9,254, for Brad Hedger and Dave Hanson, respectively.

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

Jill Schiaparelli, Senior Vice President, Business Strategy & Marketing is a principal of JS Strategic Partners, LLC ("JS"). JS provided consulting services to the Company in 2011 in the amount of \$39,050.

We are not a listed issuer and so are not subject to the director independence requirements of any exchange or inter-dealer quotation system. Nevertheless, in determining whether our directors and director nominees are independent, we use the definition of independence provided in Rule 4200(a) (15) of The NASDAQ Stock Market's Marketplace Rules. Under this definition of independence, Robert Rudelius, John Harper, and Dr. Mark Gold would be considered independent directors.

### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

#### ***Audit Fees***

Fees billed to us for audit services by our independent registered public accounting firm, Lurie Besikof Lapidus & Company, LLP ("Lurie Besikof") for the audit of our annual financial statements, for reviews of our financial statements included in our quarterly reports on Form 10-Q and other services related to the registration statement on Form S-4 and certain current report on Form 8-K for the fiscal years ended December 31, 2011 and 2010 were \$155,817 and \$60,600, respectively.

#### ***Audit-Related Fees***

No fees were billed to us by Lurie Besikof for audit-related services provided during the fiscal years ended December 31, 2011 and 2010.

#### ***Tax Fees***

Fees billed to us by Lurie Besikof for tax compliance, tax advice, and tax planning for the fiscal years ended December 31, 2011 or 2010 were \$7,500 and \$12,582, respectively.

#### ***All Other Fees***

No fees were billed to us by Lurie Besikof for other services not included above during the fiscal years ended December 31, 2011 or 2010.

#### ***Pre-Approval Policies and Procedures***

Because of our size, complexity, financial condition, and prospects, the Audit Committee is apprised of and pre-approves all fees for services provided by our independent registered public accounting firm. All fees paid to our independent registered public accounting firm for 2011 and 2010 were approved by our Audit Committee. The Audit Committee has considered whether non-audit services provided by our independent registered public accounting firm during 2011 and 2010 were compatible with maintaining the accounting firm's independence.

**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 Shareholders' Equity
- (iv) Consolidated Statements of Cash Flows
- (v) Notes to Consolidated Financial Statements

(3) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
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)
**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/A filed on January 25, 2012)

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<b>Exhibit Number</b>	<b>Description</b>
**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)
*+10.4.3	Third Amendment dated March 12, 2012 to Amended and Restated Nerve Tissue Processing Agreement, dated as of February 27, 2008, by and between AxoGen Corporation and LifeNet Health
**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
10.6	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)
10.7	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	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)
***10.15	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	Settlement Agreement and Mutual Release, dated May 29, 2009, by and between LecTec Corporation and The Mentholatum Company (Incorporated by reference to the Company's Current Report on Form 8-K filed on June 6, 2009)
*10.17	Supply and License Agreement, entered into as of January 1, 2004, by and between Novartis Consumer Health, Inc. and LecTec Corporation (Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009)

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<b>Exhibit Number</b>	<b>Description</b>
10.18	Term Sheet between Endo Pharmaceuticals Inc. and LecTec Corporation (Incorporated by reference to the Company's Current Report on Form 8-K filed on November 12, 2009)
10.19	Settlement and License Agreement, dated November 11, 2009, by and between LecTec Corporation and Endo Pharmaceuticals Inc. (Incorporated by reference to the Company's Current Report on Form 8-K filed on November 12, 2009)
*10.20	Settlement Agreement and Mutual Release, dated December 18, 2009, by and between LecTec Corporation and Johnson & Johnson Consumer Companies, Inc. (Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2010)
***+10.21	Executive Employment Agreement, effective as of October 1, 2011, by and between AxoGen, Inc. and Gregory G. Freitag
***+10.22	Executive Employment Agreement, effective as of February 27, by and between AxoGen, Inc. and Jill Schiaparelli
+10.23	Amendment dated February 27, 2012 to lease dated as of February 6, 2007, by and between AxoGen Corporation and WIGSHAW, LLC, its successors and assigns
+21.1	Subsidiary of the Registrant
+23.1	Consent of Lurie Besikof Lapidus & Company, LLP
+23.2	Consent of Cross, Fernandez & Riley, 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
+99.1	AxoGen, Inc. press release, dated March 14, 2012
+101	Interactive Data File

\* Confidential treatment has been requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

\*\* 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, on March 15, 2012.

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.

<u>/s/ Karen Zaderej</u> Karen Zaderej Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2012
<u>/s/ Gregory Freitag</u> Gregory Freitag Chief Financial Officer, General Counsel and Director (Principal Financial Officer) (Principal Accounting Officer)	March 15, 2012
<u>/s/ Jamie Grooms</u> Jamie Grooms Director	March 15, 2012
<u>/s/ Robert Rudelius</u> Robert Rudelius Director	March 15, 2012
<u>/s/ Mark Gold</u> Mark Gold, M.D. Director	March 15, 2012
<u>/s/ John Harper</u> John Harper Director	March 15, 2012
<u>/s/ Joe Mandato</u> Joe Mandato Director	March 15, 2012

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**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
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 S4 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)
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<b>Exhibit Number</b>	<b>Description</b>
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)
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+23.1	Consent of Lurie Besikof Lapidus & Company, LLP

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<b>Exhibit Number</b>	<b>Description</b>
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++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
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\* Confidential treatment has been requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

\*\* 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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**APPENDIX B  
FEE SCHEDULE**

- 1) **AXOGEN** shall pay **LIFENET HEALTH** a \$[\*\*] fee per week for processing Suite 114;
- 2) **AXOGEN** shall pay **LIFENET HEALTH** the following daily fees only if Suite 118 is needed by written request of **AXOGEN**;
  - a. \$[\*\*] per day if the hours used include hours between 7am – 3pm; or
  - b. \$[\*\*] per day if the hours used are between 3pm – 7am.
- 3) **LIFENET HEALTH** shall bill **AXOGEN** at a rate of \$[\*\*] per each [\*\*] at **LIFENET HEALTH**;
- 4) **LIFENET HEALTH** shall bill **AXOGEN** at a rate of \$[\*\*] per each [\*\*] at **LIFENET HEALTH**.

**OTHER TERMS:**

- There shall be no Minimum Batches/Year and no Maximum Batches/Year.
- The weekly Suite fee for 114 is fixed. AxoGen will have the right to use Suite 114 of the Ward Court Facility for up to three shifts per normal business day.
- AxoGen will also have the right but not the obligation to use Suite 118 for three shifts per normal business day at the fees listed in #1. If AxoGen chooses to use Suite 118 for partial operations, the rates in #2 apply. During such times as AxoGen is not using Suite 118, LifeNet, pursuant to written agreement with AxoGen as to the type, manner, time and length of use, will be permitted to use Suite 118.
- The parties will agree to review usage and space needs within the first year of the contract.
- AxoGen is to employ processors and assume supervisory and oversight responsibilities for processors who process for AxoGen in the LifeNet Health facility. LifeNet Health will provide support as described in the Quality Plan.

\*\* Certain information in this exhibit has been omitted and will be filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Request.

## AMENDMENT NO. 1 TO DISTRIBUTION AGREEMENT

This Amendment No. 1 to the Distribution Agreement (this "Amendment"), effective as of February 24, 2012 (the "Amendment Date"), is entered into by and between Cook Biotech Incorporated, an Indiana corporation having a place of business at 1425 Innovation Place, West Lafayette, Indiana 47906 ("**Cook**"), and AxoGen, Inc, a Delaware corporation having a place of business at 13859 Progress Blvd, Alachua, FL, 32615 ("**Distributor**"). Capitalized terms used herein and not otherwise defined shall have the meanings given to such terms in the Original Agreement (as defined below).

**WITNESSETH**

WHEREAS, the Parties have heretofore entered into the Distribution Agreement dated as of August 27, 2008 (the "Original Agreement"); and

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

NOW, THEREFORE, the Parties hereby agree as follows:

**1. Amendments.**

(a) Article X(A) shall be replaced in its entirety with the following:

"The term of this Agreement commences on the Effective Date and continues in full force and effect for a period of (7) seven years thereafter unless extended by mutual agreement of the parties or earlier terminated in accordance with this Article X ("Initial Term"). Following the Initial Term, the Agreement shall automatically renew for an additional seven (7) year period, unless extended by mutual agreement of the parties or earlier terminated in accordance with this Article X, and provided that the parties agree to meet at least ninety (90) days before the end of the Initial Term to review whether the Purchase Price of the Product needs to be adjusted and reasonably agree to such adjustment in writing, where such agreement shall not be unreasonably withheld ("Additional Term").

(b) Article X(C), shall be replaced in its entirety with the following:

"Distributor may terminate this Agreement, without cause, at any time upon sixty (60) days prior written notice of termination to Cook. Cook may: i) terminate this Agreement at any time upon written notice to Distributor with respect to any Product in the event that the parties fail to reach an agreement as to Minimum Quantities under Article V(G) and Distributor fails to generate commercially reasonable sales of Product 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; or ii) Cook may terminate Distributor's rights in specific countries within the Territory based upon a third party allegation within that specific country or a judgment issued by a court of proper jurisdiction in that specific country that such Product infringes a third party patent not licensed to Distributor in that specific country where such Product is being marketed, provided, that such termination shall not terminate Cook's obligations pursuant to Section F of Article IV."

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2. **Governing Law.** This Amendment shall be construed and interpreted in accordance with the laws of Delaware, without giving effect to the choice-of-law provisions thereof.
  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.
  4. **Distribution Agreement Remains in Effect.** Except as provided herein, all provisions, terms and conditions of the Distribution Agreement shall remain in full force and effect. As amended hereby, the Distribution Agreement is ratified and confirmed in all respects.

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

**AXOGEN, INC.**

By: /s/ Karen Zaderej

Name: Karen Zaderej

Title: Chief Executive Officer

Date: 3/14/2012

**COOK BIOTECH INCORPORATED**

By: /s/ Dennis D. Abbott

Name: Dennis D. Abbott

Title: Director of Global Business Development

Date: 3/14/2012

**EXECUTIVE EMPLOYMENT AGREEMENT**

**THIS EXECUTIVE EMPLOYMENT AGREEMENT** (the "Agreement"), effective as of October 1, 2011, is made by and between AXOGEN CORPORATION, a Delaware corporation ("AXOGEN" or "Employer"), and Gregory Freitag ("Employee"), whose resident address is 909 Kenwood Parkway, Minneapolis, Minnesota 55403 (collectively, the "Parties").

**RECITALS:**

A. WHEREAS, AXOGEN believes it is in its best interest to continue to employ Employee, and Employee desires to continue to be employed by AXOGEN; and

B. WHEREAS, AXOGEN and Employee desire to set forth the terms and conditions on which Employee shall continue to be employed by and perform duties on behalf of AXOGEN.

NOW, THEREFORE, in consideration of the promises set forth in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which is acknowledged by this Agreement, the Parties to this Agreement, intending to be legally bound, agree as follows:

1. **Employment**. AXOGEN hereby continues to employ Employee, and Employee hereby accepts such continued employment, all upon the terms and conditions set forth in this Agreement, including those set forth in the attached Schedules and Exhibits.

(a) **Duties of Employee**. The duties of Employee are set forth on Schedule 1 of this Agreement, which is attached hereto and incorporated herein by reference.

(b) **Compensation and Benefits**. The compensation and benefits to which Employee may be entitled pursuant to this Agreement are set forth on Schedule 2 of this Agreement, which is attached hereto and incorporated herein by reference.

2. **Invention Assignment and Confidentiality Agreement**. Contemporaneously with the execution and delivery of this Agreement, Employee shall enter into an Invention Assignment and Confidentiality Agreement attached hereto as Exhibit "A" to this Agreement (the "Invention and Confidentiality Agreement"), which shall be incorporated herein by reference.

3. **Non-Competition Agreement**. Contemporaneously with the execution and delivery of this Agreement, Employee shall enter into a Non-Solicitation and Non-Competition Agreement attached hereto as Exhibit "B" to this Agreement (the "NSNC Agreement") which shall be incorporated herein by reference.

4. **Termination**.

(a) **At-will**. Either AXOGEN or Employee may terminate this Agreement at any time during the course of Employee's employment and for any reason, upon giving written notice to the other party. Employer shall have no further liability or obligation to Employee other than to pay for services rendered through Employee's last date of employment. If

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Employee elects to terminate this Agreement and provides Employer with any notice period prior to the date of termination, Employer may elect to terminate this Agreement immediately thereon and incur no further obligation to Employee other than for wages worked through the date of termination of this Agreement. It is the intention of the Parties that at all times this shall be an at-will employment relationship during the course of Employee's employment with Employer. Nothing contained in this Agreement shall be deemed or construed to create a contractual relationship between the Parties for a specific duration of time.

