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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended DECEMBER 31, 2014

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: 001-36046

AXOGEN, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

As of June 30, 2014, the value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $29,727,246 based upon the last reported sale price of our common stock on the NASDAQ Capital Market.

The number of shares outstanding of the registrant's Common Stock as of March 4, 2015 was 24,926,014 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2015 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days after the fiscal year ended December 31, 2014.

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FORWARD-LOOKING STATEMENTS

From time to time, in reports filed with the Securities and Exchange Commission (including this Form 10-K), in press releases, and in other communications to shareholders or the investment community, the Company may provide forward-looking statements concerning possible or anticipated future results of operations or business developments. These statements are based on management's current expectations or predictions of future conditions, events or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as "expects", "anticipates", "intends", "plans", "believes", "seeks", "estimates", "projects", "forecasts", "may", "should", variations of such words and similar expressions are intended to identify such forward-looking statements. The forward-looking statements may include, without limitation, statements regarding product development, product potential, regulatory environment, sales and marketing strategies, capital resources or operating performance. The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the statements. Forward-looking statements in this Form 10-K should be evaluated together with the many uncertainties that affect the Company's business and its market, particularly those discussed in the risk factors and cautionary statements in the Company's filings with the Securities and Exchange Commission, including as described in "Risk Factors" included in Item 1A of this Form 10-K. Forward-looking statements are not guarantees of future performance, and actual results may differ materially from those projected. The forward-looking

statements are representative only as of the date they are made, and the Company assumes no responsibility to update any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

ITEM 1. BUSINESS

General

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

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

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

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

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translucence for visualization of the underlying nerve, while also allowing the patient's own cells to incorporate into the extracellular matrix to remodel and form a tissue similar to the outermost layer of the nerve (nerve epineurium).

Regenerative Medical Products Industry

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

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

Regenerative medicine products typically consist of and rely on:

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

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

Peripheral Nerves and Their Regeneration

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

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

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

Peripheral Nerve Regeneration Market Overview

Peripheral nerve injury ("PNI") is a major source of disability impairing the ability to move muscles or to feel normal sensations. Failure to treat nerve damage can, in severe cases, lead to full loss of sensation and/or function,

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pain 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 and pain.

Every day patients suffer traumatic wounds to peripheral nerves severe enough to require surgical treatment, including injuries from motor vehicle accidents, power tool injuries, gun wounds, dislocations, fractures, lacerations, or other forms of penetrating trauma. The peripheral nerves commonly injured from these traumas include the digital, median, ulnar, radial, facial, spinal accessory and brachial plexus nerves. Traumatic PNI described herein, and excluding Oral and Carpal Tunnel defined below, is referred to by AxoGen as occurring in the "Extremity" PNI market. Beyond traumatic injury to nerves described above, nerve damage also occurs due to surgical intervention and represents an additional expansion opportunity for surgical repair.

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

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

Drawbacks of repair with autograft nerve eventually led to the development of hollow tube conduits, or hollow tube nerve cuffs for peripheral nerve for Primary and Gap Repair made of, for instance, bovine collagen or polyglycolic acid. The nerve cuff is typically an absorbable hollow tube that, unlike natural peripheral nerve, does not have internal microarchitecture and endoneurial tubes to support regenerating axons; as a result, it is deficient in the qualities that natural nerve possesses to support nerve regeneration across a gap. Hollow-tubes may also lack pliability and structural integrity needed when used around joints and may be difficult to use in a confined space. Clinical data has demonstrated that hollow tubes are most effective when used in very short gaps, what AxoGen defines as Primary Repair, and the reliability of successful nerve recovery diminishes as gap length increases.

The shortcomings of hollow-tubes for nerve repair limit where they may be used effectively. Thus, AxoGen believes the nerve repair market needs alternative off-the-shelf product that offer other features such as a natural ECM scaffold and three-dimensional structure of a typical nerve for bridging nerve discontinuities without the comorbidities of an additional surgical site required for harvest of autograft nerve tissue. AxoGen believes its Avance® Nerve Graft and AxoGuard© Nerve Connector products address the market needs for both Gap and

Primary Repair.

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

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AxoGuard® Nerve Protector is a porcine submucosa extracellular matrix used for Nerve Protection. Other Nerve Protection products are usually made from bovine collagen or polyglycolic acid and are typically absorbable. AxoGuard® Nerve Protector provides the unique features of pliability, suturability, and translucence for visualization of the underlying nerve, while also allowing the patient's own cells to incorporate into the extracellular matrix to remodel and separate the nerve from the surrounding tissue.

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

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

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

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

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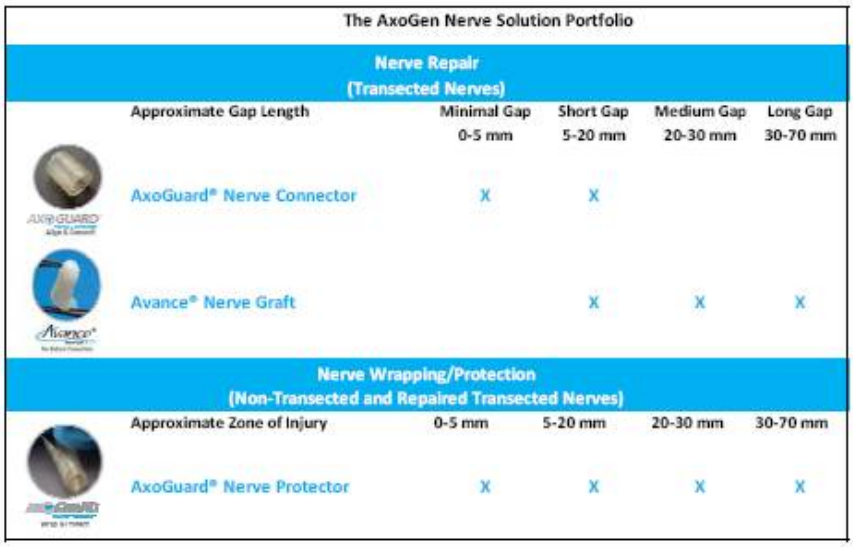
AxoGen's Product Portfolio

Overview of AxoGen's Products

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

process after surgery. The AxoGen product portfolio, depicted below, provides surgeons off-the-shelf solutions for a wide variety of peripheral nerve injuries.



Avance® Nerve Graft

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

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

The Avance® Nerve Graft provides the following key advantages:

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

AxoGuard® Nerve Connector

AxoGuard® Nerve Connector is a coaptation aid used to align and connect severed nerve ends in a tensionless repair. The product is in a

tubular shape with an open lumen on each end where the severed nerve ends are placed. It is typically used when the gap between the nerve ends is less than 5mm in length. AxoGuard® Nerve Connector is made from a minimally processed porcine ECM which allows the body's natural healing process to repair the nerve while its tube shape isolates and protects the injured nerves during the healing process. During healing, the material revascularizes and the patient's own cells incorporate into the extracellular matrix product to remodel and form a tissue similar to the outermost layer of the nerve (nerve epineurium). AxoGuard® Nerve Connector is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs.

AxoGuard® Nerve Connector can be used:

- As an alternative to direct suture repair;
- To relieve tension at the coaptation site of severed nerves;
- Aid coaptation in direct repair, grafting, or cable grafting repairs;
- To reduce the risk of forced fascicular mismatch; and
- To reinforce the coaptation site.

AxoGuard® Nerve Connector has the following advantages:

- Minimally processed porcine submucosa extra-cellular matrix product used to repair severed nerve tissue;
- Alleviates tension at the repair site;
- Revascularizes and remodels into the patient's own tissue instead of degrading;
- Reduces the number of required sutures (versus direct repair with suture) allowing for up to 40% reduced surgery time. (Boechstyns, Jhand Surg. 2013;38:2405-2411);
- Moves location of sutures away from the coaptation face;
- Reduces potential for fascicular mismatch;
- Allows visualization of underlying nerve tissue;
- Available in 7 different diameters and 2 different lengths to address a variety of nerve repair situations;
- Conforms to the nerve;
- Strong and flexible, easy to suture; and
- Stored at room temperature with an 18 month shelf life.

AxoGuard® Nerve Protector

AxoGuard® Nerve Protector is a product used to protect and wrap injured peripheral nerves and reinforce reconstructed nerve gaps while preventing soft tissue attachments. It is designed to protect and isolate the nerve during the healing process after surgery by creating a barrier between the nerve tissue and the surrounding tissue bed. The product is delivered in a sheet format allowing it to be wrapped around nerve structures. AxoGuard® Nerve Protector is made from a minimally processed porcine ECM. During healing, the material revascularizes and the patient's own cells incorporate into the extracellular matrix product to remodel and separate the nerve from the surrounding tissue. AxoGuard® Nerve Protector competes against off-the-shelf biomaterials such as reconstituted collagen as well as the use of the

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patients own tissue such as vein and hypothenar fat pad wrapping. 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:

- Protect injured nerves or nerve repair sites from surrounding tissue;
- Minimize risk of soft tissue attachments and entrapment in compressed nerves;
- Protect nerves in a traumatized wound bed; and
- Reinforce a coaptation site.

AxoGuard® Nerve Protector has the following advantages:

- Minimally processed Porcine submucosa bioscaffold used to reinforce a coaptation site, wrap a partially severed nerve or protect nerve tissue;
- Creates a protective layer that isolates and protects the nerve in a traumatized wound bed;
- Revascularizes and remodels into the patient's own tissue instead of degrading;
- Easily conforms and provides 360 degree wrapping of injured nerve tissue;
- Supports the body's own natural wound healing;
- Restores damaged soft tissue layers;
- Minimizes the potential for soft tissue attachments and nerve entrapment by physically isolating the nerve during the healing process;
- Allows nerve gliding;
- Strong and flexible, plus easy to suture;
- Is available in 5 different widths and 2 different lengths to address a variety of nerve repaire situations; and

- Stored at room temperature with an 18 month shelf life.

AxoTouch™ Two Point Discriminator

Sensibility testing plays an important role in the evaluation of nerve function. It assists the healthcare professionals in detecting changes in sensation, assessing return of sensory function, establishing effective treatment interventions, and providing feedback to the patients. The AxoTouch™ Two-Point Discriminator tool is a set of two aluminum discs each containing a series of prongs spaced between 2 to 1 millimeters apart. Additionally, 20 and 25 millimeter spacing is provided. A circular depression on either side of the disc allows ease of rotation. The discs can be rotated between a single prong for testing one-point and any of the other spaced prongs for testing two-point intervals.

AxoTouch™ Two-Point Discriminator tool can be used to measure the innervation density of any surface area of the skin. The discs are useful for determining sensation after a nerve injury, following the progression of a repaired nerve, and during the evaluation of a person with a possible nerve injury, such as nerve division or nerve compression.

AxoTouch™ Two-Point Discriminator has the following advantages:

- Capable of measuring the innervation density of any skin surface;
- Portable and easy to use;
- Strong aluminum design is resistant to bending;
- Bright colors allow for clear discrimination between discs;
- Clear numbering allows users to interpret results; and
- Reusable carry case protects discs.

Tissue Recovery and Processing for Avance® Nerve Graft

Avance® Nerve Graft Processing Overview

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

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AxoGen plans to make additional investments to continually improve its manufacturing and quality assurance processes and systems.

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

Avance® Nerve Graft Tissue Recovery and Processing

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

have been developed and validated to ensure product uniformity and quality.

Avance® Nerve Graft Packaging

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

Avance® Nerve Graft Sterilization and Labeling

After being processed and packaged, Avance® Nerve Graft is then irradiated and shipped to its Burleson, Texas distribution facility (the "Distribution Facility"). There, the product receives its final labels and is released following a final stringent technical and quality review. Orders for Avance® Nerve Graft are placed with AxoGen's customer care team and product is packaged and shipped from the Distribution Facility.