(b) Death. In the event of the death of the Employee, this Agreement shall terminate on the date of Employee's death, without any liability to or upon the Employer other than to pay for services rendered prior to the date of the Employee's death.

(c) Permanent Disability. For purposes of this Agreement, the term "Permanent Disability" shall mean a physical or mental incapacity of Employee, which renders Employee unable to perform Employee's duties pursuant to this Agreement, and which shall continue for ninety (90) consecutive days or one hundred and eighty (180) days during any twelve month period. If AXOGEN or Employee terminates Employee's employment by reason of Permanent Disability of Employee, this Agreement shall terminate immediately upon written notice by AXOGEN to Employee, or the date Employee gives notice to terminate employment to AXOGEN, without any liability to or upon the Employer other than to pay for services rendered through the termination date.

#### 5. Change in Control.

(a) Definition. For the purposes of this Agreement, a "Change in Control" shall mean the occurrence of any of the following events:

(i) any "person" (as that term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended ("Exchange Act")), who holds less than twenty percent (20%) of the combined voting power of the securities of AXOGEN or its parent company AxoGen, Inc. ("INC."), becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of AXOGEN or INC. representing fifty percent (50%) or more of the combined voting power of the securities of either AXOGEN or Inc. then outstanding; or

(ii) during any period of twenty-four (24) consecutive months, individuals, who, at the beginning of such period constitute all members of the Board of Directors of INC. (the "Board") and cease, for any reason, to constitute at least a majority of the Board, unless the election of each director who was not a director at the beginning of the period was either nominated for election by, or approved by a vote of, at least two-thirds of the directors then still in office who were directors at the beginning of the period; or

(iii) AXOGEN or INC. consolidates or merges with another company, and AXOGEN or INC. is not the continuing or surviving corporation, provided, however, that any consolidation or merger whereby INC. continues as the majority holder of AXOGEN securities or a merger or consolidation of AXOGEN and INC. will not constitute a Change in Control; or

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(iv) shares of AXOGEN's or INC.'s common stock are converted into cash, securities, or other property, other than by a merger of AXOGEN or INC., pursuant to Section 5(a)(iii), in which the holders of AXOGEN's or INC.'s common stock immediately prior to the merger have the same proportionate ownership of common stock of the surviving corporation as immediately after the merger; or

(v) AXOGEN or INC. sells, leases, exchanges, or otherwise transfers all, or substantially all, of its assets (in one transaction or in a series of related transactions), provided, however, that any such transaction related to AXOGEN whereby INC. continues as the majority holder of AXOGEN securities or INC. is the sole other party to the transaction, will not constitute a Change in Control; or

(vi) the holders of AXOGEN's or INC.'s stock approve a plan or proposal for the liquidation or dissolution of AXOGEN or INC.

(b) Severance.

(i) Termination in Connection with a Change of Control. In the event of Employee's termination of employment by AXOGEN without Substantial Cause (as defined below) upon or within one hundred and eighty (180) days following a Change in Control or by Employee for Good Reason (as defined below), Employee will be entitled to a severance payment consisting of twelve (12) months of Employee's base salary. For purposes of this Agreement, "Substantial Cause" means: (A) the commission by Employee of any act of fraud, theft, or embezzlement; (B) any material breach by Employee of this Agreement, provided that AXOGEN shall have first delivered to Employee written notice of the alleged breach, specifying the exact nature of the breach in detail, and provided, further, that Employee shall have failed to cure or substantially mitigate such breach within ten (10) days after receiving such written notice; (C) commission or conviction of any felony, or of any misdemeanor involving moral turpitude, or entry of a plea of guilty or nolo contendere to any felony or misdemeanor; (D) material failure to adhere to AXOGEN's corporate codes, policies or procedures which have been adopted in good faith for a valid business purpose as in effect from time to time; or (E) failure to meet reasonable performance standards as determined by AXOGEN. For purposes of this Agreement, "Good Reason" shall mean Employee's resignation from employment upon or within ninety (90) days following a Change of Control, if AXOGEN or INC. is not the surviving entity, provided that Substantial Cause for termination of Employee's employment does not exist at the time of such resignation and the resignation is the result of the occurrence of any one or more of the following:

a) the assignment to Employee of any duties inconsistent in any respect with his/her position (including status, offices, titles, and reporting requirements), authorities, duties, or other responsibilities as in effect immediately prior to the Change in Control of the Company or any other action of the Company which results in a diminishment in such position, authority, duties, or responsibilities, other than an insubstantial and inadvertent action which is remedied by the Company promptly after receipt of notice thereof given by Employee;

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b) a reduction by AXOGEN in Employee's base salary as in effect on the date hereof and as the same shall be increased from time to time hereafter; or

c) the failure by AXOGEN to (A) continue in effect any material compensation or benefit plan, program, policy or practice in which Employee was participating at the time of the Change in Control of the Company or (B) provide Employee with compensation and benefits at least equal (in terms of benefit levels and/or reward opportunities) to those provided for under each employee benefit plan, program, policy and practice as in effect immediately prior to the Change in Control of the Company (or as in effect following the Change in Control of the Company, if greater).

(ii) Termination not in Connection with a Change of Control. In the event of Employee's termination of employment by AXOGEN without Substantial Cause either prior to a Change of Control or following the date that is one hundred and eighty (180) days following a Change in Control, Employee shall be entitled to a severance payment consisting of (A) twelve (12) months of Employee's base salary; and (B) an amount equal to any bonuses paid to Employee during the twelve (12) month period prior to Employee's termination of employment.

(c) Payment of Severance. Payment of any severance for Employee will be made in a lump sum on the first payroll date following the 60th day following the date of Employee's termination of employment. Notwithstanding the foregoing, if the Employee is a "specified employee" on Employee's termination date, the postponement provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), as described in Section 8(n) below, shall apply, if applicable.

7. Surrender of Records and all Company Property. Upon the termination of Employee's employment for any reason, whether by AXOGEN or Employee, Employee agrees to return to AXOGEN, in good condition, (i) any and all equipment belonging to AXOGEN including, without limitation, computers, cell phones, and personal digital assistants, and (ii) any and all data, computer files, customer lists and contact information, documents and other materials in Employee's possession, or removed by Employee from AXOGEN's premises, whether now in Employee's possession or not, which materials were obtained in connection with Employee's employment with AXOGEN, including any and all copies (whether complete or partial) and extracts thereof, and (iii) any and all other company property or Confidential Information and materials as they are defined in Employee's Invention Assignment and Confidentiality Agreement, in the Employee's control or possession.

#### 8. Miscellaneous Provisions.

(a). Amendments to this Agreement only in Writing. The provisions of this Agreement and the attached Schedules and Exhibits shall only be amended, supplemented, or waived by a written agreement executed by both a duly authorized officer of AXOGEN and Employee.

(b). Assignments. Employee shall not assign Employee's rights and/or obligations pursuant to this Agreement or the attached Schedules and Exhibits. AXOGEN may assign its rights and/or obligations pursuant to this Agreement and the attached Schedules and Exhibits

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at any time without prior notice to Employee. In the event of a Change of Control in which AXOGEN or INC. is not the surviving entity, any reference to AXOGEN or INC. shall be deemed to refer to the surviving entity.

(c). Binding Effect. All of the terms and provisions of this Agreement and the attached Schedules and Exhibits, whether so expressed or not, shall be binding upon, inure to the benefit of, and be enforceable by the Parties and their respective administrators, executors, legal representatives, heirs, successors and permitted assigns.

(d). The Provisions of this Agreement are Severable. If any part of this Agreement, or any of the Schedules or Exhibits entered into pursuant to this Agreement, is contrary to, prohibited by, or deemed invalid under any applicable law or regulation, such provision shall be inapplicable and deemed omitted to the extent so contrary, prohibited or invalid, but the remainder of this Agreement and its Schedules and Exhibits shall not be so invalidated, and shall be given full force and effect so far as possible.

(e). Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 1 through 8 shall survive and remain in effect beyond the execution and delivery of this Agreement in accordance with their respective terms of duration.

(f). Waivers. The failure or delay of AXOGEN at any time to require performance by Employee of any provision of this Agreement or the attached Schedules and Exhibits, even if known, shall not affect the right of AXOGEN to require performance of that provision or to exercise any right, power or remedy pursuant to this Agreement or the attached Schedules and Exhibits. Any waiver by AXOGEN of any breach of any provision of this Agreement or the attached Schedules and Exhibits shall not be construed as a waiver of any continuing or succeeding breach of such provision, a waiver of the provision itself, or a waiver of any right, power or remedy pursuant to this Agreement or the attached Schedules and Exhibits.

(g). Notices. All notices, requests, consents and other communications required or permitted under this Agreement shall be in writing and shall be (i) hand-delivered by messenger or courier service; (ii) sent by an overnight-mail service (e.g. FedX or UPS); or (iii) mailed (airmail, if international) by registered or certified mail (postage prepaid), return receipt requested, and addressed to:

If to Employee:

Employee's most current address on file with AXOGEN.

If to AXOGEN:

AXOGEN Corporation  
13859 Progress Blvd., Ste. 100  
Alachua, FL 32615  
Attn: CEO

With a copy to:

AXOGEN Corporation  
13859 Progress Blvd., Ste. 100  
Alachua, FL 32615  
Attn: Human Resources

or to such other address as any party may designate by written notice complying with the terms of this section. Each such notice shall be deemed delivered (a) on the date delivered, if by personal delivery, or (b) on the date upon which the return receipt is signed, delivery is refused, or the notice is designated by the postal authorities as not deliverable, as the case may be, if mailed.

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(h). Governing Law. This Agreement and the attached Schedules and Exhibits and all transactions contemplated by this Agreement or the attached Schedules and Exhibits shall be governed by, and construed and enforced in accordance with, the internal laws of the State of Florida, without regard to principles of conflicts of laws.

(i). Jurisdiction and Venue. The Parties acknowledge that a substantial portion of negotiations, anticipated performance and execution of this Agreement and the attached Schedules and Exhibits occurred, or shall occur, in Alachua County, Florida, and the Parties irrevocably and unconditionally (a) agree that any suit, action or legal proceeding arising out of, or relating to, this Agreement or the attached Schedules and Exhibits shall be brought in the courts of record of the State of Florida in Alachua County, or the United States District Court, Northern District of Florida, Gainesville Division; (b) consent to the jurisdiction of each such court in any such suit, action or proceeding; (c) waive any objection which they may have to the laying of venue of any such suit, action or proceeding in any of such courts; and (d) agree that service of any court paper may be effected on such party by mail, as provided in this Agreement, or in such other manner as may be provided under applicable laws or court rules in said state.

(j). Remedies Available to Either Party Cumulative. No remedy conferred upon any party pursuant to this Agreement (or the attached Schedules and Exhibits) is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to every other remedy given pursuant to this Agreement (or the attached Schedules and Exhibits) now or hereafter existing at law or in equity or by statute or otherwise. No single or partial exercise by any party of any right, power or remedy pursuant to this Agreement (or the attached Schedules and Exhibits) shall preclude any other or further exercise of such right, power or remedy.

(k). Entire Agreement. This Agreement and the attached Schedules and Exhibits represents the entire understanding and agreement between the Parties with respect to the subject matter contained herein and supersedes all other negotiations, understandings and representations (if any) made by and between the Parties.

(l). Section and Paragraph Headings. Section and paragraph headings used throughout this Agreement and the attached Schedules and Exhibits are for convenience of reference only and in no way define, limit or describe the scope or intent of this Agreement or the attached Schedules and Exhibits.

(m). Preparation of Agreement. This Agreement shall not be construed more strongly against any party regardless of who is responsible for its preparation. The Parties acknowledge that each party contributed to its negotiations and is equally responsible for its preparation.

(n). Section 409A of the Code. Notwithstanding any provision of this Agreement to the contrary, this Agreement is intended to meet the requirements of Section 409A of the Code to the extent applicable, the Parties intend to administer this Agreement in a manner that is consistent with those requirements or an exception thereto, and this Agreement shall be construed and interpreted in accordance with such intent. Any payments that are considered deferred compensation under Section 409A of the Code and that are paid to a "specified employee" (as defined in Section 409A of the Code) upon separation from service shall be subject to a six (6) month delay, if required by Section 409A of the Code. If required by

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Section 409A of the Code, any amounts otherwise payable during the six (6) month period that commences on and follows the Employee's termination date shall be paid in one lump sum amount on the first payroll date following the six (6) month period following the Employee date of termination (or within thirty (30) days of the Employee's death, if earlier). For purposes of Section 409A of the Code, all payments to be made upon a termination of employment under this Agreement may only be made upon a "separation from service" (within the meaning of such term under Section 409A of the Code). Each payment made under this Agreement shall be treated as a separate payment. In no event shall the Employee, directly or indirectly, designate the calendar year of a payment. All reimbursements under this Agreement shall be provided in a manner that complies with Section 409A of the Code, if applicable. If required by regulations or other guidance issued under Section 409A of the Code or a court of competent jurisdiction, the provisions regarding payments hereunder shall be amended to provide for such payments to be made at the time allowed under such regulations, guidance or authority that most closely achieves the intent of this Agreement.

(o) Liability Insurance. AXOGEN shall cover the Employee under directors and officers liability insurance both during the term of this Agreement and for the one year period following the termination of this Agreement, in the same amount and to the same extent as AXOGEN covers its officers and directors.

*[Signature Page Follows]*

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EMPLOYEE AND AXOGEN have executed this Agreement as of the 1st day of October, 2011

**AXOGEN Corporation**

/s/ Karen Zaderej

Name: Karen Zaderej

Title: CEO

**EMPLOYEE:**

/s/ Gregory Freitag

Print Name: Gregory Freitag

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**SCHEDULE AND EXHIBIT LIST**

Schedule 1— Duties of Employee

Schedule 2— Compensation and Benefits

Exhibit A— Invention Assignment and Confidentiality Agreement

Exhibit B— Non-Solicitation and Non-Competition Agreement

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**SCHEDULE 1**  
**DUTIES OF EMPLOYEE**

The duties of Employee with AXOGEN Corporation (“AXOGEN” or “Employer”) are as follows:

1. Employee’s Title: AXOGEN hereby employs Employee as a Chief Financial Officer, which title may change at AXOGEN’s discretion.
2. Employee’s Duties: During employment with AXOGEN, Employee’s duties will include, without limitation, the following:

(a) Description of Duties. Employee shall perform all duties in connection with Employee’s position, or as otherwise designated by AXOGEN, including, without limitation, the following duties:

Provide both operational and programmatic support to AXOGEN and Corp. Supervise the finance unit and act as chief financial spokesperson AXOGEN and Corp. Directly assist on all strategic and tactical matters as they relate to budget management, cost benefit analysis, forecasting needs, financial statements and the securing of new funding. As a member of the senior management team, be involved in strategic planning, evaluation, and professional development initiatives.

(b) Report to AXOGEN Designated Manager. Employee shall report to the CEO of AXOGEN.

(c) Compliance With Employee Policies and Procedures. Employee shall comply with all AXOGEN policies and procedures for employees as such policies and procedures may exist from time to time.

(d) No Other Business Activities.

(i) Employee shall devote Employee’s entire professional time, energy and skill to the performance of Employee’s duties pursuant to the Agreement, the service of AXOGEN, and promotion of AXOGEN’s interests. The Parties agree that Employee may not during Employee’s employment, except as permitted in writing by AXOGEN, be engaged in any other business activity, whether or not such activity is pursued for gain, profit, or other pecuniary advantage including, without limitation, management or management consulting activities. Notwithstanding the forgoing, AXOGEN confirms and agrees that Employee is on the Board of Directors of Pressure BioSciences, on the Foundation Board of HealthEast Care System and is a principal in FreiMc, LLC. and EmployRx, LLC. Employee hereby represents and warrants that such activity is not competitive with that of Employer and any activity associated with such organizations will not interfere with Employee’s performance of his duties for Employer.

(ii) Notwithstanding the preceding subsection, Employee may invest Employee’s personal assets in businesses or real estate that are not in competition with AXOGEN where the form or manner of such investment will not require services on the part of Employee, and in which Employee’s participation is solely that of a passive investor.

(e) Compliance with AXOGEN’s Rules and Regulations. Employee agrees to abide by all rules and regulations established from time to time by AXOGEN.

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**SCHEDULE 2**  
**COMPENSATION AND BENEFITS**

Subject to the terms and conditions of the Executive Employment Agreement (the "Agreement"), Employee may be entitled to receive from AXOGEN Corporation ("AXOGEN" or "Employer") the following compensation and benefits:

1. Base Salary.

(a) Amount. Employee's salary during employment with AXOGEN will be at the rate of \$200,000 (Two Hundred Thousand Dollars) annually, (the "Base Salary") effective upon execution and delivery of the Agreement and Employee's first day of employment with AXOGEN.

(b) Payment. The Base Salary shall be payable in accordance with the existing payroll practices of AXOGEN, which practices may be changed by AXOGEN from time to time at its sole discretion. The Base Salary shall be subject to all appropriate withholding taxes.

(c) Review of Base Salary. The Base Salary shall be reviewed by AXOGEN on an annual basis; however AXOGEN reserves the right to increase or decrease the Base Salary at any time during the employment relationship in its sole discretion.

(d) Additional Compensation. In addition to the Base Salary, Employee may also be eligible to receive stock options, benefits, paid vacations and holidays during Employee's Employment.

2. Business Expenses and Reimbursements. Employee shall be eligible for reimbursement by AXOGEN in accordance with AXOGEN's normal reimbursement practices for ordinary and necessary business expenses incurred by Employee in the performance of Employee's duties for AXOGEN, so long as Employee timely submits to AXOGEN accurate invoices and receipts of all expenses submitted for reimbursement pursuant to this section.

3. Stock Options. Employee may be eligible to receive stock options in accordance with the terms of the Employee's Incentive Stock Option Agreement.

4. Benefits. Employee will be permitted to participate in such benefit plans of AXOGEN that may be in effect from time to time, to the extent Employee is eligible under the terms of those plans. Nothing herein shall be construed to require AXOGEN to institute or continue any particular plan or benefit. AXOGEN reserves the right to add, change, or eliminate any benefits at any time at its sole discretion.

5. Vacations and Holidays. Employee will be entitled to paid vacation and holidays in accordance with the vacation and holiday policies of AXOGEN in effect for its employees from time to time. Vacation must be taken by Employee at such time or times as approved by AXOGEN.

6. Bonus.

(a) Calculation. During the Employment Period, Employee may receive a bonus based on an AXOGEN bonus plan, as determined by AXOGEN in its sole discretion.

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(b) Payment. The Bonus if paid shall be paid in accordance with, and subject to, the normal payroll policies of AXOGEN with respect to similar forms of compensation, including, without limitation, being subject to all appropriate withholding taxes.

7. Compensation Review. AXOGEN shall, from time to time, but no less frequently than annually, review Employee's compensation (including benefits) and may, in its sole discretion, increase, or decrease, or eliminate any or all of the benefits. Any such increase or decrease in the compensation package shall be valid only if in writing, executed by a duly authorized officer of AXOGEN, and such writing shall constitute an amendment to this Paragraph 8 (and to the Agreement and any applicable Schedules or Exhibits) solely as to the benefits, without waiver or modification of any other terms, conditions or provisions of the Agreement.

8. No Other Compensation. Employee agrees that the compensation and benefits set forth in the Agreement and this Schedule 2 are the sole and exclusive compensation and benefits to which Employee is entitled pursuant to the Agreement and this Schedule 2, and that Employee shall have no rights to receive any other compensation or benefits of any nature from AXOGEN.

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**EXHIBIT A OF EMPLOYMENT AGREEMENT**  
**INVENTION ASSIGNMENT AND CONFIDENTIALITY AGREEMENT**

THIS INVENTION ASSIGNMENT AND CONFIDENTIALITY AGREEMENT (the "Invention and Confidentiality Agreement") is entered into as of the date first written below, by and between AXOGEN Corporation ("AXOGEN" or "Employer") and the undersigned AXOGEN employee, ("Employee") for and in consideration of Employee's continued employment by AXOGEN and the compensation that Employee shall receive during Employee's employment, the Parties agree as follows:

1. Employee's Covenants, Representations and Warranties. Both during and after the termination of Employee's employment by AXOGEN for any reason or for no reason:

A. Non-Disclosure. Employee shall not disclose to anyone outside AXOGEN any Confidential Information. "Confidential Information" shall include, without limitation,

(i) all information, which has not been made publicly available by AXOGEN or the third-party owner of such information, which was developed by AXOGEN, any of AXOGEN's employees or independent contractors, or was developed for AXOGEN, including but not limited to Developments (as defined below in Section 3), technical data, specifications, designs, programs, software, hardware, concepts, discoveries, copyrights, improvements, product plans, research and development, , personnel information, contents of manuals, financial information, customer lists, leads, marketing programs, testing programs, and/or other written materials;

(ii) all documents marked as confidential and/or containing such information; and/or

(iii) all information AXOGEN has acquired or received from a third party in confidence.

B. Use of Confidential Information. Employee shall use Confidential Information only for AXOGEN's business purposes.

C. Confidential Information and Materials Furnished by AXOGEN. Employee agrees that the Confidential Information and any other materials furnished by AXOGEN to Employee, (i) are proprietary to AXOGEN and contain specialized and unique information not obtainable from ordinary sources, (ii) have been created by AXOGEN at considerable time and expense, and (iii) shall remain, at all times, the exclusive and sole property of AXOGEN.

D. Use of Third-Party Information. Employee shall not disclose to AXOGEN, use in AXOGEN's business, or cause AXOGEN to use any information or material which is confidential to any third party unless AXOGEN has a written agreement with the third party allowing AXOGEN to receive and use the confidential information or materials.

E. Use of Copyrights. Employee will not incorporate into Employee's work any material that is subject to the copyrights of any third party unless AXOGEN has the right to copy and incorporate such copyrighted material.

F. Trade Secrets. Employee acknowledges AXOGEN's legitimate business interest in protecting its trade secrets and customer lists and in preventing direct solicitation of its customers and agrees that any unauthorized use of trade secrets shall be presumed to be an irreparable injury that may be specifically enjoined.

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2. Return of Confidential Information and Materials. Employee shall, immediately upon AXOGEN's request, or the termination of Employee's employment, for any reason, whether by Employee or AXOGEN, return to AXOGEN all Confidential Information and other materials furnished to Employee, and any and all third-party property, and/or copies of the same, and all documentation, notebooks and notes, reports and any other materials whether electronic or print media containing or derived from the Confidential Information and other materials furnished to Employee by AXOGEN.

3. Assignment of Rights. Employee hereby grants, transfers and assigns and agrees to grant, transfer and assign to AXOGEN all of Employee's rights, title and interest, if any, in any and all Developments, including rights to translation and reproductions in all forms or formats and the copyrights, patent rights and moral rights to the same, if any, and agrees that AXOGEN may further perfect AXOGEN's United States and foreign rights in, and to any and all, Developments under patents and copyrights. "Developments" shall mean any idea, invention, process, design, concept, or useful article (whether the design is ornamental or otherwise), computer program, trademark, trade secret, documentation, literary work, audiovisual work and any other work of authorship, hereafter expressed, made or conceived solely or jointly by Employee during Employee's employment, whether or not subject to patent, copyright or other forms of protection that is:

A. related to the actual or anticipated business, research or development of AXOGEN; and/or

B. suggested by or resulting from any task assigned to Employee or work performed by Employee for or on behalf of AXOGEN.

4. Copyrights. Employee acknowledges that the copyrights in Developments created by Employee in the scope of Employee's employment belong to AXOGEN by operation of law, or may belong to a party engaged by AXOGEN by operation of law pursuant to a works-for-hire contract between AXOGEN and such contracted third party. To the extent the copyrights in such works may not be owned by AXOGEN or such contracted party by operation of law, Employee hereby assigns and agrees to assign to AXOGEN or such contracted party, as the case may be, all copyrights (if any) Employee may have in Developments.

5. Assistance in Obtaining Copyrights and Patents. At all times after the date of this Invention Assignment and Confidentiality Agreement, Employee agrees to assist AXOGEN in obtaining patents or copyrights on any Developments assigned to AXOGEN that AXOGEN, in its sole discretion, seeks to patent or copyright. Employee also agrees to sign all documents, and do all things necessary to obtain such patents or copyrights, to further assign them to AXOGEN, and to reasonably protect them and AXOGEN against infringement by other parties at AXOGEN expense with AXOGEN prior approval.

6. Appointment of Attorney-In-Fact. Employee irrevocably appoints any AXOGEN-selected designee to act, at all times hereafter, as Employee's agent and attorney-in-fact to perform all acts necessary to obtain patents and/or copyrights as required by this Invention Assignment and Confidentiality Agreement if Employee (i) refuses to perform those acts or (ii) is unavailable, within the meaning of the United States Patent and Copyright laws. It is expressly intended by Employee that the foregoing power of attorney is coupled with an interest.

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7. Record Keeping. Employee shall keep complete, accurate, and authentic information and records of all Developments in the manner and form reasonably requested by AXOGEN. Such information and records, and all copies of the same, shall be the property of AXOGEN as to any Developments assigned AXOGEN. Employee agrees to promptly surrender such information and records at the request of AXOGEN as to any Developments.