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Avance® Nerve Graft Product Release

The AxoGen Quality System meets the requirements set forth under 21 CFR Part 1271 for Human Cells, Tissues and Cellular and Tissue-Based Products, including Good Tissue Practices ("GTP") and is compliant with the 21 CFR Part 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 Part1271, state regulations, international regulations and AATB standards. Furthermore, AxoGen utilizes validated processes for the handling of raw material components, environmental control, processing, packaging and terminal sterilization. In addition to ongoing monitoring activities for product conformity to specifications and sterility, product biocompatibility, shipping methods and shelf life have been validated in accordance with applicable industry standards.

Manufacturing for the AxoGuard® Product Line

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

The agreement has an initial seven-year term from the date of the original agreement and following such initial term, the agreement automatically renews for an additional seven (7) year period pursuant to AxoGen's and Cook's agreement as to meeting the parameters for such renewal. AxoGen and Cook Biotech have agreed that the parameters for renewal have been met and the contract will automatically renew for the additional seven (7) year period. The Cook Biotech agreement also requires certain minimum purchases, although through mutual agreement the parties have not established such minimums and to date have not enforced such provision, and establishes a formula for the transfer cost of the AxoGuard® products. Under the agreement, AxoGen provides purchase orders to Cook Biotech, and Cook Biotech fulfills the purchase orders.

Sales and Marketing

Overview

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

Increase Awareness of AxoGen's Products

Prior to the introduction of AxoGen's portfolio of products, surgeons had a limited number of options available for the surgical repair of nerve injuries. AxoGen entered the market to improve the standard of care for patients. Unlike other off-the-shelf nerve repair options, all of AxoGen's products are composed of an extracellular matrix which remodels into the patient's own tissue and provides physical support for the body's natural healing process.

AxoGen intends to increase market share by improving awareness of nerve repair techniques and AxoGen's products through the continued use of educational conferences and presentations, surgical resident and fellow training, scientific publications, and a knowledgeable and professional sales team. AxoGen works to increase usage with existing customers as well as expand the overall customer base. AxoGen is focused on plastic reconstructive

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surgeons and orthopedic and plastic surgeons who perform surgeries on patients suffering traumatic nerve injuries and who perform hand reconstructive surgeries and certain oral surgeons who repair oral nerve injuries.

Expand Clinical and Scientific Data Regarding the Performance of AxoGen Products

Generating clinical data is an important component of AxoGen's marketing strategy. AxoGen will continue to accept patients in its RANGER® clinical study (defined below in "Government Regulations"), a utilization registry of Avance® Nerve Graft. Two publications and 35 scientific conference presentations have been generated to date from the registry. A multicenter prospective randomized comparative pilot study of hollow tube conduits and Avance® Nerve Graft has completed subject enrollment and outcome follow-up. Case series in digital nerve repair have been published from the Mayo Clinic, Georgetown University Medical Center and Philadelphia Hand Center. A number of additional investigator initiated case reports, studies and publications have been completed. A pilot study on the repair of the cavernous nerves in prostate cancer patients has completed enrollment and follow-up at Vanderbilt and data analysis and report are underway. Case series in brachial plexus, military trauma, neurotization of breast reconstruction and compressive neuropathy are also being developed. AxoGen also supports outside research and will continue to work with investigators working on grants with a translational focus.

Expand the AxoGen Sales Team

AxoGen provides full sales and distribution services through both a direct sales force and a team of independent distributors. As of December 31, 2014, we had 29 direct sales professionals and 23 independent distributors. AxoGen provides support and resources for independent distributors both within and outside the United States and is increasing its direct sales force in selected United States territories. AxoGen provides products to hospitals, surgery centers and military hospitals, calling on plastic reconstructive surgeons and orthopedic and plastic hand surgeons and certain oral surgeons to review the benefits of the AxoGen products. While surgeons make the decision to implant the products in appropriate patients, hospitals make the decision to buy the products from AxoGen. In today's budget constrained environment, hospital committees review new technologies for cost effectiveness as well as quality. AxoGen believes that it has been successful in meeting the needs of these hospital committees by demonstrating the cost/benefit of its products and providing a fair value to the hospital.

AxoGen Strengths

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

Established Surgical Nerve Repair and Regeneration Expertise

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

Surgical Implant Commercialization Experience

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

Avance® Nerve Graft Performance

AxoGen has worked with leading institutions, researchers and surgeons to support innovation in the field of surgical peripheral nerve repair. We believe AxoGen's RANGER® study (defined below in "Government Regulations") is the largest multi-center clinical study conducted in peripheral nerve gap repair. AxoGen's A Multicenter, Prospective, Randomized, Subject and Evaluator Blinded Comparative Study of Nerve Cuffs and Avance® Nerve Graft Evaluating Recovery Outcomes for the Repair of Nerve Discontinuities ("RECON") study, the phase 3 trial to support the BLA, will also continue AxoGen's clinical work, providing a new multi-center, prospective, randomized, clinical study on the Avance® Nerve Graft. (See "- Government Regulations"). The January, 2012 edition of *Microsurgery* and November 2012 edition of *The Journal of Hand Surgery* each contain an

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article summarizing the RANGER® study results. The Brooks et al. publication reported on 55 Avance® Nerve Graft nerve repairs and resulted in meaningful motor and sensory recovery in 87% of nerve discontinuities between 5 and 50 mm. Additionally no implant related adverse events were reported. (Brooks, D. N., Weber, R. V., Chao, J. D., Rinker, B. D., Zoldos, J., Robichaux, M. R., Ruggeri, S. B., Anderson, K. A., Bonatz, E. E., Wisotsky, S. M., Cho, M. S., Wilson, C., Cooper, E. O., Ingari, J. V., Safa, B., Parrett, B. M. and Buncke, G. M. (2012), Processed nerve allografts for peripheral nerve reconstruction: A multicenter study of utilization and outcomes in sensory,

mixed, and motor nerve reconstructions. Microsurgery, 32: 1—14. doi: 10.1002/micr.20975 and Cho, et al. 2012, J Hand Surg Am 37(11):2340-9). A meta-analysis of available clinical outcomes data from published papers on the leading synthetic collagen conduit showed meaningful improvement in only 40-74% of cases bridging a gap in the nerve. A similar meta-analysis for nerve autograft reported meaningful improvement in 60-88% of nerve repairs.

International Opportunity for Product Sales

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

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 and other nerve repair products may be developed. In this regard, AxoGen introduced an AxoGuard® Connector line extension in February 2014 by providing a new longer 15mm product. AxoGen works with academic institutions in the expansion of treatments for peripheral nerve and is involved in a number of grants from government agencies related to nerve repair or use of our products and/or technologies. For the years ended December 31, 2014 and 2013, AxoGen spent approximately $3,033,000 and $2,125,000, respectively, on research and development expenses and recognized grant revenue of $314,000 and $67,000, respectively.

Competition

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

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

AxoGen believes that surgeons use Avance® Nerve Graft because, it provides them with the natural three-dimensional structure and familiar handling characteristics of a typical nerve for bridging nerve discontinuities (severed nerves) without the comorbidities and additional surgical site of an autograft as well as confidence in the

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performance of the product as a result of the growing body of clinical literature. AxoGuard® Nerve Protector and AxoGuard® Nerve Connector provide the unique features of pliability, suturability, and translucence for visualization of the underlying nerve while also allowing the patient's own cells to incorporate into the extracellular matrix to remodel and form a tissue similar to the outermost layer of the nerve (nerve epineurium).

AxoGen believes any current or future competitors face the following important barriers to entry as it relates to the market for its products. AxoGen's intellectual property, and that of its partners, including patents, patents-pending and know how, is believed to be an important barrier. Additionally, AxoGen has developed knowledge and experience in understanding and meeting FDA regulatory requirements for Avance® Nerve Graft, including having made a substantial investment in conducting the preclinical and clinical testing necessary to support a submission for a FDA Biologics License Application ("BLA"). 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 intellectual property ("IP") laws, to protect IP rights. In addition, AxoGen utilizes license, non-disclosure, and assignment agreements to protect these IP rights. Specifically, AxoGen requires vendors, contract organizations, consultants, advisors and employees to execute nondisclosure agreements. AxoGen also requires consultants, advisors and employees who develop IP to assign to AxoGen any of their rights to all IP conceived in connection with their relationship with AxoGen.

License Agreements

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

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

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

Patents

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

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Patent No.	Description	Estimated expiration date
US 6,972,168	Materials and Methods for Nerve Grafting, Selection of Nerve Grafts, and in vitro Nerve Tissue Culture	August 2021
US 7,402,319	Cell Free Tissue Replacement for Tissue Engineering	September 2023
US 7,732,200	Materials and Methods for Nerve Grafting, Selection of Nerve Grafts, and in vitro Nerve Tissue Culture	December 2022
US 6,696,575	Biodegradable, electrically conducting polymer for tissue engineering applications	March 2021
US 7,851,447	Materials and Methods for Nerve Repair	November 2023
US 8,545,485	Nerve Elevator and Method of Use	May 2032

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

U.S. Patent No.	Description	Estimated expiration date
6,206,931	Graft Prosthesis Material	August 2017
6,241,981	Composition and Method for Repairing Neurological Tissue	September 2017
7,652,077	Graft Prosthesis, Materials and Methods	November 2018

6,358,284	Tubular Grafts from Purified Submucosa	December 2017

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

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 over 50 domain names.

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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. Cook Biotech is responsible for the regulatory compliance of the AxoGuard® product line. AxoGuard® products are regulated as medical devices and subject to premarket notification requirements under section 510(k) of the FD&C Act, that usually result in the marketing of devices, 21 CFR Part 820 ("Quality System Regulation") and related laws and regulations. Cook Biotech has obtained a 510(k) premarket clearance from the FDA for the use of porcine (pig) small intestine submucosa for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. Cook Biotech has also obtained a 510(k) premarket clearance for the AxoGuard® Nerve Protector for the repair of peripheral nerve injuries in which there is no gap or where a gap closure is achieved by flexion of the extremity. We sell the 510(k)-cleared device under the trade name AxoGuard® Nerve Protector and AxoGuard® Nerve Connector

AxoTouch™ Two-Point Discriminator is manufactured for AxoGen and distributed from the Burleson Facility. The AxoTouch™ is a Class I device (general controls) that is exempt from premarket notification and the Quality System Regulation except for its Records and Complaint file requirement. It is classified by FDA under 21 CFR 882.1200 (Two-point discriminator) (Device Code: GWI).

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

AxoGen met with CBER in July 2010 and, between July 2010 and November 2010, provided information to CBER that resulted in the FDA issuing a letter stating the agency's intent to exercise enforcement discretion with respect to the introduction or delivery for introduction into interstate commerce of the Avance® Nerve Graft assuming that certain conditions are met relating to the transition of the Avance® Nerve Graft to regulation as a biological product under section 351 of the PHS Act. FDA is permitting the product to be distributed, subject to FDA enforcement discretion, provided that:

- AxoGen transitions to compliance with 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 Parts 210 and 211 and the applicable regulations and standards in 21 CFR Parts 600-610 prior to initiation of a phase 3 clinical trial; designed to demonstrate the safety, purity, and potency of the Avance® Nerve Graft;

    - AxoGen has performed several gap analyses of its quality system for compliance with 21 CFR Parts 210/211 and 600-610 regulations. The gap analyses have identified areas in which our quality system could improve with respect to compliance to the regulations. The transition is in process and we periodically review the 21 CFR Parts 210/211 and 600-610 regulations to ensure that we create and implement appropriate changes, including new quality procedures. Through our internal auditing process, we periodically assess our compliance to the regulations. As AxoGen initiates the phase 3 clinical trial and eventual BLA submission, we will retain an external

audit firm with experience in auditing to 21 CFR Parts 210/211 and 600-610 regulations to verify quality system compliance to the regulations. The associated costs for these activities are not material and the Company believes it can appropriately implement all necessary changes;

- AxoGen will conduct a phase 3 clinical trial to demonstrate safety, purity and potency of the Avance® Nerve Graft under a Special Protocol Assessment ("SPA").