8. Developments. In connection with any of the Developments assigned by this Invention Assignment and Confidentiality Agreement, Employee hereby agrees:

A. to disclose them promptly to AXOGEN;

B. at AXOGEN's request, to execute separate written assignments to AXOGEN;

C. to provide AXOGEN with notice of any inadvertent disclosure of Confidential Information related to any Development; and

D. to do all things reasonably necessary to enable AXOGEN to secure patents, register copyrights or obtain any other form of protection for Developments in the United States and in other countries. If Employee fails or is unable to do so, Employee hereby authorizes AXOGEN to act under power of attorney for Employee to do all things to secure such rights.

9. No Designation as Author. AXOGEN, its subsidiaries, licensees, successors or assigns, (direct or indirect) is not required to designate Employee as author of any Developments when such Developments are distributed publicly or otherwise. Employee waives and releases, to the extent permitted by law, all Employee's rights to such designation and any rights concerning future modifications of such Developments.

10. Assignability. Rights, assignments, and representations made or granted by Employee in this Invention Assignment and Confidentiality Agreement are assignable by AXOGEN without notice, and are for the benefit of AXOGEN's successors, assigns, and parties contracting with AXOGEN.

11. Trade Secrets. Employee acknowledges that Employee is aware that a theft of trade secrets of an employer by an employee in Florida, such as is prohibited by this Invention Assignment and Confidentiality Agreement, constitutes a criminal violation of Florida Statute 812.081, punishable as a third-degree felony under Florida Statute 775.082, conviction for which carries a term of imprisonment not exceeding five (5) years. Employee acknowledges AXOGEN will seek vigorous prosecution under Florida Statutes for any violation thereof arising out of a breach by Employee of any of the material terms of this Invention Assignment and Confidentiality Agreement.

12. Advice of Counsel. Employee acknowledges and agrees that Employee has read and understands the terms set forth in this Invention Assignment and Confidentiality Agreement and has been given a reasonable opportunity to consult with an attorney prior to execution of this Invention Assignment and Confidentiality Agreement and has either done so, or knowingly declined to do so.

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13. Miscellaneous Provisions.

A. Further Assurances. The Parties hereby agree from time to time to execute and deliver such further and other transfers, assignments and documents and do all matters and things that may be convenient or necessary to more effectively and completely carry out the intentions of this Invention Assignment and Confidentiality Agreement.

B. Survival. All covenants, agreements, representations and warranties made in this Invention Assignment and Confidentiality Agreement or otherwise made in writing by any party pursuant to this Invention Assignment and Confidentiality Agreement shall survive the execution and delivery of this Invention Assignment and Confidentiality Agreement and the termination of employment of Employee.

C. Injunctive Relief. Employee acknowledges that AXOGEN will be irreparably damaged (and damages at law would be an inadequate remedy) if this Invention Assignment and Confidentiality Agreement is not specifically enforced. Therefore, in the event of a breach or threatened breach by Employee of any provision of this Invention Assignment and Confidentiality Agreement, AXOGEN shall be entitled, in addition to all other rights or remedies, to injunctions restraining such breach or threatened breach, without being required to show any actual damage or to post any bond or other security.

THE PARTIES TO THIS AGREEMENT have executed this Invention Assignment and Confidentiality Agreement as of the 1<sup>st</sup> day of October, 2011.

**AXOGEN Corporation**

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Name: Karen Zaderej  
Title: CEO

**EMPLOYEE**

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Print Name: Gregory Freitag

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**EXHIBIT B TO EMPLOYMENT AGREEMENT**  
**NON-SOLICITATION AND NON-COMPETITION AGREEMENT**

THIS NON-SOLICITATION AND NON-COMPETITION AGREEMENT (the "NSNC Agreement") is entered into as of the date written below by and between AXOGEN Corporation ("AXOGEN" or "Employer") and the undersigned AXOGEN employee ("Employee").

**RECITALS:**

A. WHEREAS, Employee has agreed to accept employment with AXOGEN; and

B. WHEREAS, the Parties desire to reflect their agreement as to Employee's promises regarding Employee's solicitation and competition, which have induced AXOGEN to employ Employee.

NOW, THEREFORE, in consideration of Employee's employment with AXOGEN and the covenants set forth in this Agreement and other good and valuable consideration, the Parties, intending to be legally bound by this Agreement, agree as follows:

1. Non-solicitation. Employee shall not, at any time while employed by AXOGEN and for two (2) years after the termination of Employee's employment with AXOGEN for any reason whatsoever, or for no reason, directly or indirectly (by assisting or suggesting to another, or otherwise) solicit, otherwise attempt to induce or accept the initiative of another in such regard, alone or by combining or conspiring with any employees, officers, directors, agents, consultants, representatives, contractors, suppliers, distributors, customers or other business contacts of AXOGEN to terminate or modify its position as an employee, officer, director, agent, consultant, representative, contractor, supplier, distributor, customer or business contact with AXOGEN or to compete against AXOGEN.

2. Non-competition. Employee shall not, at any time while employed by AXOGEN and for two (2) years after such termination of Employee's employment for any reason whatsoever, or for no reason (the "No-Compete Period"), directly or indirectly, as owner, officer, director, employee, agent, lender, broker, investor, consultant or representative of any corporation or as owner of any interest in, or as an employee, agent, consultant, partner, independent contractor, affiliate or in any other capacity whatsoever, or representative of any other form of business association, sole proprietorship or partnership, conduct or assist in any way any business that relates to the regeneration of nerves or the treatment of neurological injuries and defects, or any business that competes directly with AxoGen's then-current or planned products or business.

3. Non-Interference. In addition to, and not in limitation of, the other provisions of this Agreement, or of any other agreement between Employee and AXOGEN, Employee shall not at any time, in any manner, interfere with, disturb, disrupt, decrease or otherwise jeopardize the business of AXOGEN, or give to any person the benefit or advantage of AXOGEN's or Corp.'s methods of operation, advertising, publicity, training, business customers or accounts, or any other information relating or useful to AXOGEN's or Corp.'s business.

4. Representations and Warranties. Employee does hereby represent and warrant to the Employer that:

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(i) Employee is not presently employed by, and/or have any ownership interest, either directly or indirectly, in any entity or business, and is not presently engaged in any outside business activity in competition with AXOGEN;

(ii) this NSNC Agreement is executed by Employee to protect the legitimate business interests of the Employer;

(iii) legitimate business interests of the Employer to be protected by this NSNC Agreement include, without limitation, the protection of:

- a. valuable trade secrets of the Employer;
- b. the customer and vendor base of the Employer;
- c. confidential customer and vendor information belonging to the Employer;
- d. substantial business relationships between the Employer and its existing and prospective customers and vendors;
- e. goodwill associated with the specialized expertise of Employer; and
- f. specialized training undertaken by the Employer and its employees.

(iv) the other covenants and restrictions of this NSNC Agreement are appropriate and reasonable in all respects in light of the legitimate business interests of the Employer to be protected.

(v) the Employer and Employee have considered the public's health, safety and welfare, and that nothing contained in this NSNC Agreement will adversely affect the public's health, safety or welfare.

(vi) the execution and delivery of this NSNC Agreement, and the restrictions contained herein, the performance by Employee of the covenants and agreements contained herein, and the enforcement by the Employer of the provisions contained herein, will cause no undue hardship on Employee.

5. Other Restrictions. In consideration of Employer's agreement to employ, or to continue the employment of, Employee, and in accordance with the terms and conditions of this NSNC Agreement, the Employee hereby agrees as follows:

(i) The restrictions on employment contained above are essential elements of this NSNC Agreement, and that, but for the agreement of Employee to comply with such restrictions, the Employer would not have entered into the NSNC Agreement or the Agreement. The restrictions contained within this NSNC Agreement are reasonably necessary to protect the legitimate business interests of the Employer. The restrictions assist in assuring the continuity and growth of the Employer in the achievement of its goals and objectives. The legitimate business interests justifying the restrictions include, but are not limited to, trade secrets, valuable business information or professional information that otherwise do not qualify as trade secrets, substantial relationships with prospective and existing customers and vendors, or goodwill associated with the name of the Employer.

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6. Remedies for Breach. Employee acknowledges and agrees that, in the event of a breach or threatened breach of any of the provisions of this NSNC Agreement, the Employer would suffer irreparable harm for which monetary damages would be inadequate. Accordingly, in addition to any other remedies available, at law or in equity, in the event of a breach or threatened breach by Employee of such provisions, the Employer will be entitled to equitable relief in the form of an injunction against such breach, both preliminary and permanent, without the requirement to post a bond or other security or to prove irreparable injury or inadequate remedy at law, specific performance or other appropriate relief.

7. Tolling. In the event that the Employer shall file a lawsuit in any court of competent jurisdiction alleging a breach of any of Employee's obligations under this NSNC Agreement, then any time period set forth in this NSNC Agreement, including the time periods set forth above, shall be deemed tolled as of the time such lawsuit is filed and shall remain tolled until such dispute finally is resolved either by written settlement agreement resolving all claims raised in such lawsuit or by entry of a final judgment in such lawsuit, including the final resolution of any post-judgment appellate proceedings.

8. Assignment. This NSNC Agreement and all rights and benefits hereunder are personal to Employee, and neither this NSNC Agreement, nor any right or interest herein of Employee shall be voluntarily or involuntarily sold, transferred or assigned by Employee; provided, however, that the Employer may assign its rights, duties and obligations hereunder without the prior written consent of Employee.

9. Severability. In the event any provision of this NSNC Agreement is held illegal or invalid, the remaining provisions of this NSNC Agreement and the Agreement shall not be affected thereby. If any of the restrictions contained in this NSNC Agreement or any part thereof is held to be unenforceable, the Parties agree that the court making such determination will have the power to reform the provisions of this NSNC Agreement to the extent permitted by applicable law.

10. No Defense to Enforcement. The existence of any claim or cause of action by Employee against AXOGEN predicated on the Agreement herein, shall not constitute a defense to the enforcement by AXOGEN of this NSNC Agreement.

THE PARTIES TO THIS AGREEMENT have executed this Agreement as of the 1<sup>st</sup> day of October, 2011.

**AXOGEN Corporation**

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Name: Karen Zaderej  
Title: CEO

**EMPLOYEE**

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Print Name: Gregory Freitag

**EXECUTIVE EMPLOYMENT AGREEMENT**

**THIS EXECUTIVE EMPLOYMENT AGREEMENT** (the "Agreement"), effective as of February 27, 2012, is made by and between AXOGEN CORPORATION, a Delaware corporation ("AXOGEN" or "Employer"), and Jill F. Schiaparelli ("Employee"), whose resident address is 6671 Ross Lane, Mason, Ohio 45040 (collectively, the "Parties").

**RECITALS:**

A. WHEREAS, AXOGEN believes it is in its best interest to employ Employee, and Employee desires to be employed by AXOGEN; and

B. WHEREAS, AXOGEN and Employee desire to set forth the terms and conditions on which Employee shall be employed by and perform duties on behalf of AXOGEN.

NOW, THEREFORE, in consideration of the promises set forth in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which is acknowledged by this Agreement, the Parties to this Agreement, intending to be legally bound, agree as follows:

1. **Employment**. AXOGEN hereby employs Employee, and Employee hereby accepts such employment, all upon the terms and conditions set forth in this Agreement, including those set forth in the attached Schedules and Exhibits.

(a) **Duties of Employee**. The duties of Employee are set forth on Schedule 1 of this Agreement, which is attached hereto and incorporated herein by reference.

(b) **Compensation and Benefits**. The compensation and benefits to which Employee may be entitled pursuant to this Agreement are set forth on Schedule 2 of this Agreement, which is attached hereto and incorporated herein by reference.

2. **Invention Assignment and Confidentiality Agreement**. Contemporaneously with the execution and delivery of this Agreement, Employee shall enter into an Invention Assignment and Confidentiality Agreement attached hereto as Exhibit "A" to this Agreement (the "Invention and Confidentiality Agreement"), which shall be incorporated herein by reference.

3. **Non-Competition Agreement**. Contemporaneously with the execution and delivery of this Agreement, Employee shall enter into a Non-Solicitation and Non-Competition Agreement attached hereto as Exhibit "B" to this Agreement (the "NSNC Agreement") which shall be incorporated herein by reference.

4. **Termination**.

(a) **At-will**. Either AXOGEN or Employee may terminate this Agreement at any time during the course of Employee's employment and for any reason, upon giving written notice to the other party. Employer shall have no further liability or obligation to Employee other than to pay for services rendered through Employee's last date of employment. If

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Employee elects to terminate this Agreement and provides Employer with any notice period prior to the date of termination, Employer may elect to terminate this Agreement immediately thereon and incur no further obligation to Employee other than for wages worked through the date of termination of this Agreement. It is the intention of the Parties that at all times this shall be an at-will employment relationship during the course of Employee's employment with Employer. Nothing contained in this Agreement shall be deemed or construed to create a contractual relationship between the Parties for a specific duration of time.

(b) Death. In the event of the death of the Employee, this Agreement shall terminate on the date of Employee's death, without any liability to or upon the Employer other than to pay for services rendered prior to the date of the Employee's death.

(c) Permanent Disability. For purposes of this Agreement, the term "Permanent Disability" shall mean a physical or mental incapacity of Employee, which renders Employee unable to perform Employee's duties pursuant to this Agreement, and which shall continue for ninety (90) consecutive days or one hundred and eighty (180) days during any twelve month period. If AXOGEN or Employee terminates Employee's employment by reason of Permanent Disability of Employee, this Agreement shall terminate immediately upon written notice by AXOGEN to Employee, or the date Employee gives notice to terminate employment to AXOGEN, without any liability to or upon the Employer other than to pay for services rendered through the termination date.

#### 5. Change in Control.

(a) Definition. For the purposes of this Agreement, a "Change in Control" shall mean the occurrence of any of the following events:

(i) any "person" (as that term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended ("Exchange Act")), who holds less than twenty percent (20%) of the combined voting power of the securities of AXOGEN or its parent company AxoGen, Inc. ("INC."), becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of AXOGEN or INC. representing fifty percent (50%) or more of the combined voting power of the securities of either AXOGEN or Inc. then outstanding; or

(ii) during any period of twenty-four (24) consecutive months, individuals, who, at the beginning of such period constitute all members of the Board of Directors of INC. (the "Board") and cease, for any reason, to constitute at least a majority of the Board, unless the election of each director who was not a director at the beginning of the period was either nominated for election by, or approved by a vote of, at least two-thirds of the directors then still in office who were directors at the beginning of the period; or

(iii) AXOGEN or INC. consolidates or merges with another company, and AXOGEN or INC. is not the continuing or surviving corporation, provided, however, that any consolidation or merger whereby INC. continues as the majority holder of AXOGEN securities or a merger or consolidation of AXOGEN and INC. will not constitute a Change in Control; or

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(iv) shares of AXOGEN's or INC.'s common stock are converted into cash, securities, or other property, other than by a merger of AXOGEN or INC., pursuant to Section 5(a)(iii), in which the holders of AXOGEN's or INC.'s common stock immediately prior to the merger have the same proportionate ownership of common stock of the surviving corporation as immediately after the merger; or

(v) AXOGEN or INC. sells, leases, exchanges, or otherwise transfers all, or substantially all, of its assets (in one transaction or in a series of related transactions), provided, however, that any such transaction related to AXOGEN whereby INC. continues as the majority holder of AXOGEN securities or INC. is the sole other party to the transaction, will not constitute a Change in Control; or

(vi) the holders of AXOGEN's or INC.'s stock approve a plan or proposal for the liquidation or dissolution of AXOGEN or INC.

(b) Severance.

(i) Termination in Connection with a Change of Control. In the event of Employee's termination of employment by AXOGEN without Substantial Cause (as defined below) upon or within one hundred and eighty (180) days following a Change in Control or by Employee for Good Reason (as defined below), Employee will be entitled to a severance payment consisting of twelve (12) months of Employee's base salary. For purposes of this Agreement, "Substantial Cause" means: (A) the commission by Employee of any act of fraud, theft, or embezzlement; (B) any material breach by Employee of this Agreement, provided that AXOGEN shall have first delivered to Employee written notice of the alleged breach, specifying the exact nature of the breach in detail, and provided, further, that Employee shall have failed to cure or substantially mitigate such breach within ten (10) days after receiving such written notice; (C) commission or conviction of any felony, or of any misdemeanor involving moral turpitude, or entry of a plea of guilty or nolo contendere to any felony or misdemeanor; (D) material failure to adhere to AXOGEN's corporate codes, policies or procedures which have been adopted in good faith for a valid business purpose as in effect from time to time; or (E) failure to meet reasonable performance standards as determined by AXOGEN. For purposes of this Agreement, "Good Reason" shall mean Employee's resignation from employment upon or within ninety (90) days following a Change of Control, if AXOGEN or INC. is not the surviving entity, provided that Substantial Cause for termination of Employee's employment does not exist at the time of such resignation and the resignation is the result of the occurrence of any one or more of the following:

a) the assignment to Employee of any duties inconsistent in any respect with his/her position (including status, offices, titles, and reporting requirements), authorities, duties, or other responsibilities as in effect immediately prior to the Change in Control of the Company or any other action of the Company which results in a diminishment in such position, authority, duties, or responsibilities, other than an insubstantial and inadvertent action which is remedied by the Company promptly after receipt of notice thereof given by Employee;

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b) a reduction by AXOGEN in Employee's base salary as in effect on the date hereof and as the same shall be increased from time to time hereafter; or

c) the failure by AXOGEN to (A) continue in effect any material compensation or benefit plan, program, policy or practice in which Employee was participating at the time of the Change in Control of the Company or (B) provide Employee with compensation and benefits at least equal (in terms of benefit levels and/or reward opportunities) to those provided for under each employee benefit plan, program, policy and practice as in effect immediately prior to the Change in Control of the Company (or as in effect following the Change in Control of the Company), if greater.

(ii) Termination not in Connection with a Change of Control. In the event of Employee's termination of employment by AXOGEN without Substantial Cause either prior to a Change of Control or following the date that is one hundred and eighty (180) days following a Change in Control, Employee shall be entitled to a severance payment consisting of (A) twelve (12) months of Employee's base salary; and (B) an amount equal to any bonuses paid to Employee during the twelve (12) month period prior to Employee's termination of employment.

(c) Payment of Severance. Payment of any severance for Employee will be made in a lump sum on the first payroll date following the 60th day following the date of Employee's termination of employment. Notwithstanding the foregoing, if the Employee is a "specified employee" on Employee's termination date, the postponement provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), as described in Section 8(n) below, shall apply, if applicable.

7. Surrender of Records and all Company Property. Upon the termination of Employee's employment for any reason, whether by AXOGEN or Employee, Employee agrees to return to AXOGEN, in good condition, (i) any and all equipment belonging to AXOGEN including, without limitation, computers, cell phones, and personal digital assistants, and (ii) any and all data, computer files, customer lists and contact information, documents and other materials in Employee's possession, or removed by Employee from AXOGEN's premises, whether now in Employee's possession or not, which materials were obtained in connection with Employee's employment with AXOGEN, including any and all copies (whether complete or partial) and extracts thereof, and (iii) any and all other company property or Confidential Information and materials as they are defined in Employee's Invention Assignment and Confidentiality Agreement, in the Employee's control or possession.

#### 8. Miscellaneous Provisions.

(a). Amendments to this Agreement only in Writing. The provisions of this Agreement and the attached Schedules and Exhibits shall only be amended, supplemented, or waived by a written agreement executed by both a duly authorized officer of AXOGEN and Employee.

(b). Assignments. Employee shall not assign Employee's rights and/or obligations pursuant to this Agreement or the attached Schedules and Exhibits. AXOGEN may assign its rights and/or obligations pursuant to this Agreement and the attached Schedules and Exhibits

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at any time without prior notice to Employee. In the event of a Change of Control in which AXOGEN or INC. is not the surviving entity, any reference to AXOGEN or INC. shall be deemed to refer to the surviving entity.

(c). Binding Effect. All of the terms and provisions of this Agreement and the attached Schedules and Exhibits, whether so expressed or not, shall be binding upon, inure to the benefit of, and be enforceable by the Parties and their respective administrators, executors, legal representatives, heirs, successors and permitted assigns.

(d). The Provisions of this Agreement are Severable. If any part of this Agreement, or any of the Schedules or Exhibits entered into pursuant to this Agreement, is contrary to, prohibited by, or deemed invalid under any applicable law or regulation, such provision shall be inapplicable and deemed omitted to the extent so contrary, prohibited or invalid, but the remainder of this Agreement and its Schedules and Exhibits shall not be so invalidated, and shall be given full force and effect so far as possible.

(e). Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 1 through 8 shall survive and remain in effect beyond the execution and delivery of this Agreement in accordance with their respective terms of duration.

(f). Waivers. The failure or delay of AXOGEN at any time to require performance by Employee of any provision of this Agreement or the attached Schedules and Exhibits, even if known, shall not affect the right of AXOGEN to require performance of that provision or to exercise any right, power or remedy pursuant to this Agreement or the attached Schedules and Exhibits. Any waiver by AXOGEN of any breach of any provision of this Agreement or the attached Schedules and Exhibits shall not be construed as a waiver of any continuing or succeeding breach of such provision, a waiver of the provision itself, or a waiver of any right, power or remedy pursuant to this Agreement or the attached Schedules and Exhibits.

(g). Notices. All notices, requests, consents and other communications required or permitted under this Agreement shall be in writing and shall be (i) hand-delivered by messenger or courier service; (ii) sent by an overnight-mail service (e.g. FedX or UPS); or (iii) mailed (airmail, if international) by registered or certified mail (postage prepaid), return receipt requested, and addressed to:

If to Employee:

Employee's most current address on file with AXOGEN.

If to AXOGEN:

AXOGEN Corporation  
13859 Progress Blvd., Ste. 100  
Alachua, FL 32615  
Attn: CEO

With a copy to:

AXOGEN Corporation  
13859 Progress Blvd., Ste. 100  
Alachua, FL 32615  
Attn: Human Resources

or to such other address as any party may designate by written notice complying with the terms of this section. Each such notice shall be deemed delivered (a) on the date delivered, if by personal delivery, or (b) on the date upon which the return receipt is signed, delivery is refused, or the notice is designated by the postal authorities as not deliverable, as the case may be, if mailed.

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(h). Governing Law. This Agreement and the attached Schedules and Exhibits and all transactions contemplated by this Agreement or the attached Schedules and Exhibits shall be governed by, and construed and enforced in accordance with, the internal laws of the State of Florida, without regard to principles of conflicts of laws.

(i). Jurisdiction and Venue. The Parties acknowledge that a substantial portion of negotiations, anticipated performance and execution of this Agreement and the attached Schedules and Exhibits occurred, or shall occur, in Alachua County, Florida, and the Parties irrevocably and unconditionally (a) agree that any suit, action or legal proceeding arising out of, or relating to, this Agreement or the attached Schedules and Exhibits shall be brought in the courts of record of the State of Florida in Alachua County, or the United States District Court, Northern District of Florida, Gainesville Division; (b) consent to the jurisdiction of each such court in any such suit, action or proceeding; (c) waive any objection which they may have to the laying of venue of any such suit, action or proceeding in any of such courts; and (d) agree that service of any court paper may be effected on such party by mail, as provided in this Agreement, or in such other manner as may be provided under applicable laws or court rules in said state.

(j). Remedies Available to Either Party Cumulative. No remedy conferred upon any party pursuant to this Agreement (or the attached Schedules and Exhibits) is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to every other remedy given pursuant to this Agreement (or the attached Schedules and Exhibits) now or hereafter existing at law or in equity or by statute or otherwise. No single or partial exercise by any party of any right, power or remedy pursuant to this Agreement (or the attached Schedules and Exhibits) shall preclude any other or further exercise of such right, power or remedy.

(k). Entire Agreement. This Agreement and the attached Schedules and Exhibits represents the entire understanding and agreement between the Parties with respect to the subject matter contained herein and supersedes all other negotiations, understandings and representations (if any) made by and between the Parties.

(l). Section and Paragraph Headings. Section and paragraph headings used throughout this Agreement and the attached Schedules and Exhibits are for convenience of reference only and in no way define, limit or describe the scope or intent of this Agreement or the attached Schedules and Exhibits.

(m). Preparation of Agreement. This Agreement shall not be construed more strongly against any party regardless of who is responsible for its preparation. The Parties acknowledge that each party contributed to its negotiations and is equally responsible for its preparation.

(n). Section 409A of the Code. Notwithstanding any provision of this Agreement to the contrary, this Agreement is intended to meet the requirements of Section 409A of the Code to the extent applicable, the Parties intend to administer this Agreement in a manner that is consistent with those requirements or an exception thereto, and this Agreement shall be construed and interpreted in accordance with such intent. Any payments that are considered deferred compensation under Section 409A of the Code and that are paid to a "specified employee" (as defined in Section 409A of the Code) upon separation from service shall be subject to a six (6) month delay, if required by Section 409A of the Code. If required by

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Section 409A of the Code, any amounts otherwise payable during the six (6) month period that commences on and follows the Employee's termination date shall be paid in one lump sum amount on the first payroll date following the six (6) month period following the Employee date of termination (or within thirty (30) days of the Employee's death, if earlier). For purposes of Section 409A of the Code, all payments to be made upon a termination of employment under this Agreement may only be made upon a "separation from service" (within the meaning of such term under Section 409A of the Code). Each payment made under this Agreement shall be treated as a separate payment. In no event shall the Employee, directly or indirectly, designate the calendar year of a payment. All reimbursements under this Agreement shall be provided in a manner that complies with Section 409A of the Code, if applicable. If required by regulations or other guidance issued under Section 409A of the Code or a court of competent jurisdiction, the provisions regarding payments hereunder shall be amended to provide for such payments to be made at the time allowed under such regulations, guidance or authority that most closely achieves the intent of this Agreement.