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- AxoGen and the FDA agreed to the SPA in August 2011 and in accordance with FDA regulations 21CFR § Part 312, AxoGen submitted an Investigational New Drug Application ("IND") to the FDA in April 2013 and we are currently responding to FDA comments regarding the IND., which is not yet effective We expect enrollment of patients into the phase 3 clinical trial to begin in the second half of 2015. On June 7, 2013, the FDA placed the IND on Clinical Hold, pending the FDA's receipt of additional information relating to the potency, mechanical characterization, and labeling of the product. The phase 3 clinical trial, RECON, cannot begin until the FDA lifts the Clinical Hold. AxoGen is developing the data and information to respond to the FDA's requests.

- AxoGen continues to comply with the regulations and standard for 21 CFR Part 1271. and

- AxoGen was audited by the FDA in March 2013 and the quality system was found to be in compliance with 21 CFR Part 1271. In addition, AxoGen is working to ensure compliance with the applicable regulations by having ongoing discussions on the transition of the quality system to 21 CFR Parts 210/211 and 600-610 regulations with the FDA and being audited by the FDA for compliance to 21 CFR Part1271 of the regulations. Final determination of regulatory compliance will be made during FDA's pre-license inspection as part of the BLA review. If FDA is unable to agree with AxoGen, or if AxoGen is unable to meet the standards required of it by the FDA, regarding preclinical studies, clinical studies and Chemistry, Manufacturing, and Controls, the approval of the BLA would become impossible or delayed.

- AxoGen continues to exercise due diligence in executing its requirements under the transition program.

The FDA will end the period of enforcement discretion upon a final determination of AxoGen's BLA future submission or if the FDA finds that AxoGen does not meet the conditions for the transition plan, or is not exercising due diligence in executing the transition (e.g., progress toward the IND submission, study completion, or BLA submission is neither timely nor adequate) . If final action on the BLA is negative or AxoGen is found to not meet the conditions for the transition plan or its execution, AxoGen will not be able to continue to distribute the Avance® Nerve Graft. AxoGen continues to work diligently with the FDA and, in this context, continues to distribute Avance® Nerve Graft.

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

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

- Application Fee: Each new BLA has a fee required upon submission. In FY 2015, this fee for a BLA requiring clinical data is $2,335,200. The fee is adjusted each year so we cannot provide an accurate estimate of what our fee will be upon submission of our BLA. For small companies (fewer than 500 employees and no other approved biologic product on the market) submitting its first application, a waiver of the application fee is available. AxoGen expects to apply for this waiver for the Avance® Nerve Graft BLA.
- Establishment Fee: Establishment fees (for where the biologic product is manufactured) are based on the FDA budget divided by the total number of establishments. In FY 2015, the Establishment Fee is $569,200. This fee is adjusted each year so we cannot provide an accurate estimate of what our fee will be upon approval of our BLA. AxoGen will have to pay an establishment fee after BLA approval and then pay such fee annually thereafter.
- Product Fee: A product fee is assessed for each potency in which the approved (non-revoked, non-suspended) product is manufactured in final dosage form. The product fee is based on an estimate of the number of products that would be subjected to, and would pay, product fees. The product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees by the estimated products (uses previous year fee revenue) subjected to the product fee (excluding product

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fee waivers and reductions granted by the FDA). For FY 2015, the product fee has been established at $110,370. AxoGen may have to pay a Product Fee after BLA approval. AxoGen expects to apply for a product fee waiver for 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;
- 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 a 510(k) premarket notification submission or a Pre-Market Approval ("PMA") from the FDA. Medical devices are classified into one of three classes—Class I, Class II, or Class III—depending on the degree of risk, the level of control necessary to assure the safety and effectiveness of each medical device and how much is known about the type of device. For devices first intended for marketing after May 28, 1976, 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 by finding a device substantially equivalent to a legally marketed Class I or II device, unless the device is exempt. The majority of 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 for which Class II controls are inadequate to assure safety or effectiveness, and novel devices, including devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III. Class III devices require an approved PMA prior to marketing.

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

FDA's Premarket Approval Requirements - Biologic Products

Biological Product License Application (BLA) Pathway

Biological products subject to BLA requirements are approved under the Public Health Service Act. Biological products require FDA approval of a BLA to be marketed. In order to be approved, a BLA must demonstrate the safety, purity and potency of the product candidate based on results of preclinical studies and clinical trials. A BLA must also contain extensive CMC and other manufacturing information, and the applicant must pass an FDA pre-approval inspection of the manufacturing facility or facilities at which the biologic product is produced to assess compliance with the FDA's current good manufacturing practice. Satisfaction of FDA approval requirements for biologics typically takes several years and the actual time required may vary substantially based on the type,

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complexity and novelty of the product. AxoGen cannot be certain that any BLA approvals for its products will be granted on a timely basis, or at all.

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

- completion of preclinical laboratory tests, animal studies and formulation studies under the FDA's good laboratory practices regulations;
- submission to the FDA of an IND, for human clinical testing, which must become effective before human clinical trials may begin and which must include independent Institutional Review Board, or IRB, approval at each clinical site before the trials may be initiated;
- performance of an adequate and well-controlled clinical trial in accordance with Good Clinical Practices to establish the safety and efficacy of the product for each indication;
- submission to the FDA of a BLA, which contains detailed information about the CMC for the product, reports of the

outcomes and full data sets of the clinical trials, and proposed labeling and packaging for the product;

- satisfactory review of the contents of the BLA by the FDA, including the satisfactory resolution of any questions raised during the review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP regulations, to assure that the facilities, methods and controls are adequate to ensure the product's identity, strength, quality and purity; and
- FDA approval of the BLA including agreement on post-marketing commitments, if applicable.

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

Biosimilar Biological Products

A new regulatory approval pathway for biosimilars was established by The Biologics Price Competition and Innovation Act ("BPCIA"), as part of the Patient Protection and Affordable Care Act of 2010. An important component of the legislation specified that a manufacturer of a reference biological product would be granted 12 years of exclusive, non-patent market exclusivity before a biosimilar could be approved for marketing in the US. An application for a biosimilar product may not be submitted to FDA until 4 years after the approval date of the BLA for the reference biological product. BPCIA provides for an abbreviated licensure process for a biosimilar, which is defined to mean a biological product that is highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency. At its discretion, FDA can waive a requirement for any required element in an application for a biosimilar product. In addition, the legislation distinguished approval of a biosimilar from approval of such a product as a substitute for the reference biological products. Where a product is approved as a substitute for the reference biologic, it is considered an interchangeable product. Approval as interchangeable requires that the product is biosimilar and can be expected to produce the same clinical results as the reference product in any given patient, and if intended for repeat dosing, a demonstration that the risk in terms of safety or diminished efficacy of alternating or switching between the use of the interchangeable and reference product is not greater than the risk of using the reference product without such alternating or switching Several states have enacted or are considering laws that also regulate the use and substitution of biosimilar drugs. Interchangeable products can be substituted for a reference product without intervention of the prescribing healthcare provider. The FDA has not yet promulgated regulatory standards for determining interchangeability or naming of biosimilars. For example, Virginia requires licensure as interchangeable by FDA for a pharmacist to dispense a biosimilar in place of a prescribed biological product (Virginia § 54.1-3408.04).

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FDA's Pre-Approval and Pre-Licensing Requirements

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

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

Post-Approval Requirements

After regulatory approval of a product is obtained, AxoGen will be required to comply with a number of post-approval requirements. For example, as a condition of approval of a BLA, the FDA may require post marketing testing and surveillance to monitor the product's safety or efficacy. In addition, holders of an approved BLA are required to keep extensive records, to report certain adverse reactions and production problems such as biologic deviation reports to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP regulations as well as the manufacturing conditions of approval set forth in the BLA. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP regulations, which imposes certain procedural, substantive and recordkeeping requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Future FDA inspections may identify compliance issues at AxoGen's facilities or at the facilities of its contract manufacturers that may

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

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

Clinical Trials

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

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

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

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

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

Investigational New Drug Application

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

- Animal Pharmacology and Toxicology Studies - Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experiences with the product in humans (often foreign use).
- Manufacturing Information - Information pertaining to the composition, manufacturer, stability, and controls used for manufacturing of the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.
- Clinical Protocols and Investigator Information - Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators

—professionals (generally physicians) who oversee the administration of the experimental compound—to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an IRB, and to adhere to the investigational new drug regulations.

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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 Trials

AxoGen is currently performing three clinical studies to gather data on the Avance® Nerve Graft. The studies are "A Multicenter Retrospective Study of Avance® Nerve Graft Utilization, Evaluations and Outcomes in Peripheral Nerve Injury Repair ("RANGER®")", "A Multicenter, Prospective, Randomized, Comparative Study of Hollow Nerve Conduit and Avance® Nerve Graft Evaluation Recovery Outcomes of the Nerve Repair in the Hand ("CHANGE")" and a pilot study to evaluate the use of Avance® Nerve Graft in the reconstruction of nerves following prostatectomy.

AxoGen will continue to accept patients in the RANGER® clinical study, a utilization registry of Avance® Nerve Graft. Two publications and 35 scientific conference presentations have been generated to date from the registry. The RANGER® Study is an observational study in current enrollment. It is designed to allow enrollment of up to a total of 1,000 subjects over the next several years. The follow-up for the RANGER® Study is standard of care up to 36 months post nerve repair. At the time of the BLA submission, if 1,000 subjects have not been enrolled and follow-up completed, AxoGen will submit an interim report in the BLA for the enrolled subjects.

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

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

AxoGen conducted the CHANGE study as a pilot comparative study. It is a multicenter prospective randomized comparative pilot study of hollow tube conduits and Avance® Nerve Graft. Subject enrollment and follow-up have been completed and report development is in process. A pilot study on the repair of the cavernous nerves in prostate cancer patients at Vanderbilt has completed enrollment and a 24 month follow-up. The post nerve repair data analysis and report development are in process for this study and should be available the first half of 2015. Case series in digital nerve repair have been published from the Mayo Clinic, Georgetown University Medical Center and

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Philadelphia Hand Center. A number of additional investigator initiated case reports, studies and publications have been 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 obtain the patients' written informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. AxoGen, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the biological product or device, or

may otherwise not be sufficient to obtain FDA approval to market the product in the U.S. Similarly, in Europe, the clinical study for a medicine product must be authorized by the Competent Authority in each Member State in which the clinical trial is to be conducted, and must receive a favorable opinion from an ethics committee.

Pervasive and Continuing Regulation

There are numerous regulatory requirements that apply after a product is cleared or approved. For medical devices, these include, but are not limited to: the FDA's regulations for device labeling (21 CFR Part 801), medical device reporting (21 CFR Part 803), reporting of corrections and removals (21 CFR Part 806), establishment registration and device listing requirements (21 C.F.R. Part 807); and compliance with the Quality System Regulation (QSR) per 21 CFR Part 820.Distribution of medical devices is subject to license/registration requirements in some states. For tissue and biologic products, these include: the FDA's registration and listing requirements, donor eligibility, and Good Tissue Practices (GTP) per 21 CFR Part1271 for human tissue products, the FDA's Good Manufacturing Practices (GMP) per 21 CFR Parts 210, 211, and 600 for biological products, and postmarket BLA requirements (21 CFR Part 601). Among other things, these regulations require manufacturers, including third-party manufacturers:

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

AxoGen has not had any adverse events concerning the Avance® Nerve Graft product. Two adverse events have been reported for the AxoGuard® products (one in 2013 and one in 2014). AxoGen has not had to submit any Medical Device Reports ("MDRs"), biological deviation reports, or tissue adverse reaction reports to the FDA. Cook Biotech submitted an MDR for the AxoGuard® adverse events in 2013 and 2014. Although AxoGen's AxoGuard® products have had just two adverse events reported to date, there may have been other incidents, including patient

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deaths, which may have occurred during procedures utilizing AxoGen's products without AxoGen being aware of any such incidents. In addition, there can be no assurance that in the future AxoGen will not have an adverse event or will not submit any MDRs, biological deviation reports, or tissue adverse reaction reports to the FDA.

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

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

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

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

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

Educational Grants

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

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

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

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- whether the information about the company's products is further disseminated after the initial program, by or at the direction of the company, other than in response to an unsolicited request or through an independent provider;
- whether the provider is compliant with standards for independence, balance, objectivity, and scientific rigor when putting on ostensibly independent educational programs.

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

Fraud, Abuse and False Claims

AxoGen is directly and indirectly subject to various federal and state laws governing relationships with healthcare providers and pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG") has issued a series of regulations, known as the "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute for activities that fit within a safe harbor. 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, and are at risk activities unless a favorable advisory opinion is obtained from the OIG.

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

AdvaMed is one of the primary voluntary U.S. trade associations for medical device manufacturers. This association has established guidelines and protocols for medical device manufacturers in their relationships with healthcare professionals on matters including research and development, product training and education, grants and charitable contributions, support of third-party educational conferences, and consulting arrangements. Adoption of the AdvaMed Code by a medical device manufacturer is voluntary, and while the OIG and other federal and state healthcare regulatory agencies encourage its adoption and may look to the AdvaMed Code, they do not view adoption of the AdvaMed Code as proof of compliance with applicable laws. AxoGen has incorporated the principles of the AdvaMed Code in its standard operating procedures, sales force training programs, and relationships with doctors. Key to the underlying principles of the AdvaMed Code

is the need to focus the relationships between manufacturers and healthcare professionals on matters of training, education and scientific research, and limit payments between manufacturers and healthcare professionals to fair market value for legitimate services provided and payment of modest meal, travel and other expenses for a healthcare professional under limited circumstances. AxoGen has incorporated these principles into its relationships with healthcare professionals under its consulting agreements, payment of travel and lodging expenses, research and educational grant procedures and sponsorship of third-party conferences. In addition, AxoGen has conducted training sessions on these principles. Finally, the Sunshine act, as defined below, imposes additional new reporting and disclosure requirements on AxoGen for any "transfer of value" made or distributed to physicians and teaching hospitals, as well as reporting of

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certain physician ownership interests. AxoGen cannot provide any assurance that regulatory or enforcement authorities will view its relationships with physicians or policies as being in compliance with applicable regulations and 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 biological 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 biological 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 biological product may also be exported under an IND if a listed investigator is in a foreign country and certain requirements specified in FDA's regulations are met. AxoGen currently complies with applicable regulations when exporting its products and intends to continue such compliance in the event there are any regulatory changes regarding its products in the United States.

The primary regulatory body in Europe is the European Union ("E.U."), which has adopted numerous directives and promulgated voluntary standards regulating the design, manufacture and labeling of, and clinical trials and adverse event reporting for, medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the E.U. and other countries that comply with these directives. The method for assessing conformity varies depending on the type and class of the device, 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. In the second Quarter of 2014, AxoGen's Quality System became registered to ISO 13485 for Receipt, Handling, Storage and Distribution of Medical Devices related to nerve repair.

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

Tissue products are not currently regulated under the CE Mark

Although some standards of harmonization exist, each country in which AxoGen conducts business has its own specific regulatory requirements. AxoGen procures and processes its tissue products in the U.S., and markets in the U.S., the United Kingdom, Singapore, Israel, Canada, Switzerland, Austria and Spain under compliance with the individual country regulations. These requirements are dynamic in nature and, as such, are continually changing. New regulations may be promulgated at any time and with limited notice. AxoGen will review the regulations at the time of submission of the product dossier for regulatory review. This review involves reviewing the appropriate

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MOH regulations, discussion with in-country distributors and use of consultants. It typically takes less than 9 months from the initiation of

the product to develop a product dossier (specific for that country), submission of the documentation and MOH review of the product filing. While AxoGen believes that it is in compliance with all existing pertinent international and domestic laws and regulations, there can be no assurance that changes in governmental administrations and regulations will not negatively impact AxoGen's operations.

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

Environmental

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

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

Employees

At December 31, 2014, AxoGen had 84 full time employees which included 10 in administration, information technology and finance, 10 in manufacturing and quality control, 9 in research and development and regulatory and 55 in sales and marketing. As of the date of this 10-K AxoGen has not had a work stoppage and no employees are represented by a labor union. AxoGen believes its relationship with its employees is satisfactory.

Executive Officers of the Registrant

The following table lists the names and positions of the individuals who are, as of March 5, 2015, executive officers AxoGen:

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

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

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Karen Zaderej, President, Chief Executive Officer and Director (Age 53)

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

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

Gregory G. Freitag, JD, CPA, General Counsel, Senior Vice President Business Development and Director (Age 53)

Mr. Freitag, J.D., CPA, has been AxoGen's General Counsel and a member of its Board of Directors since September 2011, Senior Vice President Business Development since May 2014 and was AxoGen's Chief Financial Officer from September 2011 to May 2014. He was Chief Executive Officer, Chief Financial Officer and a board member from June 2010 through September 2011 of LecTec Corporation, an

intellectual property licensing and holding company that merged with AxoGen in September 2011. From May 2009 to the present, Mr. Freitag has been a principal of FreiMc, LLC, a healthcare and life science consulting and advisory firm he founded that provides strategic guidance and business development advisory services. Prior to founding FreiMc, LLC, Mr. Freitag was a Director of Business Development at Pfizer Health Solutions, a former subsidiary of Pfizer, Inc., from January 2006 to May 2009. From July 2005 to January 2006, Mr. Freitag worked for Guidant Corporation in their business development group. Prior to Guidant Corporation, Mr. Freitag was the Chief Executive Officer of HTS Biosystems, a biotechnology tools start-up company, from March 2000 until its sale in early 2005. Mr. Freitag was the Chief Operating Officer, Chief Financial Officer and General Counsel of Quantech, Ltd., a public point of care diagnostic company, from December 1995 to March 2000. Prior to that time, Mr. Freitag practiced corporate law in Minneapolis, Minnesota. Mr. Freitag is also a director of the Foundation Board of HealthEast Care System, a health care system in Minnesota, and PDS Biotechnology Corporation, a private, clinical stage Biopharmaceutical Company developing immunotherapies for cancer and other disease areas such as infectious disease. Mr. Freitag holds a JD from the University of Chicago and a BA Economics & Business and Law & Society from Macalester College, Minnesota.

Mr. Lee Robert Johnston, Jr, MBA, Chief Financial Officer (54)

Mr. Johnston has served as AxoGen's Chief Financial Officer since May, 2014. From April 2013 until April 2014 he was Senior Vice President of Corporate Development and Chief Financial Officer of Scientific Protein Laboratories, LLC, a private company that was acquired by Hepalink in April 2014. Scientific Protein Laboratories is a manufacturer of active pharmaceutical ingredients for sale to pharmaceutical companies for blood thinner and cystic fibrosis drug products. From December 2009 to November 2011, Mr. Johnston was Chief Financial Officer and Chief Operating Officer of Ascension Orthopedics, Inc., a private company that was acquired by Integra LifeSciences, and was a global medical device company providing surgical implants/devices for the extremities markets: hand/wrist, foot/ankle and shoulder/elbow. From January 2006 until its acquisition by RTI Biologics, Inc. in April 2008, Mr. Johnston was Chief Financial Officer of Tutogen Medical, Inc., a global public medical device company providing biological surgical implants for the spine, dental, hernia repair, ophthalmic, breast reconstruction and urologic markets. After RTI's purchase of Tutogen, Mr. Johnston was Vice President of Finance for RTI until April, 2009. From March 2004 to August 2005, Mr. Johnston was Chief Financial Officer of Power Medical Interventions, a medical device company providing surgical stapling products. Mr. Johnston prior to Power Medical Interventions held a number of financial positions with companies mainly in the life sciences area. He has a MBA, concentration in Finance, from the The Colgate Darden Graduate School of Business Administration University of Virginia and a BA from The University of Virginia.

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John P. Engels, Vice President (Age 43)

Mr. Engels has served as AxoGen's Vice President since September 2011. He is a co-founder of AxoGen Corporation and has served as AxoGen Corporation's Vice President since June 2006, having provided operational and financial leadership and managing AxoGen's strategic and product development partnerships until January, 2012 when he assumed the leadership of international sales. 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, Chief Marketing Officer (Age 49)

Ms. Schiaparelli has served as AxoGen's Chief Marketing Officer since December 2014 and was Senior Vice President, Business Strategy & Marketing from February 2012 until she assumed the Chief Marketing position. From January 2011 to February 2012 and from June 2007 to December 2008, Ms. Schiaparelli was employed by JS Strategic Partners, LLC, a consulting firm she founded to provide business strategy, commercialization and marketing services to biotechnology companies and health care providers. From December 2008 to December 2010, Ms. Schiaparelli was the Vice President, Commercial Strategy & Business Development for ApaTech, a venture-back global orthopedic graft company based in the UK that was later acquired by Baxter Healthcare. From 1996 to 2007, Ms. Schiaparelli was employed by Johnson & Johnson family of companies where she held several senior positions in strategic marketing, marketing, sales operations and healthcare analytics within the Ethicon Endo-Surgery, Ethicon and Healthcare Systems operating companies. Prior to working in the healthcare industry, Ms. Schiaparelli worked for 8 years in the investment banking and financial services industry. Ms. Schiaparelli has an MBA from the Stern School of Business at New York University and a BS in Business Administration from Boston University.

Mark Friedman, Ph.D., Vice President of Regulatory and Quality (Age 57)

Dr. Friedman has served as AxoGen's Vice President of Regulatory and Quality since September 2011. He has served as AxoGen Corporation's Vice President of Regulatory and Quality since June 2011 and served as AxoGen Corporation's Director of Quality Assurance and Regulatory Affairs from September 2006 to June 2011. Prior to joining AxoGen, Dr. Friedman held several regulatory and quality leadership positions at Enable Medical Corporation, a medical device company, including Director of Quality Assurance from 1997 to 1998 and Vice President of Quality and Regulatory from 1998 to 2001 and from 2004 to 2005. Dr. Friedman also worked for AtriCure, Inc., a company that develops, manufactures and sells surgical ablation systems to treat atrial fibrillation, as Vice President of Quality and Regulatory from 2001 to 2004 and as Vice President of Operations in 2004. AtriCure acquired Enable Medical in 2005. Mr. Friedman has over 25 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 54)

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

Shawn McCarrey, Vice President of Sales (Age 57)

Mr. McCarrey has served as AxoGen's Senior Vice President of Sales since February 2013. Mr. McCarrey was Executive Vice President of North American Cardiovascular Sales at Bayer Interventional/MEDRAD Interventional from January 2009 to May 2012. Bayer HealthCare, a subgroup of Bayer AG, is one of the world's leading,

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

Erick DeVinney, Vice President of Clinical and Translational Sciences (Age 39)

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

ITEM 1A. RISK FACTORS

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

Risks Related To Company

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

AxoGen has historically operated with negative cash flow from its operations. As of December 31, 2014, AxoGen had an accumulated deficit of approximately $90 million. If AxoGen product sales do not increase as anticipated, then it will continue to experience negative cash flows and adverse operating conditions. AxoGen's continuing capital needs and other factors could cause the Company to raise additional funds through public or private equity offerings, debt financings or from other sources. The sale of additional equity may result in dilution to AxoGen's shareholders. There is no assurance that AxoGen will be able to secure funding on terms acceptable to it, or at all.