(o) Liability Insurance. AXOGEN shall cover the Employee under directors and officers liability insurance both during the term of this Agreement and for the one year period following the termination of this Agreement, in the same amount and to the same extent as AXOGEN covers its officers and directors.

*[Signature Page Follows]*

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EMPLOYEE AND AXOGEN have executed this Agreement as of the 27th day of February 2012.

**AXOGEN Corporation**

/s/ Karen Zaderej  
Karen Zaderej, CEO

**EMPLOYEE:**

/s/ Jill F. Schiaparelli  
Jill F. Schiaparelli

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**SCHEDULE AND EXHIBIT LIST**

- Schedule 1 — Duties of Employee
- Schedule 2 — Compensation and Benefits
- Exhibit A — Invention Assignment and Confidentiality Agreement
- Exhibit B — Non-Solicitation and Non-Competition Agreement

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**SCHEDULE 1**  
**DUTIES OF EMPLOYEE**

The duties of Employee with AXOGEN Corporation (“AXOGEN” or “Employer”) are as follows:

1. Employee’s Title: AXOGEN hereby employs Employee as Senior Vice President, Business Strategy & Marketing, which title may change at AXOGEN’s discretion.

2. Employee’s Duties: During employment with AXOGEN, Employee’s duties will include, without limitation, the following:

(a) Description of Duties. Employee shall perform all duties in connection with Employee’s position, or as otherwise designated by AXOGEN, including, without limitation, the following duties:

- Assist in determining and guiding the strategic direction of the company
- Define and execute marketing programs for awareness, demand creation and lead generation to drive the growth of sales volume. Strive for the tipping point in market demand.
- Develop market segmentation, targeting, positioning, key messaging and competitive analysis
- Develop and execute marketing communications including public relations, sales collateral creation, company website, conference and education events
- Work directly with thought leaders to assess the clinical and technology needs of the marketplace and the underlying broadly held assumptions
- Determine pricing and discounting strategy
- Support the negotiation and execution of contracts with hospitals and IDNs as needed
- Selection and use of proper information technology including CRM software
- Demonstrate creative, insightful ideas and implement them quickly and effectively
- Create a world class customer service function to provide service and to communicate effectively with customers and maximize customer retention
- Evaluate and recommend markets/products for growth in peripheral nerve
- Provide input and guidance on the clinical and product development programs
- Effectively manage P&L responsibility & budgeting.
- Coordinate with operations to optimize the manufacturing forecast
- Create and monitor market and business metrics to demonstrate effectiveness in sales growth and market penetration
- Idea generation and creativity in this position are a must, as are the ability to work with deadlines, manage and complete projects through commercialization, and develop techniques in the clinical sale of concepts and products.
- Follows company policies, procedures and SOP’s.
- Completes other duties as designated by supervisor

(b) Report to AXOGEN Designated Manager. Employee shall report to the CEO of AXOGEN.

(c) Compliance With Employee Policies and Procedures. Employee shall comply with all AXOGEN policies and procedures for employees as such policies and procedures may exist from time to time.

(d) No Other Business Activities.

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(i) Employee shall devote Employee's entire professional time, energy and skill to the performance of Employee's duties pursuant to the Agreement, the service of AXOGEN, and promotion of AXOGEN's interests. The Parties agree that Employee may not during Employee's employment, except as permitted in writing by AXOGEN, be engaged in any other business activity, whether or not such activity is pursued for gain, profit, or other pecuniary advantage including, without limitation, management or management consulting activities.

(ii) Notwithstanding the preceding subsection, Employee may invest Employee's personal assets in businesses or real estate that are not in competition with AXOGEN where the form or manner of such investment will not require services on the part of Employee, and in which Employee's participation is solely that of a passive investor.

(e) Compliance with AXOGEN's Rules and Regulations. Employee agrees to abide by all rules and regulations established from time to time by AXOGEN.

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**SCHEDULE 2**  
**COMPENSATION AND BENEFITS**

Subject to the terms and conditions of the Executive Employment Agreement (the "Agreement"), Employee may be entitled to receive from AXOGEN Corporation ("AXOGEN" or "Employer") the following compensation and benefits:

1. Base Salary.

(a) Amount. Employee's salary during employment with AXOGEN will be at the rate of \$215,000 (Two Hundred and Fifteen Thousand Dollars) annually, (the "Base Salary") effective upon execution and delivery of the Agreement and Employee's first day of employment with AXOGEN.

(b) Payment. The Base Salary shall be payable in accordance with the existing payroll practices of AXOGEN, which practices may be changed by AXOGEN from time to time at its sole discretion. The Base Salary shall be subject to all appropriate withholding taxes.

(c) Review of Base Salary. The Base Salary shall be reviewed by AXOGEN on an annual basis; however AXOGEN reserves the right to increase or decrease the Base Salary at any time during the employment relationship in its sole discretion.

(d) Bonuses.

(i) Employee will be eligible in calendar year 2012 for specific bonuses as follows:

(1) up to 2.5% of base salary per quarter (pro-rated for first quarter based on the number of days employed), based upon meeting company quarterly bonus goals as established, and determined to be met, in the sole discretion of AXOGEN; and

(2) for every \$100,000 in AXOGEN gross revenue in fiscal 2012 is above \$15,300,000 Employee will receive \$3,071 in bonus compensation to a maximum aggregate amount of \$64,500 (example if AXOGEN gross revenue is \$16,225,000, the aggregate bonus will be \$27,639 and if AXOGEN gross revenue is \$17,800,000 the aggregate bonus will be \$64,500).

(ii) Employee will not be eligible for other bonuses for calendar 2012 except as provided in this sub-section (d).

(iii) Bonuses for future years, if any, will be negotiated between Employee and AXOGEN.

(iv) Bonuses if paid shall be paid in accordance with, and subject to, the normal payroll policies of AXOGEN with respect to similar forms of compensation, including, without limitation, being subject to all appropriate withholding taxes.

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(e) Additional Compensation. In addition to the Base Salary, Employee may also be eligible to receive stock options, benefits, paid vacations and holidays during Employee's Employment.

2. Business Expenses and Reimbursements. Employee shall be eligible for reimbursement by AXOGEN in accordance with AXOGEN's normal reimbursement practices for ordinary and necessary business expenses incurred by Employee in the performance of Employee's duties for AXOGEN, so long as Employee timely submits to AXOGEN accurate invoices and receipts of all expenses submitted for reimbursement pursuant to this section.

3. Stock Options. Employee may be eligible to receive stock options in accordance with the terms of the Employee's Incentive Stock Option Agreement.

4. Benefits. Employee will be permitted to participate in such benefit plans of AXOGEN that may be in effect from time to time, to the extent Employee is eligible under the terms of those plans. Nothing herein shall be construed to require AXOGEN to institute or continue any particular plan or benefit. AXOGEN reserves the right to add, change, or eliminate any benefits at any time at its sole discretion.

5. Vacations and Holidays. Employee will be entitled to paid vacation and holidays in accordance with the vacation and holiday policies of AXOGEN in effect for its employees from time to time. Vacation must be taken by Employee at such time or times as approved by AXOGEN.

6. Compensation Review. AXOGEN shall, from time to time, but no less frequently than annually, review Employee's compensation (including benefits) and may, in its sole discretion, increase, or decrease, or eliminate any or all of the benefits. Any such increase or decrease in the compensation package shall be valid only if in writing, executed by a duly authorized officer of AXOGEN, and such writing shall constitute an amendment to this Paragraph 8 (and to the Agreement and any applicable Schedules or Exhibits) solely as to the benefits, without waiver or modification of any other terms, conditions or provisions of the Agreement.

7. No Other Compensation. Employee agrees that the compensation and benefits set forth in the Agreement and this Schedule 2 are the sole and exclusive compensation and benefits to which Employee is entitled pursuant to the Agreement and this Schedule 2, and that Employee shall have no rights to receive any other compensation or benefits of any nature from AXOGEN.

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**EXHIBIT A OF EMPLOYMENT AGREEMENT**  
**INVENTION ASSIGNMENT AND CONFIDENTIALITY AGREEMENT**

THIS INVENTION ASSIGNMENT AND CONFIDENTIALITY AGREEMENT (the "Invention and Confidentiality Agreement") is entered into as of the date first written below, by and between AXOGEN Corporation ("AXOGEN" or "Employer") and the undersigned AXOGEN employee, ("Employee") for and in consideration of Employee's continued employment by AXOGEN and the compensation that Employee shall receive during Employee's employment, the Parties agree as follows:

1. Employee's Covenants, Representations and Warranties. Both during and after the termination of Employee's employment by AXOGEN for any reason or for no reason:

A. Non-Disclosure. Employee shall not disclose to anyone outside AXOGEN any Confidential Information. "Confidential Information" shall include, without limitation,

(i) all information, which has not been made publicly available by AXOGEN or the third-party owner of such information, which was developed by AXOGEN, any of AXOGEN's employees or independent contractors, or was developed for AXOGEN, including but not limited to Developments (as defined below in Section 3), technical data, specifications, designs, programs, software, hardware, concepts, discoveries, copyrights, improvements, product plans, research and development, , personnel information, contents of manuals, financial information, customer lists, leads, marketing programs, testing programs, and/or other written materials;

(ii) all documents marked as confidential and/or containing such information; and/or

(iii) all information AXOGEN has acquired or received from a third party in confidence.

B. Use of Confidential Information. Employee shall use Confidential Information only for AXOGEN's business purposes.

C. Confidential Information and Materials Furnished by AXOGEN. Employee agrees that the Confidential Information and any other materials furnished by AXOGEN to Employee, (i) are proprietary to AXOGEN and contain specialized and unique information not obtainable from ordinary sources, (ii) have been created by AXOGEN at considerable time and expense, and (iii) shall remain, at all times, the exclusive and sole property of AXOGEN.

D. Use of Third-Party Information. Employee shall not disclose to AXOGEN, use in AXOGEN's business, or cause AXOGEN to use any information or material which is confidential to any third party unless AXOGEN has a written agreement with the third party allowing AXOGEN to receive and use the confidential information or materials.

E. Use of Copyrights. Employee will not incorporate into Employee's work any material that is subject to the copyrights of any third party unless AXOGEN has the right to copy and incorporate such copyrighted material.

F. Trade Secrets. Employee acknowledges AXOGEN's legitimate business interest in protecting its trade secrets and customer lists and in preventing direct solicitation of its customers and agrees that any unauthorized use of trade secrets shall be presumed to be an irreparable injury that may be specifically enjoined.

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2. Return of Confidential Information and Materials. Employee shall, immediately upon AXOGEN's request, or the termination of Employee's employment, for any reason, whether by Employee or AXOGEN, return to AXOGEN all Confidential Information and other materials furnished to Employee, and any and all third-party property, and/or copies of the same, and all documentation, notebooks and notes, reports and any other materials whether electronic or print media containing or derived from the Confidential Information and other materials furnished to Employee by AXOGEN.

3. Assignment of Rights. Employee hereby grants, transfers and assigns and agrees to grant, transfer and assign to AXOGEN all of Employee's rights, title and interest, if any, in any and all Developments, including rights to translation and reproductions in all forms or formats and the copyrights, patent rights and moral rights to the same, if any, and agrees that AXOGEN may further perfect AXOGEN's United States and foreign rights in, and to any and all, Developments under patents and copyrights. "Developments" shall mean any idea, invention, process, design, concept, or useful article (whether the design is ornamental or otherwise), computer program, trademark, trade secret, documentation, literary work, audiovisual work and any other work of authorship, hereafter expressed, made or conceived solely or jointly by Employee during Employee's employment, whether or not subject to patent, copyright or other forms of protection that is:

A. related to the actual or anticipated business, research or development of AXOGEN; and/or

B. suggested by or resulting from any task assigned to Employee or work performed by Employee for or on behalf of AXOGEN.

4. Copyrights. Employee acknowledges that the copyrights in Developments created by Employee in the scope of Employee's employment belong to AXOGEN by operation of law, or may belong to a party engaged by AXOGEN by operation of law pursuant to a works-for-hire contract between AXOGEN and such contracted third party. To the extent the copyrights in such works may not be owned by AXOGEN or such contracted party by operation of law, Employee hereby assigns and agrees to assign to AXOGEN or such contracted party, as the case may be, all copyrights (if any) Employee may have in Developments.