AxoGen's revenue growth depends on its ability to expand its sales force, increase sales to existing customers 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 increase sales to existing customers and 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, increase sales to existing customers and develop new customers, it may not be able to grow revenue or maintain its current level of revenue generation.

AxoGen's revenue depends primarily on three products.

Substantially 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,

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results of operations, financial condition and growth prospects. In addition, AxoGen's expenditures for research and development are minimal and funding to develop, or increase efforts to find collaboration or licensing opportunities to obtain, additional products will be necessary.

The AxoGuard® products are only available through an exclusive distribution agreement with Cook Biotech. Such contract is for an initial seven year term and following such initial term, the agreement automatically renews for an additional seven (7) year period. AxoGen and Cook Biotech have agreed that the parameters for renewal have been met and the contract will automatically renew for the additional seven (7) year period. However, there are conditions for continuation of the agreement, including payment terms and minimum purchase requirements, that if breached could result in an earlier termination of the agreement; except that through mutual agreement the parties have not established such minimums and to date have not enforced such minimum purchase provision. Additionally, in the event that AxoGen and Cook Biotech were to fail to reach an agreement as to minimum purchase quantities, Cook Biotech could terminate the agreement if it was deemed that AxoGen had failed to generate commercially reasonable sales of AxoGuard® as measured by sales similar to a competitive product at the same stage in its commercial launch as verified by a mutually acceptable third-party. Although there are products that AxoGen believes it could develop or obtain that would replace the AxoGuard® products, the loss of the ability to sell the AxoGuard® products could have a material adverse effect on AxoGen's business until other replacement products are available.

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

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

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

AxoGen is highly dependent on its ability to recover cadaveric nerves from tissue donors for its Avance® Nerve Graft product. The availability of acceptable donors is relatively limited, and this availability is impacted by regulatory changes, general public opinion of the donation process and AxoGen's reputation for its handling of the donation process. Media reports or other negative publicity concerning both improper methods of tissue recovery from donors and disease transmission from donated cadaver tissue (allografts) including bones, tendon, etc. may limit widespread acceptance of AxoGen's Avance® Nerve Graft. Unfavorable reports of improper or illegal tissue recovery practices, both in the U.S. and internationally, as well as incidents of improperly processed tissue leading to transmission of disease, may broadly affect the rate of future tissue donation and market acceptance of allograft technologies. Potential patients may not be able to distinguish AxoGen products, technologies, and tissue recovery and processing procedures from others engaged in tissue recovery. In addition, unfavorable reports could make families of potential donors from whom AxoGen is required to obtain consent before processing tissue reluctant to agree to donate tissue to for-profit tissue processors. Any disruption in the supply could have negative consequences for AxoGen's revenue, operating results and continued operations.

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

Any failure in the physical infrastructure of AxoGen's facilities, including the facility it leases from LifeNet Health, could lead to significant costs and disruptions that could reduce its revenues and harm its business reputation and financial results. Any natural or man-made event that impacts AxoGen's ability to utilize its facilities could have a significant impact on its operating results, reputation and ability to continue operations. This includes termination of the LifeNet Health facility lease which can occur upon six months' notice from either party. Although AxoGen believes it can find and make operational a new facility in less than six months, the regulatory process for approval of facilities is time-consuming and unpredictable. AxoGen's ability to rebuild or find acceptable lease facilities would take a considerable amount of time and expense and could cause a significant disruption in service

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to its customers. Although AxoGen has business interruption insurance which would, in instances other than lease termination, cover certain costs, it may not cover all costs nor help to regain AxoGen's standing in the market.

AxoGen must maintain high quality manufacturing and processing.

AxoGen's Avance® Nerve Graft is processed through its Avance® Process which requires careful calibration and precise, high-quality

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

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

Most of the raw materials used in the Avance® Process for the production of Avance® Nerve Graft are available from more than one supplier. However, one of the chemicals AxoGen uses in the manufacture of Avance® Nerve Graft is no longer provided by the original single source provider. AxoGen has inventory of such chemical which it believes provides more than one year of production. AxoGen is currently evaluating multiple avenues including a new supplier of the chemical and acceptable substitutes for the chemical. In addition, some of the test results, packaging and reagents/chemicals AxoGen uses in its manufacturing process are also obtained from single suppliers. We do not have written contracts with any of our single source suppliers, and at any time they could stop supplying our orders. FDA approval of a new supplier may be required if these materials become unavailable from AxoGen's current suppliers. Although there may be other suppliers that have equivalent materials that would be available to AxoGen, FDA approval of any alternate suppliers if required could take several months or years to obtain, if able to be obtained at all. Any delay, interruption or cessation of production by AxoGen's third-party suppliers of important materials, or any delay in qualifying new materials, if necessary, would prevent or delay AxoGen's ability to manufacture products. In addition, an uncorrected impurity, a supplier's variation in a raw material or testing, either unknown to AxoGen or incompatible with its manufacturing process, or any other problem with AxoGen's materials, testing or components, would prevent or delay its ability to manufacture products. These delays may limit AxoGen's ability to meet demand for its products and delay its clinical trial, which would have a material adverse impact on its business, results of operations and financial condition.

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

AxoGen relies upon third parties for certain recovery, distribution, storage 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.

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

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

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

There can be no assurance that AxoGen will be able to manage its future growth efficiently or profitably. Its business is unproven on a large scale and actual revenue and operating margins, or revenue and margin growth, may be less than expected. If AxoGen is unable to scale its production capabilities efficiently, it may fail to achieve expected operating margins, which would have a material and adverse effect on its operating results. Growth may also stress AxoGen's ability to adequately manage its operations, quality of products, safety and regulatory compliance. If growth significantly decreases it will negatively impact AxoGen's cash reserves, and 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

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- public and private research organizations.

AxoGen products compete with autograft, hollow-tube conduits and commercially available wraps, as well as with alternative medical procedures. For the foreseeable future, AxoGen believes a significant number of surgeons will continue to choose to perform autograft procedures when feasible, despite the necessity of performing a second operation and its drawbacks. In addition, many members of the medical community will continue to prefer the use of hollow-tube conduits due in part to their familiarity with these products and the procedures required for their use. Also, steady improvements have been made in synthetic human tissue substitutes, which could compete with AxoGen's products. Unlike allografts, synthetic tissue technologies are not dependent on the availability of human or animal tissue. Although AxoGen's growth strategy contemplates the introduction of new technologies, the development of these technologies is a complex and uncertain process, requiring a high level of innovation, as well as the ability to accurately predict future technology and market trends. AxoGen may not be able to respond effectively to technological changes and emerging industry standards, or to successfully identify, develop or support new technologies or enhancements to existing products in a timely and cost effective manner, if at all. Finally, there can be no assurance that in the future AxoGen's competitors will not develop products that have superior performance or are less expensive relative to its products rendering them obsolete or noncompetitive. Due to its limited resources, its smaller size and its relatively early stage, AxoGen may face competitive challenges and barriers that are difficult to overcome and could negatively impact its growth

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

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

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

Many factors affect the supply, quantity and timing of donor medical releases, such as effectiveness of donor screening (currently performed by donor recovery groups), the effective recovery of tissue, the timely receipt, recording and review of required medical documentation, and employee loss and turnover in AxoGen's and its contractor's recovery department. AxoGen can provide no assurance that tissue recovery or donor medical releases will occur at levels that will maximize processing efficiency and minimize AxoGen's cost per allograft processed.

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

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

AxoGen's payment obligations under the Three Peaks Term Loan Agreement and Three Peaks Revenue Interest Agreement may adversely affect our financial position and our ability to obtain additional funds, and may increase our vulnerability to economic or business downturns.

As described in "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources," AxoGen borrowed $25 million under the term loan agreement (the "Term Loan Agreement") dated November 12, 2014, by and among us, as borrower, our wholly owned subsidiary AxoGen

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Corporation ("AC"), as guarantor, the lenders party thereto and Three Peaks Capital S.a.r.l. ("Three Peaks"), an indirect wholly-owned subsidiary of Oberland Capital Healthcare Master Fund LP, as administrative and collateral agent for the lenders. The Term Loan Agreement and the indebtedness under the Term Loan Agreement is secured by substantially all of AxoGen's tangible and intangible assets. AxoGen used the $25 million proceeds under the Term Loan Agreement, together with the $3.55 million proceeds from the registered direct offering to Three Peaks in November 2014 and $1.75 million cash from AxoGen's own account, to pay off our obligations under the Revenue Interests Purchase Agreement by and between us and PDL BioPharma, Inc. dated October 5, 2012.

Outstanding debt could have important negative consequences to the holders of AxoGen's securities, including the following:

- a portion of our cash flow from operations will be needed to pay debt service and will not be available to fund future operations;
- AxoGen has increased vulnerability to adverse general economic and industry conditions; and
- AxoGen may be vulnerable to higher interest rates because interest expense on the Term Loan in limited circumstances could increase.

In addition, AxoGen also entered into a ten year Revenue Interest Agreement (the "Revenue Interest Agreement") with Three Peaks. Royalty payments are based on a royalty rate of 3.75% of AxoGen's revenues up to a maximum of $30 million in revenues in any 12 month period. In the event AxoGen makes any subsequent borrowing under the Term Loan Agreement, the royalty rate increases proportionally up to a maximum of 4.80%. In addition, under the Revenue Interest Agreement, AxoGen is required to maintain certain covenants including those covenants under the Term Loan.

Payment requirements under the Term Loan Agreement and the Revenue Interest Agreement increase AxoGen's cash burden. AxoGen's future operating performance is subject to market conditions and business factors that are beyond its control. If AxoGen's cash flows and capital resources are insufficient to allow AxoGen to make required payments, AxoGen may have to reduce or delay capital expenditures, sell assets, seek additional capital or restructure or refinance its debt. If AxoGen raises funds by selling additional equity, such sale would result in dilution to its shareholders. There is no assurance that if AxoGen is required to secure funding it can do so on terms acceptable to it, or at all. Failure to pay interest or the principal amount when due would result in a default under the Term Loan Agreement and result in foreclosure on AxoGen's assets which would have a material adverse effect.

The Three Peaks Term Loan Agreement and the Three Peaks Revenue Interest Agreement contain certain covenants and failure to comply with the terms of such indebtedness could result in a default that could have material adverse consequences for us.

The Term Loan Agreement and the Revenue Interest Agreement contain covenants that place restrictions on AxoGen's operations, including, without limitation, covenants related to debt restrictions, investment restrictions, dividend restrictions, restrictions on transactions with affiliates and certain revenue covenants. AxoGen's ability to comply with these covenants may be affected by general economic and industry conditions, as well as market fluctuations and other events beyond AxoGen's control. AxoGen does not know if it will be able to satisfy all such covenants in the future. AxoGen's breach of the covenants could result in a default under such agreement. In the event of a default under the Term Loan Agreement, the lender could require AxoGen to repay some of its outstanding debt prior to maturity, and/or to declare all amounts borrowed by it, together with accrued interest, to be due and payable. In the event that this occurs, AxoGen may be unable to repay all such accelerated indebtedness. Any indebtedness that it incurs under the Term Loan Agreement is secured by substantially all of its tangible and intangible assets. If AxoGen defaults under the indebtedness secured by its assets, those assets would be available to the secured creditors to satisfy AxoGen's obligations to the secured creditors.

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

As a public company, AxoGen incurs legal, accounting and other expenses to comply with relevant securities laws and regulations,

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

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

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

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

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

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

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

Risks Related to the Regulatory Environment in which AxoGen Operates

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

AxoGen is subject to extensive regulation by foreign and domestic government entities and healthcare professionals, such as physicians, hospitals and those to whom and through whom we may market our products. We are subject to scrutiny under various federal, state and territorial laws in the United States and other jurisdictions in which we conduct business. These include, for example, anti-kickback laws, physician self-referral laws, false claims laws, criminal health care fraud laws, and anti-bribery laws e.g. the United States Foreign Corrupt Practices Act. Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, fines, imprisonment and, within the United States, exclusion from participation in government healthcare programs, including Medicare, Medicaid and Veterans Administration health programs. These laws are administered by, among others, the U.S. Department of Justice, the Office of Inspector General of the Department of Health and Human Services, state attorneys general, and their respective counterparts in the applicable foreign jurisdictions in which we conduct business. Many of these agencies have increased their enforcement activities with respect to medical device manufacturers in recent years.

Our products are also subject to regulation by the FDA in the U.S. The FDA regulates the development, clinical testing, marketing, distribution, manufacturing, labeling, and promotion of biological products, such as that of AxoGen's Avance® Nerve Graft product. The FDA also regulates medical devices, for example the AxoGuard® products. The FDA requires the approval of a biological product, like the Avance® Nerve Graft product, through a biological license application, or BLA, prior to marketing. Although the Avance® Nerve Graft product has not yet been approved by FDA through a BLA, FDA is permitting the product to be distributed, subject to FDA enforcement discretion, provided that AxoGen: (1) transitions to compliance with section 501(a)(2)(B) of the

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FD&C Act, the current good manufacturing practice regulations in 21 CFR Parts 210 and 211 and the applicable regulations and standards in 21 CFR Parts 600-610 prior to initiation of a phase 3 clinical trial designed to demonstrate the safety, purity, and potency of the Avance® Nerve Graft; (2) conducts a phase 3 clinical trial to demonstrate safety, purity and potency of the Avance® Nerve Graft under an SPA; (3) continues to comply with the requirements of 21 CFR Part 1271; and (4) exercises due diligence in executing the transition plan. See

"Business — Government Regulations — U.S. Government Regulation Review."

The FDA also regulates medical devices and requires certain medical devices, such as the AxoGuard® products, be cleared through the 510(k) premarket notification process prior to marketing. The FDA's premarket review process for new and modified existing devices that precedes product marketing can be time consuming and expensive. Some of the future products and enhancements to such products that AxoGen expects to develop and market may require marketing clearance or approval from the FDA.

There can be no assurance, however, that clearance or approval will be granted with respect to any of AxoGen's device products or enhancements of marketed products or that AxoGen's Avance® Nerve Graft will achieve an effective IND or ultimately an approved BLA. FDA review of AxoGen's devices or biological products may encounter significant delays during FDA's premarket review process that would adversely affect AxoGen's ability to market its products or enhancements. In addition, there can be no assurance that AxoGen products, including the Avance® Nerve Graft, or enhancements will not be subject to a lengthy and expensive approval process with the FDA.

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

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

In addition, there may be increased risk of injury if physicians or others attempt to use AxoGen products off-label. Furthermore, the use of AxoGen's product for indications other than those for which its products have been approved, cleared or licensed by the FDA may not effectively treat the conditions not referenced in product indications, which could harm AxoGen's reputation in the marketplace among physicians and patients. Physicians may also misuse AxoGen's product or use improper techniques if they are not adequately trained in the particular

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use, potentially leading to injury and an increased risk of product liability. Product liability claims are expensive to defend and could divert management's attention from its primary business and result in substantial damage awards against AxoGen. Any of these events could harm AxoGen's business, results of operations and financial condition.

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

The FDA considers the AxoGen's Avance® Nerve Graft product to be a biological product, subject to BLA approval requirements. Although the Avance® Nerve Graft product has not yet been approved by FDA through a BLA, AxoGen's Avance® Nerve Graft product is currently distributed under the controls applicable to a HCT/P pursuant to section 361 of the Public Health Service Act and 21 CFR Part 1271 of FDA's regulations, subject to FDA's enforcement discretion and AxoGen's compliance with a transition plan established by the FDA. See "Business — Government Regulations — U.S. Government Regulation Review." AxoGen has continued to communicate with FDA's CBER since the acceptance of the transition plan on clinical trial design, preclinical studies, Chemistry, Manufacturing, and Controls ("CMC") for the Avance® Nerve Graft., and other issues related to the pending IND Subject to the FDA's enforcement discretion, AxoGen can commercially distribute the Avance® Nerve Graft until FDA makes a final determination on an Avance® Nerve Graft BLA submission, assuming AxoGen remains in compliance with the transition plan. and exercises due diligence in executing the transition plan In the event that the FDA becomes dissatisfied with AxoGen's progress or actions with respect to the transition plan or FDA changes its position for any reason regarding its use of enforcement discretion to permit AxoGen to distribute and sell the Avance® Nerve Graft product

in accordance with the transition plan, AxoGen would no longer be able to sell the Avance® Nerve Graft product, which would have a material adverse effect on AxoGen's operations and financial viability. In addition, if AxoGen does not meet the conditions of the transition plan, or fails to comply with applicable regulatory requirements the FDA could impose civil penalties, including fines, product seizures, injunctions or product recalls and, in certain cases, criminal sanctions. These consequences also would have a material adverse effect on AxoGen's operations and financial viability.

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

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

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

If AxoGen's products are defective or otherwise pose safety risks, the FDA could require their recall, or AxoGen may initiate a voluntary recall of its products. The FDA may require recall of a marketed medical device product, such as the AxoGuard® products, in the event that it determines the medical device presents a reasonable probability of serious adverse health consequences or death. However, most device recalls do not rise to this level of health significance and result from voluntary action. FDA has authority to recall biological products when a batch, lot or other quantity of the product presents an imminent or substantial hazard to the public health. However, the agency usually requests, voluntary recalls of biological products, such as the Avance® Nerve Graft. If a company does not comply with an FDA request for a recall, FDA can order one under the above-referenced circumstances or take other enforcement actions, such as product seizure. In addition, manufacturers may, on their own initiative, recall a product to remove or correct a deficiency or to remedy a violation of the Federal Food, Drug, and Cosmetic Act that may pose a risk to health. A government-mandated, government-requested or voluntary recall could occur as a result of an unacceptable risk to health, reports of safety issues, failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls and other field corrections for any of AxoGen's products would divert managerial and financial resources and have an adverse effect on its business, results of operations and financial condition. A recall could harm AxoGen's reputation with customers and negatively affect its sales.

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AxoGen may initiate recalls involving some of its products in the future that it determines do not require notification of the FDA. If the FDA were to disagree with AxoGen's determinations, it could request that it report those actions as recalls, and take regulatory or enforcement action against AxoGen or the product.

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

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

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

Sales of AxoGen human tissue products outside the U.S. are subject to foreign regulatory requirements that vary from country to country. In the E.U., human tissue regulations, if applicable, differ from one E.U. member state to the next. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the E.U., as well as for other countries, the approval process for human derived cell or tissue based medical products may be extensive, lengthy, expensive and unpredictable. AxoGen products will be subject to E.U. member states' regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage, and distribution of human tissues and cells and cellular or tissue-based products. In addition, some E.U. member states have their own tissue banking regulations. The inability to meet foreign regulatory requirements could materially affect AxoGen's future growth and compliance with such requirements could place a significant financial burden on AxoGen.

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

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

AxoGen submitted an IND for the Avance® Nerve Graft in April, 2013. On June 7, 2013, the FDA placed the IND on Clinical Hold, pending the FDA's receipt of additional information relating to the potency, mechanical characterization, and labeling of the product. The phase 3 clinical trial cannot begin until the FDA lifts the Clinical Hold. AxoGen is developing the data and information to respond to the FDA's requests, but there can be no assurance that an effective IND will be obtained on a timely basis or at all. Additionally AxoGen was audited by the FDA in March 2013 and the quality system was found to be in compliance with 21 CFR Part 1271.AxoGen is working to ensure compliance with the applicable regulations by having ongoing discussions on the transition of the quality system to 21 CFR Parts 210/211 and 600-610 regulations with the FDA and being audited by the FDA for compliance to 21 CFR Part1271 of the regulations. Final determination of regulatory compliance will be made during FDA's pre-license inspection as part of the BLA review. If FDA is unable to agree with AxoGen, or AxoGen is unable to meet the standards required of it by the FDA, regarding preclinical studies, clinical studies and CMC, the approval of AxoGen's BLA would become impossible or delayed.

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

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 the company to pursue additional non-clinical studies or clinical trials, or not approve AxoGen's BLA. If AxoGen is unable to demonstrate the safety and efficacy of its product through its clinical trials, it will be unable to obtain regulatory approval to market the Avance® Nerve Graft and will not be able to continue to sell it.

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

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

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

In addition to the FDA requirements for biological products, the Avance® Nerve Graft will continue to be subject to various requirements for human tissue under 21 CFR Part 1271 controls. Human tissues intended for transplantation have been regulated by the FDA since 1993. In May 2005, three new comprehensive regulations went into effect that address manufacturing activities associated with HCT/P. The first requires that companies that produce and distribute HCT/Ps register with the FDA. The second provides criteria that must be met for donors to be eligible to donate tissues and is referred to as the "Donor Eligibility" rule. The third rule governs the processing and distribution of the tissues and is often referred to as the Current Good Tissue Practices rule. The Current Good Tissue Practices rule covers all stages of allograft processing, from procurement of tissue to distribution of final allografts. Together, the three basic requirements of 21 CFR Part 1271 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 actions, which affects the conduct of its business. Additional regulations or guidance documents may be implemented by the FDA in the future. These changes may require new documentation requirements, process changes or testing that could increase costs and regulatory burden. See "Business — Government Regulations." These regulations can also increase the cost of tissue recovery activities. Additionally,

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the Avance® Nerve Graft is subject to certain state and local regulations, as well as compliance to the standards of the tissue bank industry's accrediting organization, the American Association of Tissue Banks ("AATB").

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

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

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

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

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

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

- a 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the U.S., with limited exceptions, beginning in 2013, referred to as the Device Tax;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research;
- new reporting and disclosure requirements on healthcare manufacturers for any "transfer of value" made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests ("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;
- an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate; and
- a new abbreviated pathway for the licensure of biologic products that are demonstrated to be biosimilar or interchangeable with a licensed biologic product.

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

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

hospitals, as well as reporting of certain physician ownership interests.

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

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

Risks Related to AxoGen's Intellectual Property

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

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

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

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

- it, or its licensors, were the first to make the inventions covered by each of AxoGen's patents;
- it, or its licensors, were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of AxoGen's technologies;
- any of AxoGen's pending patent applications will result in issued patents;
- any of AxoGen's issued patents or those of its licensors will be valid and enforceable;
- any patents issued to AxoGen or its collaborators will provide any competitive advantages or will not be challenged by third parties;
- it will develop additional proprietary technologies that are patentable;

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- the patents of others will not have a material adverse effect on its business rights; or
- the measures AxoGen relies on to protect its IP underlying their products may not be adequate to prevent third parties from using its technology, all of which could harm its ability to compete in the market.

AxoGen's commercial success depends in part on its ability and the ability of its collaborators and licensors to avoid infringing patents and proprietary rights of third parties which could expose it to litigation or commercially unfavorable licensing arrangements. Third parties may accuse AxoGen or collaborators and licensors of employing their proprietary technology in AxoGen products, or in the materials or processes used to research or develop AxoGen products, without authorization. Any legal action against AxoGen collaborators, licensors or it claiming damages and/or seeking to stop AxoGen's commercial activities relating to the affected products, materials and processes could, in addition to subjecting AxoGen to potential liability for damages, require it or its collaborators and licensors to obtain a license to continue to utilize the affected materials or processes or to manufacture or market the affected products. AxoGen cannot predict whether AxoGen or its collaborators and licensors would prevail in any of these actions or whether any license required under any of these patents would be made available on commercially reasonable terms, if at all. If AxoGen were unable to obtain such a license, it and its collaborators and licensors may be unable to continue to utilize the affected materials or processes, or manufacture or market the affected products, or AxoGen may be obligated by a court to pay substantial royalties and/or other damages to the patent holder. Even if AxoGen were able to obtain such a license, the terms of such a license could substantially reduce the commercial value of the affected product or products and impair AxoGen's prospects for profitability. Accordingly, AxoGen cannot predict whether, or to what extent, the commercial value of the affected product or products, or AxoGen's prospects for profitability may be harmed as a result of any of the liabilities discussed above. Furthermore, infringement and other IP claims, with or without merit, can be expensive and time-consuming to litigate and can divert management's attention from its core business. AxoGen and its licensors may be unable to obtain and enforce IP rights to adequately protect its products and related IP.