5. Assistance in Obtaining Copyrights and Patents. At all times after the date of this Invention Assignment and Confidentiality Agreement, Employee agrees to assist AXOGEN in obtaining patents or copyrights on any Developments assigned to AXOGEN that AXOGEN, in its sole discretion, seeks to patent or copyright. Employee also agrees to sign all documents, and do all things necessary to obtain such patents or copyrights, to further assign them to AXOGEN, and to reasonably protect them and AXOGEN against infringement by other parties at AXOGEN expense with AXOGEN prior approval.

6. Appointment of Attorney-In-Fact. Employee irrevocably appoints any AXOGEN-selected designee to act, at all times hereafter, as Employee's agent and attorney-in-fact to perform all acts necessary to obtain patents and/or copyrights as required by this Invention Assignment and Confidentiality Agreement if Employee (i) refuses to perform those acts or (ii) is unavailable, within the meaning of the United States Patent and Copyright laws. It is expressly intended by Employee that the foregoing power of attorney is coupled with an interest.

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7. Record Keeping. Employee shall keep complete, accurate, and authentic information and records of all Developments in the manner and form reasonably requested by AXOGEN. Such information and records, and all copies of the same, shall be the property of AXOGEN as to any Developments assigned AXOGEN. Employee agrees to promptly surrender such information and records at the request of AXOGEN as to any Developments.

8. Developments. In connection with any of the Developments assigned by this Invention Assignment and Confidentiality Agreement, Employee hereby agrees:

A. to disclose them promptly to AXOGEN;

B. at AXOGEN's request, to execute separate written assignments to AXOGEN;

C. to provide AXOGEN with notice of any inadvertent disclosure of Confidential Information related to any Development; and

D. to do all things reasonably necessary to enable AXOGEN to secure patents, register copyrights or obtain any other form of protection for Developments in the United States and in other countries. If Employee fails or is unable to do so, Employee hereby authorizes AXOGEN to act under power of attorney for Employee to do all things to secure such rights.

9. No Designation as Author. AXOGEN, its subsidiaries, licensees, successors or assigns, (direct or indirect) is not required to designate Employee as author of any Developments when such Developments are distributed publicly or otherwise. Employee waives and releases, to the extent permitted by law, all Employee's rights to such designation and any rights concerning future modifications of such Developments.

10. Assignability. Rights, assignments, and representations made or granted by Employee in this Invention Assignment and Confidentiality Agreement are assignable by AXOGEN without notice, and are for the benefit of AXOGEN's successors, assigns, and parties contracting with AXOGEN.

11. Trade Secrets. Employee acknowledges that Employee is aware that a theft of trade secrets of an employer by an employee in Florida, such as is prohibited by this Invention Assignment and Confidentiality Agreement, constitutes a criminal violation of Florida Statute 812.081, punishable as a third-degree felony under Florida Statute 775.082, conviction for which carries a term of imprisonment not exceeding five (5) years. Employee acknowledges AXOGEN will seek vigorous prosecution under Florida Statutes for any violation thereof arising out of a breach by Employee of any of the material terms of this Invention Assignment and Confidentiality Agreement.

12. Advice of Counsel. Employee acknowledges and agrees that Employee has read and understands the terms set forth in this Invention Assignment and Confidentiality Agreement and has been given a reasonable opportunity to consult with an attorney prior to execution of this Invention Assignment and Confidentiality Agreement and has either done so, or knowingly declined to do so.

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13. Miscellaneous Provisions.

A. Further Assurances. The Parties hereby agree from time to time to execute and deliver such further and other transfers, assignments and documents and do all matters and things that may be convenient or necessary to more effectively and completely carry out the intentions of this Invention Assignment and Confidentiality Agreement.

B. Survival. All covenants, agreements, representations and warranties made in this Invention Assignment and Confidentiality Agreement or otherwise made in writing by any party pursuant to this Invention Assignment and Confidentiality Agreement shall survive the execution and delivery of this Invention Assignment and Confidentiality Agreement and the termination of employment of Employee.

C. Injunctive Relief. Employee acknowledges that AXOGEN will be irreparably damaged (and damages at law would be an inadequate remedy) if this Invention Assignment and Confidentiality Agreement is not specifically enforced. Therefore, in the event of a breach or threatened breach by Employee of any provision of this Invention Assignment and Confidentiality Agreement, AXOGEN shall be entitled, in addition to all other rights or remedies, to injunctions restraining such breach or threatened breach, without being required to show any actual damage or to post any bond or other security.

THE PARTIES TO THIS AGREEMENT have executed this Invention Assignment and Confidentiality Agreement as of the 27th day of February, 2012.

**AXOGEN Corporation**

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Karen Zaderej, CEO

**EMPLOYEE**

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Jill F. Schiaparelli

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**EXHIBIT B TO EMPLOYMENT AGREEMENT**  
**NON-SOLICITATION AND NON-COMPETITION AGREEMENT**

THIS NON-SOLICITATION AND NON-COMPETITION AGREEMENT (the "NSNC Agreement") is entered into as of the date written below by and between AXOGEN Corporation ("AXOGEN" or "Employer") and the undersigned AXOGEN employee ("Employee").

**RECITALS:**

A. WHEREAS, Employee has agreed to accept employment with AXOGEN; and

B. WHEREAS, the Parties desire to reflect their agreement as to Employee's promises regarding Employee's solicitation and competition, which have induced AXOGEN to employ Employee.

NOW, THEREFORE, in consideration of Employee's employment with AXOGEN and the covenants set forth in this Agreement and other good and valuable consideration, the Parties, intending to be legally bound by this Agreement, agree as follows:

1. Non-solicitation. Employee shall not, at any time while employed by AXOGEN and for two (2) years after the termination of Employee's employment with AXOGEN for any reason whatsoever, or for no reason, directly or indirectly (by assisting or suggesting to another, or otherwise) solicit, otherwise attempt to induce or accept the initiative of another in such regard, alone or by combining or conspiring with any employees, officers, directors, agents, consultants, representatives, contractors, suppliers, distributors, customers or other business contacts of AXOGEN to terminate or modify its position as an employee, officer, director, agent, consultant, representative, contractor, supplier, distributor, customer or business contact with AXOGEN or to compete against AXOGEN.

2. Non-competition. Employee shall not, at any time while employed by AXOGEN and for one (1) year after such termination of Employee's employment for any reason whatsoever, or for no reason (the "No-Compete Period"), directly or indirectly, as owner, officer, director, employee, agent, lender, broker, investor, consultant or representative of any corporation or as owner of any interest in, or as an employee, agent, consultant, partner, independent contractor, affiliate or in any other capacity whatsoever, or representative of any other form of business association, sole proprietorship or partnership, conduct or assist in any way any business that relates to the regeneration of nerves or the treatment of neurological injuries and defects, or any business that competes directly with AxoGen's then-current or planned products or business.

3. Non-Interference. In addition to, and not in limitation of, the other provisions of this Agreement, or of any other agreement between Employee and AXOGEN, Employee shall not at any time, in any manner, interfere with, disturb, disrupt, decrease or otherwise jeopardize the business of AXOGEN, or give to any person the benefit or advantage of AXOGEN's or Corp.'s methods of operation, advertising, publicity, training, business customers or accounts, or any other information relating or useful to AXOGEN's or Corp.'s business.

4. Representations and Warranties. Employee does hereby represent and warrant to the Employer that:

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(i) Employee is not presently employed by, and/or have any ownership interest, either directly or indirectly, in any entity or business, and is not presently engaged in any outside business activity in competition with AXOGEN;

(ii) this NSNC Agreement is executed by Employee to protect the legitimate business interests of the Employer;

(iii) legitimate business interests of the Employer to be protected by this NSNC Agreement include, without limitation, the protection of:

- a. valuable trade secrets of the Employer;
- b. the customer and vendor base of the Employer;
- c. confidential customer and vendor information belonging to the Employer;
- d. substantial business relationships between the Employer and its existing and prospective customers and vendors;
- e. goodwill associated with the specialized expertise of Employer; and
- f. specialized training undertaken by the Employer and its employees.

(iv) the other covenants and restrictions of this NSNC Agreement are appropriate and reasonable in all respects in light of the legitimate business interests of the Employer to be protected.

(v) the Employer and Employee have considered the public's health, safety and welfare, and that nothing contained in this NSNC Agreement will adversely affect the public's health, safety or welfare.

(vi) the execution and delivery of this NSNC Agreement, and the restrictions contained herein, the performance by Employee of the covenants and agreements contained herein, and the enforcement by the Employer of the provisions contained herein, will cause no undue hardship on Employee.

5. Other Restrictions. In consideration of Employer's agreement to employ, or to continue the employment of, Employee, and in accordance with the terms and conditions of this NSNC Agreement, the Employee hereby agrees as follows:

(i) The restrictions on employment contained above are essential elements of this NSNC Agreement, and that, but for the agreement of Employee to comply with such restrictions, the Employer would not have entered into the NSNC Agreement or the Agreement. The restrictions contained within this NSNC Agreement are reasonably necessary to protect the legitimate business interests of the Employer. The restrictions assist in assuring the continuity and growth of the Employer in the achievement of its goals and objectives. The legitimate business interests justifying the restrictions include, but are not limited to, trade secrets, valuable business information or professional information that otherwise do not qualify as trade secrets, substantial relationships with prospective and existing customers and vendors, or goodwill associated with the name of the Employer.

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6. Remedies for Breach. Employee acknowledges and agrees that, in the event of a breach or threatened breach of any of the provisions of this NSNC Agreement, the Employer would suffer irreparable harm for which monetary damages would be inadequate. Accordingly, in addition to any other remedies available, at law or in equity, in the event of a breach or threatened breach by Employee of such provisions, the Employer will be entitled to equitable relief in the form of an injunction against such breach, both preliminary and permanent, without the requirement to post a bond or other security or to prove irreparable injury or inadequate remedy at law, specific performance or other appropriate relief.

7. Tolling. In the event that the Employer shall file a lawsuit in any court of competent jurisdiction alleging a breach of any of Employee's obligations under this NSNC Agreement, then any time period set forth in this NSNC Agreement, including the time periods set forth above, shall be deemed tolled as of the time such lawsuit is filed and shall remain tolled until such dispute finally is resolved either by written settlement agreement resolving all claims raised in such lawsuit or by entry of a final judgment in such lawsuit, including the final resolution of any post-judgment appellate proceedings.

8. Assignment. This NSNC Agreement and all rights and benefits hereunder are personal to Employee, and neither this NSNC Agreement, nor any right or interest herein of Employee shall be voluntarily or involuntarily sold, transferred or assigned by Employee; provided, however, that the Employer may assign its rights, duties and obligations hereunder without the prior written consent of Employee.

9. Severability. In the event any provision of this NSNC Agreement is held illegal or invalid, the remaining provisions of this NSNC Agreement and the Agreement shall not be affected thereby. If any of the restrictions contained in this NSNC Agreement or any part thereof is held to be unenforceable, the Parties agree that the court making such determination will have the power to reform the provisions of this NSNC Agreement to the extent permitted by applicable law.

10. No Defense to Enforcement. The existence of any claim or cause of action by Employee against AXOGEN predicated on the Agreement herein, shall not constitute a defense to the enforcement by AXOGEN of this NSNC Agreement.

THE PARTIES TO THIS AGREEMENT have executed this Agreement as of the 27<sup>th</sup> day of February, 2011.

**AXOGEN Corporation**

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Karen Zaderej

**EMPLOYEE**

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Jill F. Schiaparelli

**FIRST AMENDMENT TO LEASE**

This First Amendment to Lease (this "First Amendment") is entered into as of February 27, 2012 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 "Lease") for certain premises in the building known as the Progress One Building and located at 13859 Progress Boulevard, Alachua, Florida; and

WHEREAS, Landlord succeeded to the interest of Original Landlord under the Lease; and

WHEREAS, the Lease is scheduled to expire on April 30, 2012; and

WHEREAS, Landlord and Tenant have agreed to amend the Lease to extend the term thereof, 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.

2. The Term of the Lease is hereby extended and shall expire on April 30, 2013.

3. For the period commencing on May 1, 2012 and expiring on April 30, 2013, Tenant shall pay Annual Gross Rent in equal monthly installments, in advance, of \$7,903.33.

4. Tenant acknowledges that it is currently in possession of the Leased Premises and is agreeing to an extension of the Term with the Leased Premises being accepted in "as is" condition as of the date of this First Amendment.

5. Section 1.1(a) of the Lease is hereby amended to reflect that until further notice to Tenant from Landlord, Landlord's address for payment of Rent shall be P.O. Box 84-5446, Boston, Massachusetts 02284-5446.