The patent protection for our products may expire before we are able to maximize their commercial value which may subject us to

increased competition and reduce or eliminate our opportunity to generate product revenue.

The patents for our commercialized products and products in development have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. For example, U.S. patents covering the formulations used in our AxoGuard® product line, which are held by Cook Biotech, are scheduled to expire from August 17 2017 through November 2018. Although we expect that Cook Biotech is using best efforts to take any action possible to extend the life of these patents, there can be no assurance that any action is possible or action taken will be successful. If these patents expire while we have the right to distribute and market the AxoGuard® products, it could adversely affect our ability to successfully execute our business strategy to maximize the value of AxoGuard® products and could likely negatively impact our future financial condition and results of operations.

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

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

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adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party. This is especially true in IP cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

AxoGen depends on maintenance of exclusive licenses.

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

Risk Related to Our Common Stock

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

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

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

- economic and other external factors;
- period-to-period fluctuations in financial results; and
- other events or factors, many of which are beyond our control.

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

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

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

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

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

In general, Section 302A.671 of the MBCA provides that a corporation's shares acquired in a control share acquisition have no voting rights unless voting rights are approved in a prescribed manner. A "control share acquisition" is a direct or indirect acquisition of beneficial ownership of shares that would, when added to all other shares beneficially owned by the acquiring person, entitle the acquiring person to have voting power of 20% or more in the election of directors.

In general, Section 302A.673 of the MBCA prohibits a public Minnesota corporation from engaging in a business combination with an interested shareholder for a period of four years after the date of the transaction in which the person became an interested shareholder, unless the business combination is approved in a prescribed manner. The term "business combination" includes mergers, asset sales and other transactions resulting in a financial benefit to the interested shareholder. An "interested shareholder" is a person who is the beneficial owner, directly or indirectly, of 10% or more of a corporation's voting stock, or who is an affiliate or associate of the corporation, and who, at any time within four years before the date in question, was the beneficial owner, directly or indirectly, of 10% or more of the corporation's voting stock. Section 302A.673 does not apply if a committee of our Board of Directors consisting of all of its disinterested directors (excluding current and former officers) approves the proposed transaction or the interested shareholder's acquisition of shares before the interested shareholder becomes an interested shareholder.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

On November 12, 2013, AxoGen Corporation, a wholly owned subsidiary of AxoGen, entered into the Third Amendment to Lease with SNH Medical Office Properties Trust ("SNH"). SNH was the landlord of AxoGen's corporate headquarters leased facility in Alachua, Florida and AxoGen and SNH agreed to the amendment by which AxoGen relocated and expanded its corporate headquarters to a new space owned by SNH within the same office park. The lease amendment provides for 11,761 square feet of office space until October 31, 2018, renewable thereafter by agreement of the parties, subject to AxoGen's right to earlier termination after three years from the effective date of the lease. AxoGen's annual cost of such property ranges from approximately $194,000 to $206,000 per year.

AxoGen also leases 963 square feet of laboratory space in University of Florida's Sid Martin Biotechnology Incubator in Alachua, Florida on a month to month basis.

On October 25, 2013, AxoGen entered into a Commercial Lease with Ja-Cole. Under the terms of the Commercial Lease AxoGen leased 5,400 square feet of warehouse/office space in Burleson, Texas until November 30, 2016, renewable thereafter by agreement of the parties, at an annual cost of $43,200 per year. The Distribution Facility houses raw material storage and product distribution, allowing AxoGen to

fulfill same day orders for both east and west coasts of the United States.

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

The Company's aggregate cost of such properties is approximately $288,000 per year. AxoGen believes that these facilities are sufficient to operate its business for the next 12 months and that lease obligations will not change materially.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Prior to August 16, 2013, the Company's common stock was traded on the OTCQB Marketplace, operated by OTC Markets Group, under the symbol "AXGN." Since August 16, 2013, the Company's common stock has been traded on the NASDAQ Capital Market under the symbol "AXGN." On March 4, 2015, the last reported closing sale price of the Company common stock on the NASDAQ Capital Market was $3.13 per share.

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

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

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

	Year Ended December 31, 2014		Year Ended December 31, 2013	
	High	Low	High	Low
First Quarter	$ 4.86	$ 2.87	$ 4.25	$ 2.75
Second Quarter	$ 3.08	$ 2.32	$ 5.08	$ 3.66
Third Quarter	$ 2.74	$ 2.15	$ 4.53	$ 2.97
Fourth Quarter	$ 3.85	$ 2.40	$ 4.54	$ 3.35

Dividend Policy

AxoGen currently intends to retain earnings, if any, to finance the growth and development of its business, and does not expect to pay any cash dividends to its shareholders in the foreseeable future. In addition, the Term Loan Agreement and the Revenue Interest Agreement place certain restrictions on AxoGen's ability to pay dividends.

Shareholders

As of March 4, 2015, the Company had 24,926,014 shares of common stock outstanding, and approximately 316 common shareholders of record, based upon information received from our stock transfer agent. However, this number does not include beneficial owners whose shares were held of record by nominees or broker dealers. The Company estimates that there are approximately less than 1,000 individual owners.

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Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our securities during the year of 2014.

Recent Sales of Unregistered Securities

We had no sales of unregistered securities during 2014 that have not been previously disclosed in a Current Report on Form 8-K or Quarterly Reports on Form 10-Q.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

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

Overview

AxoGen is a leading medical technology company dedicated to peripheral nerve repair. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body and their damage can result in the loss of function and feeling. In order to improve surgical repair and regeneration of peripheral nerves, AxoGen has developed and licensed regenerative medicine technologies. AxoGen's innovative approach to regenerative medicine has resulted in first-in-class products that it believes are redefining the peripheral nerve repair market. AxoGen's products offer a full suite of surgical nerve repair solutions including Avance® Nerve Graft, a proprietary off-the-shelf processed nerve allograft (human nerve tissue obtained from a donor) used for bridging severed nerves without the comorbidities associated with a nerve autograft additional surgical site, AxoGuard® Nerve Connector, a porcine submucosa ExtraCellular Matrix ("ECM") coaptation aid for tensionless repair of severed nerves, and AxoGuard® Nerve Protector, a porcine submucosa ECM product used to wrap and protect injured peripheral nerves and reinforce coaptation sites while preventing soft tissue attachments. AxoGen also sells AxoTouch™ Two Point Discriminator, a measurement tool for determining innervation density and sensory function.

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 2014 compared to 2013 primarily as a result of increased product usage by existing accounts. AxoGen has continued to broaden its sales and marketing focus which is expected to have a positive contribution to its revenue growth in the long term. In the near term revenue growth lags behind the expense increases for market development such as hiring and training of new sales representatives and surgeon education programs.

Recent Developments

We completed a refinancing in November 2014, under which (i) we borrowed $25 million under the Term Loan Agreement and Revenue Interest Agreement with Three Peaks, and (ii) we terminated the Revenue Interests Purchase Agreement by and between us and PDL BioPharma, Inc. ("PDL") dated October 5, 2012 and paid off our obligation thereunder using the $25 million proceeds from the Term Loan Agreement, the $3.55 million proceeds from the registered direct offering of our common shares to Three Peaks pursuant to the equity purchase provisions in the Term Loan Agreement, and $1.75 million cash from our own account. The Term Loan Agreement is secured by substantially all of our tangible and intangible assets (including, without limitation, our intellectual property). We also conducted a registered offering to PDL in November 2014 and sold an aggregate offering amount of $1.75 million of our common shares. See "— Liquidity and Capital Resources."

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Results of Operations

Critical Accounting Policies and Estimates

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

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

Accounts Receivable and Concentration of Credit Risk — Doubtful Accounts

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

Effective Interest Rate on Note Payable

The PDL Royalty Contract was accounted for as long-term debt. AxoGen recorded interest using its best estimate of the effective interest rate. This estimate took into account both the internal rate of return (IRR) of the PDL agreement and the rate of return as the result of exercise of the Put option. The IRR of the PDL Royalty Contract was based on the actual payments to date, projected future revenues and required minimum payments, and was calculated at 20.535%. The PDL Royalty Contract Put option provided PDL a 20% return, if exercised. As a result of the return of the Put option being higher than the IRR of the PDL agreement, management believed the best estimate of the effective interest rate on this instrument would be the Put rate. As a result, AxoGen was accruing interest using the specified internal rate of return for the Put which was 20%. The PDL Royalty Contract was paid in full on November 12, 2014. The Company has no further obligation under the PDL Royalty Contract.

The Three Peaks Term Loan Agreement and Revenue Interest Agreement are used in calculating the effective interest rate. AxoGen records interest using its best estimate of the effective interest rate. This estimate takes into account both the rate on the Term Loan Agreement and the rate associated with the 10 year Revenue Interest Agreement with Three Peaks. The effective interest rate is based on actual payments to date, projected future revenues and the projected royalty payments and the quarterly interest payments due on the Term Loan Agreement. From time to time, AxoGen will reevaluate the expected cash flows and may adjust the effective interest rate. Determining the effective interest rate requires judgment and is based on significant assumptions related to estimates of the amounts and timing of future revenue streams. Determination of these assumptions is highly subjective and different assumptions could lead to materially different outcomes.

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Income Taxes

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

Comparison of the Years Ended December 31, 2014 and 2013

Revenues

Revenues for the year ended December 31, 2014 increased 53.6% to approximately $16,817,000 as compared to approximately $10,947,000 for the year ended December 31, 2013. This increase was primarily a result of the sales strategy to focus on growing sales and increasing product usage in existing accounts and adding new accounts. In addition, the company received grant revenue of approximately $314,000 in the year ended December 31, 2014, as compared to grant revenue of approximately $70,000 in the year ended December 31, 2013. The strategy of focusing on breadth, depth and quality has enabled the Company to experience growth in our existing accounts and extend the growth to new accounts. With regards to new accounts, each new customer in a defined period has the potential to become an established customer with repeat orders and increased account penetration. As such, revenue growth occurs from increased purchasing from established customers and new customers who purchase for the first time. Each new period of measurement is thus benefited from growth in existing customers and the additional new customers added.

Gross Profit

Gross profit for the year ended December 31, 2014 increased 57.2% to approximately $13,375,000 as compared to approximately $8,508,000 for the year ended December 31, 2013. This increase is primarily attributable to the increased revenues in 2014, manufacturing efficiencies, a favorable product mix and a product price increase instituted in March 2014. As a result, gross profit margin also improved to 79.5% in 2014 as compared to 77.7% for 2013.

Costs and Expenses

Total cost and expenses increased 28.0% to approximately $23,176,000 for the year ended December 31, 2014 as compared to approximately $18,100,000 for the year ended December 31, 2013. These increases were primarily due to increasing sales and marketing activities, which includes increased compensation as a result of increased sales, increases in research and development expenses, including

AxoGen's product development and clinical efforts substantially focused on its BLA for Avance® Nerve Graft and increases in compensation as AxoGen hires to meet growth needs.