6. Section 19.5 of the Lease is hereby amended to reflect that Landlord's address for notices is as follows:

SNH Medical Office Properties Trust  
c/o Reit Management & Research LLC  
1775 The Exchange, Suite 170  
Atlanta, GA 30350

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Attention: Vice President, Southeast Region

with a copy to:

Reit Management & Research LLC  
Two Newton Place  
255 Washington Street, Suite 300  
Newton, MA 02458  
Attention: Jennifer B. Clark

7. Tenant shall not assert nor seek to enforce any claim for breach of the Lease against any of Landlord's assets other than Landlord's interest in the Building, and Tenant agrees to look solely to such interest for the satisfaction of any liability or claim against Landlord under the Lease, it being specifically agreed that in no event whatsoever shall Landlord ever be personally liable for any such liability. Tenant furthermore agrees that no trustee, officer, director, general or limited partner, member, shareholder, beneficiary, employee or agent of Landlord (including any person or entity from time to time engaged to supervise and/or manage the operation of Landlord) shall be held to any liability, jointly or severally, for any debt, claim, demand, judgment, decree, liability or obligation of any kind (in tort, contract or otherwise) of, against or with respect to Landlord or arising out of any action taken or omitted for or on behalf of Landlord.

8. Tenant warrants and represents that it has dealt with no broker in connection with the consummation of this First Amendment, other than Coldwell Banker Commercial, and in the event of any brokerage claims or liens, other than by Coldwell Banker Commercial, 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.

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

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

**LANDLORD:**

SNH MEDICAL OFFICE PROPERTIES TRUST

By: Reit Management & Research LLC, its agent

By: /s/David M. Lepore

David M. Lepore

Senior Vice President

**TENANT:**

AXOGEN CORPORATION

By: /s/Karen Zaderej

Name: Karen Zaderej

Title: CEO

**SUBSIDIARY OF AXOGEN, INC.**

As of December 31, 2011, AxoGen Inc.'s sole subsidiary was AxoGen Corporation, a Delaware corporation.

**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 15, 2012, appearing in this annual report on form 10-K of AxoGen, Inc. for the year ended December 31, 2011.

/s/ LURIE BESIKOF LAPIDUS & COMPANY, LLP

Minneapolis, Minnesota  
March 15, 2012

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby 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 AxoGen, Inc. of our report dated May 25, 2011 relating to the financial statements which appear in this Form 10-K.

/s/ Cross, Fernandez & Riley, LLP

Orlando, Florida

March 15, 2012

**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 15, 2012

/s/ Karen Zaderej

Karen Zaderej

Chief Executive Officer

**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 15, 2012

/s/ Gregory G. Freitag

Gregory G. Freitag  
Chief Financial Officer

**CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES –OXLEY ACT OF 2002**

In connection with the Annual Report of LecTec Corporation (the “Company”) on Form 10-K for the year ended December 31, 2011 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 15, 2012

/s/ Gregory G. Freitag

Gregory G. Freitag  
Chief Financial Officer  
March 15, 2012



**AxoGen Reports Year-End 2011 Results**

**2011 Highlights**

- Increased revenues 61% from 2010 to \$4.85 million
- Increased gross profit 49% to \$2.42 million
- Expanded U.S. sales force to 12 direct and 21 independent representatives
- Published peer-reviewed article in Microsurgery summarizing RANGER study, the first multi-center clinical trial on processed nerve allografts
- Completed successful merger with LecTec Corporation

**ALACHUA, FL – March 14, 2012**– AxoGen, Inc. (OTCBB: AXGN) today reported revenues for the year ended December 31, 2011 of \$4.85 million, a 61% increase over 2010 revenues of \$3.0 million.

“We delivered solid results in what was a transition year,” commented Karen Zaderej, Chief Executive Officer of AxoGen, Inc. “In 2011, we completed our merger, expanded our sales force, published clinical results from the RANGER study and established a solid platform to drive sales growth in 2012 and beyond. Our goal is to continue executing on our commercialization strategy, solidifying our position as a leading peripheral nerve company and delivering increases in top-line performance.”

**Revenues**

Revenues for the period increased \$1.85 million, or 61%, to \$4.85 million in 2011, compared to \$3.0 million reported during 2010. The higher revenues reflect increased penetration into key accounts as a result of the Company’s direct sales force and independent distributor expansion efforts.

**Gross Profit**

Gross profit reached \$2.42 million, a 49% increase, for 2011 up from \$1.63 million reported for 2010. This improvement was realized despite a \$0.83 million impact associated with inventory and raw-materials write-offs, as well as higher processing, travel, and temporary labor costs due to the resumption of Avance® Nerve Graft processing following a temporary shut-down in 2010 to allow the Company to manage inventory levels.

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The Company also reported a gross profit margin of 50% for the year, a decrease from the reported gross profit margin of 55% for 2010. Excluding inventory write-offs, the gross profit margin for 2011 was 66%.

### **Sales and Marketing Expenses**

Sales and marketing expenses increased to \$4.38 million in 2011, compared to \$3.0 million reported last year. This increase was primarily due to expansion of the Company's direct sales force and increased support for the direct and independent sales force.

### **Research and Development Expenses**

Research and development expenses increased to \$0.70 million in 2011 due primarily to investments in clinical research and activities.

### **General and Administrative Expenses**

General and administrative expenses increased to \$4.32 million in 2011, compared to \$2.66 million reported last year. This increase was driven in large part by an increase in consulting, accounting and legal services and other expenses associated with securing additional funding and completing the Company's merger.

### **Operating Loss**

In addition, the Company reported a net loss of \$9.22 million, or \$2.77 per common share, compared to a net loss of \$5.42 million, or \$8.35 per common share, reported during the same period in 2010.

The loss reported for the period included financing and merger related expenses and \$0.83 million associated with a one-time, inventory write-off.

### **Financial Liquidity**

At December 31, 2011, the Company had \$8.19 million in cash and cash equivalents, with \$4.40 million in long-term debt and \$0.43 million as the current portion of long-term debt.

### **Earnings Call Information**

As previously announced, AxoGen, Inc. management will review year-end 2011 financials during a conference call scheduled for March 15, 2012 at 9:00 AM Eastern Time. The conference call information is as follows:

**Conference dial-in:** 877-879-6207  
**International dial-in:** 719-325-4837  
**Conference ID:** 8414594  
**Webcast:** [www.axogeninc.com/investors.html](http://www.axogeninc.com/investors.html)

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A webcast replay of the conference call will be available under the “Investor” tab on the Company’s website, [www.axogeninc.com](http://www.axogeninc.com).

### **About AxoGen, Inc.**

AxoGen (OTCBB: AXGN) is a regenerative medicine company with a portfolio of proprietary products and technologies for peripheral nerve reconstruction and regeneration. Every day, people suffer traumatic injuries or undergo surgical procedures that impact the function of their peripheral nerves. 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 reconstruction and regeneration of peripheral nerves, AxoGen has developed and licensed patented and patent-pending technologies, which are used in its portfolio of products. This portfolio includes Avance® Nerve Graft, which AxoGen believes is the first and only commercially available allograft nerve for bridging nerve discontinuities (a gap created when the nerve is severed).

AxoGen’s portfolio also includes AxoGuard® Nerve Connector, a coaptation aid allowing for close approximation of severed nerves, and AxoGuard® Nerve Protector, a bioscaffold used to reinforce a coaptation site, wrap a partially severed nerve or isolate and protect nerve tissue. AxoGen is bringing the science of nerve repair to life with thousands of surgical implants of AxoGen products performed in hospitals and surgery centers across the United States, including military hospitals serving U.S. service men and women.

AxoGen is the parent of its wholly owned operating subsidiary, AxoGen Corporation. AxoGen’s principal executive office and operations are located in Alachua, FL.

### **Cautionary Statements Concerning Forward-Looking Statements**

This Press Release contains “forward-looking” statements as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management’s current expectations or predictions of future conditions, events or results based on various assumptions and management’s estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as “expects”, “anticipates”, “intends”, “plans”, “believes”, “seeks”, “estimates”, “projects”, “forecasts”, “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 or financial 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 release should be evaluated together with the many uncertainties that affect AxoGen’s business and its market, particularly those discussed in the risk factors and cautionary statements in AxoGen’s filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made, and AxoGen assumes no responsibility to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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**Contact:**

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**AXOGEN, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
December 31, 2011 and 2010

	December 31, 2011	December 31, 2010
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 8,190,781	\$ 1,799,048
Accounts receivable	797,654	407,350
Inventory	1,760,540	1,902,789
Prepaid expenses and other	133,500	74,437
Deferred financing costs	—	1,083,630
<b>Total current assets</b>	<b>10,882,475</b>	<b>5,267,254</b>
<b>Property and equipment, net</b>	<b>247,824</b>	<b>500,742</b>
<b>Goodwill</b>	<b>169,987</b>	<b>—</b>
<b>Intangible assets</b>	<b>899,480</b>	<b>637,771</b>
<b>Deferred financing costs</b>	<b>295,276</b>	<b>—</b>
	<b><u>\$ 12,495,042</u></b>	<b><u>\$ 6,405,767</u></b>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 1,585,100	\$ 967,896
Current portion of long-term debt, related party	—	1,338,455
Current portion of long-term debt	434,734	7,080,512
<b>Total current liabilities</b>	<b>2,019,834</b>	<b>9,386,863</b>
<b>Long-term debt</b>	<b>4,403,737</b>	<b>—</b>
<b>Preferred stock dividends payable</b>	<b>—</b>	<b>6,048,378</b>
<b>Warrant liability</b>	<b>—</b>	<b>2,669,815</b>
<b>Total liabilities</b>	<b>6,423,571</b>	<b>18,105,056</b>
<b>Commitments and contingencies</b>		
<b>Temporary equity:</b>		
Series B convertible preferred stock, \$.00001 par value; 17,065,217 shares authorized; 9,782,609 shares issued and outstanding at December 31, 2010	—	4,243,948
Series C convertible preferred stock, \$.00001 par value; 16,798,924 shares authorized; 11,072,239 shares issued and outstanding at December 31, 2010	—	8,092,568
Series D convertible preferred stock, \$.00001 par value; 67,000,000 shares authorized; 30,156,259 shares issued and outstanding at December 31, 2010	—	3,075,523
<b>Total temporary equity</b>	<b>—</b>	<b>15,412,039</b>
<b>Stockholders' equity (deficit):</b>		
Common stock, \$.01 par value; 50,000,000 shares authorized; 11,062,188 and 1,205,624 shares issued and outstanding	110,622	12,056
Series A convertible preferred stock, \$.00001 par value; 2,544,750 shares authorized, issued and outstanding at December 31, 2010	—	1,125,000
Additional paid-in capital	54,391,784	9,934,980
Accumulated deficit	(48,430,935)	(38,183,364)
<b>Total stockholders' equity (deficit)</b>	<b>6,071,471</b>	<b>(27,111,328)</b>
	<b><u>\$ 12,495,042</u></b>	<b><u>\$ 6,405,767</u></b>

**AXOGEN, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
Years ended December 31, 2011 and 2010

	2011	2010
<b>Revenues</b>	\$ 4,849,470	\$ 3,004,445
<b>Cost of goods sold</b>	<u>2,426,544</u>	<u>1,378,936</u>
<b>Gross profit</b>	2,422,926	1,625,509
<b>Costs and expenses:</b>		
Sales and marketing	4,378,694	3,007,163
Research and development	697,355	436,008
General and administrative	<u>4,315,604</u>	<u>2,663,908</u>
<b>Total costs and expenses</b>	<u>9,391,653</u>	<u>6,107,079</u>
<b>Loss from operations</b>	<u>(6,968,727)</u>	<u>(4,481,570)</u>
<b>Other income (expense):</b>		
Interest expense	(1,094,657)	(814,994)
Interest expense – deferred financing costs	(1,223,126)	(1,322,413)
Gain from termination of distribution agreement	—	1,119,094
Change in fair value of warrant liability	62,305	78,306
Other income (expense)	<u>4,985</u>	<u>(1,584)</u>
<b>Total other income (expense)</b>	<u>(2,250,493)</u>	<u>(941,591)</u>
<b>Net loss</b>	(9,219,220)	(5,423,161)
Preferred Stock dividends (assumes all paid)	<u>(1,028,351)</u>	<u>(1,566,361)</u>
<b>Net loss available to common shareholders</b>	<u><u>\$(10,247,571)</u></u>	<u><u>\$(6,989,522)</u></u>
Weighted Average Common Shares outstanding – basic and diluted	<u>3,697,390</u>	<u>836,645</u>
<b>Loss Per Common share – basic and diluted</b>	<u><u>\$ (2.77)</u></u>	<u><u>\$ (8.35)</u></u>