Sales and marketing expenses increased 28.6% to approximately $13,194,000 for the year ended December 31, 2014 as compared to approximately $10,259,000 for the year ended December 31, 2013. This increase was primarily due to increased expenses related to AxoGen's direct sales force and independent distributors, sales training and surgeon education. As a percentage of revenues, sales and marketing expenses were 78.5% for the year ended December 31, 2014 compared to 93.7% for the year ended December 31, 2013. The decrease in sales and marketing expenses as a percentage of revenue was a result of the revenues outpacing expenses, primarily due to the fact that the direct sales force personnel and independent distributors are gaining penetration into existing and new accounts as the sales activities, professional education and other training events are contributing to increases in revenues.

General and administrative expenses increased 21.6% to approximately $6,949,000 for the year ended December 31, 2014 as compared to approximately $5,715,000 for the year ended December 31, 2013. As a percentage of revenues, general and administrative expenses were 41.3% for the year ended December 31, 2014 compared to 52.2% for the year ended December 31, 2013. The increase in aggregate dollars spent were a result of increased compensation including non-cash stock option compensation of approximately $285,000, increased

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facility costs, increased insurance expenses and increased depreciation, offset by a reduction in travel expenses. As a percentage of revenue, general and administrative expenses decreased as a result of sales increasing.

Research and development expenses increased 42.7% to approximately $3,033,000 in the year ended December 31, 2014 as compared to approximately $2,125,000 for the year ended December 31, 2013. Development includes AxoGen's product development and clinical and other efforts substantially focused on its biological license application ("BLA") for the Avance® Nerve Graft. A substantial portion of the increase in research and development expenses from 2013 to 2014 is related to expenditures for clinical activity. AxoGen conducts limited research and product development focused on new products and new applications to existing products. AxoGen pursues research grants to support this research where applicable. AxoGen's product pipeline development also contributed to a portion of the research and development expense increase in 2014, with grant revenue partially offsetting a portion of this activity. As a percentage of revenues, research and development expenses declined from 19.4% in 2013 to 18% in 2014.

Other Income and Expenses

Interest expense increased 41.3% to approximately $6,812,000 in 2014 as compared to approximately $4,820,000 for the year ended December 31, 2013. This increase was primarily due to the interest related to the PDL debt facility extinguishment. As a result of the accounting treatment for the Three Peaks transaction, interest expense for 2014 included approximately $88,000 of non-cash expense that is expected to be paid in the future based upon the terms of the Three Peaks transaction and increases in AxoGen revenues. The $88,000 of non-cash expense was derived from taking the imputed interest for 2014 on the Three Peaks agreement less the actual cash payment made to Three Peaks for the year. Other than the $88,000 non-cash expense, the remaining $6,724,000 in interest expense for 2014 is related to cash paid for interest on the note payable with PDL and the interest paid on the Term Loan Agreement with Three Peaks.

Interest expense— deferred financing costs increased to approximately $1,101,000 for 2014 as compared to approximately $179,000 in 2013. This increase is primarily due to the write off of the remaining PDL financing costs of approximately $901,000 as the result of the extinguishment of that debt facility.

Income Taxes

AxoGen had no income tax expenses or income tax benefit for 2014 due to incurrence of net operating loss for the year. AxoGen does not believe there are any additional tax expenses or benefits currently available.

Effect of Inflation

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

Liquidity and Capital Resources

Note Payable

On October 5, 2012, AxoGen entered into the Royalty Contract with PDL. The Royalty Contract had a term of eight years. Under the Royalty Contract, PDL received royalty payments paid weekly based on a 9.95% royalty rate of certain of AxoGen's Net Revenues (the "Assigned Interests"), subject to certain guaranteed quarterly payment amounts of approximately $1.3 to $2.5 million per quarter that commenced in the quarter ending December 31, 2014. The minimum annual payment amounts were as follows: 2014 - $1,250,805, 2015 - $6,781,440, 2016 - $9,232,642, 2017 and 2018 - $9,000,000, 2019 - $9,063,000 and 2020 - $6,939,000. The royalty payment was based on only that portion of Company Net Revenue that was generated by the sale, distribution or other use of AxoGen's products Avance® Nerve Graft, AxoGuard® Nerve Protector and AxoGuard® Nerve Connector (the "Acquired Revenues"), which at that time represented all of AxoGen's Net Revenue with the exception of shipping and handling fees which represented less than 3% of total revenues The total consideration PDL paid to AxoGen was $20,800,000 (the "Funded Amount"), including $19,050,000 PDL paid to AxoGen on October 5, 2012, and $1,750,000 PDL paid to AxoGen on August 14, 2012 pursuant to the Interim Royalty Contract. Upon the closing of PDL's purchase of the specified royalties described above, which was concurrent with the execution of the Royalty Contract, the Interim Royalty Contract was terminated. There were no financial covenants or other restrictions on the use of capital by AxoGen as a result of the Royalty

Contract, however, PDL had a first perfected security interest

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in the Assigned Interests. On November 12, 2014, the Company paid PDL $30.3 million to fully extinguish the Royalty Contract. The Company has no further obligations under the Royalty Contract.

On November 12, 2014, (the "Signing Date"), AxoGen, Inc. (the "Company" or "AxoGen"), as borrower, and the Company's wholly owned subsidiary AxoGen Corporation ("AC"), as guarantor, entered into a term loan agreement (the "Term Loan Agreement") with the lenders party thereto and Three Peaks Capital S.a.r.l. ("Three Peaks"), an indirect wholly owned subsidiary of Oberland Capital Healthcare Master Fund LP ("Oberland"), as administrative and collateral agent for the lenders. Under the Term Loan Agreement, Three Peaks has agreed to lend to AxoGen a term loan of $25 million (the "Initial Term Loan") which has a six year term and requires interest only payments and a final principal payment due at the end of the term. Interest is payable quarterly at 9.00% per annum plus the greater of LIBOR or 1.0% which as of November 13, 2014 ("the Initial Closing Date") and December 31, 2014 resulted in a 10% rate. Under certain conditions, the Company has the option to draw an additional $7 million ("Subsequent Borrowing" and, together with the Initial Term Loan, the "Term Loan") during the period of April 1, 2016 through June 29, 2016 (the closing date of each such Subsequent Borrowing, a "Subsequent Closing Date" and, together with the Initial Closing Date, the "Closing Dates") under similar terms and conditions. The Company has to maintain certain covenants including limiting new indebtedness, restriction of the payment of dividends and maintain certain levels of revenue. Three Peaks has a first perfected security interest in the assets of the Company.

As of the Signing Date, the Company also entered into a 10 year Revenue Interest Agreement ("Revenue Interest Agreement") with Three Peaks. Royalty payments are based on a royalty rate of 3.75% of the Company's revenues up to a maximum of $30 million in revenues in any 12 month period. In the event the Subsequent Borrowing is drawn, the royalty rate increases proportionally up to a maximum of 4.80%. The Company has to maintain certain covenants including those covenants under the Term Loan.

Under the Term Loan Agreement, the Company has the option at any time to prepay the Term Loan, in whole or in part, and the Revenue Interest Agreement by making the following payment, and Three Peaks has the right to demand the following payment upon a change of control of the Company, sale of the majority of the Company's assets or a material adverse change to the Company: (i) on or prior to the first anniversary of the applicable Closing Date, 120% of the outstanding principal amount of the Term Loan or any portion being prepaid; (ii) after the first anniversary but no later than the second anniversary of the applicable Closing Date, 135% of the outstanding principal amount of the Term Loan or any portion being prepaid; (iii)) after the second anniversary but no later than the third anniversary of the applicable Closing Date, 150% of the outstanding principal amount of the Term Loan or any portion being prepaid; or (iv)) after the third anniversary of the applicable Closing Date, an amount generating an Internal Rate of Return of 16.25% of the outstanding principal amount of the Term Loan or any portion being prepaid. In all cases, the amount due is reduced by the sum of interest and principal previously paid and all amounts received under the Revenue Interest Agreement. In each such case the Company will also owe an additional 3% of the originally advanced Term Loan amount. Upon payment to Three Peaks, the Company would have no further obligations to Three Peaks under the Term Loan or the Revenue Interest Agreement.

In addition, on the Initial Closing Date, the Company sold 1,375,969 shares of common stock to Three Peaks for a total of $3.55 million in cash ("Three Peaks Equity Sale") at a public offering price of $2.58 per share. The proceeds from the Initial Term Loan, the Three Peaks Equity Sale and $1.75 million of capital from the Company, were used to fully repay the Royalty Contract with PDL. The Company has no further obligations to PDL under the Royalty Contract. Pursuant to the equity purchase provisions in the Three Peaks Term Loan Agreement, in the event that we sell prior to November 12, 2016 our securities at a lower price per share than the $2.58 per share paid by Three Peaks, or where the terms of such subsequent sale are otherwise more favorable, then in such case we have agreed to match the more favorable terms of such subsequent sale with respect to the shares purchased by Three Peaks. A subsequent sale does not include the issuance of securities or options to our employees, officers, directors or consultants pursuant to our approved employee option pool or any other employee stock purchase or option plan existing as of November 12, 2014. In February 2015 AxoGen completed a public offering of 5,437,200 shares of Common Stock at $2.75 per share resulting in gross proceeds to AxoGen from the offering of approximately $15.0 million, before deducting underwriting discounts and commissions and other estimated offering expenses payable by AxoGen estimated at approximately $1.4 million. The Company believes it has sufficient cash resources to meet its liquidity requirements for at least the next 12 months.

In connection with the Term Loan Agreement, on the Signing Date, the Company and AC entered into a Security Agreement (the "Security Agreement") with Three Peaks, pursuant to which each of the Company and AC grants to Three Peaks a security interest in certain collateral as specified in the Security Agreement to guarantee the payment in full when due of the Secured Obligations.

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As a result of the accounting treatment for the Three Peaks transaction, interest expense for 2014 included approximately $86,000 of non-cash expense that is expected to be paid in the future based upon the terms of the Three Peaks transaction and increases in AxoGen revenues. The $86,000 of non-cash expense was derived from taking the imputed interest for 2014 on the Three Peaks agreement less the actual cash payment made to Three Peaks for the year. Other than the $86,000 non-cash expense, the remaining $6,724,000 in interest expense for 2014 is related to cash paid for interest on the note payable with PDL and the interest paid on the Term Loan with Three Peaks.

Subsequent to the closing of the Term Loan and Revenue Interest Agreements, also on the Initial Closing Date, the Company sold 643,382 shares of common stock for a total of $1.75 million to PDL ("PDL Equity Sale") at a public offering price of $2.72 per share

pursuant to a Securities Purchase Agreement by and between the Company and PDL dated the Signing Date. The Company intends to use the proceeds from the PDL Equity Sale for general corporate purposes.

The Company had no material commitments for capital expenditures at December 31, 2014 or 2013.

Cash Flow Information

AxoGen had working capital of approximately $11.97 million and a current ratio of 5.89 at December 31, 2014, compared to working capital of $23.56 million and a current ratio of 12.23 at December 31, 2013. The decrease in working capital and the current ratio at December 31, 2014 as compared to December 31, 2013 was primarily due to the use of working capital for operations. In February 2015 AxoGen completed a public offering of 5,437,200 shares of Common Stock at $2.75 per share resulting in gross proceeds to AxoGen from the offering of approximately $15.0 million, before deducting underwriting discounts and commissions and other estimated offering expenses payable by AxoGen estimated at approximately $1.4 million. The Company believes it has sufficient cash resources to meet its liquidity requirements for at least the next 12 months.

AxoGen's future capital requirements depend on a number of factors, including, without limitation, revenue increases consistent with its business plan, and pursuant to AxoGen's licensing agreements in connection with Avance® Nerve Graft, cost of products and acquisition and/or development of new products. AxoGen could face increasing capital needs. Such capital needs could be substantial depending on the extent to which AxoGen is unable to increase revenue.

If AxoGen needs additional capital in the future, it may raise additional funds through public or private equity offerings, debt financings or from other sources. The sale of additional equity would result in dilution to AxoGen's shareholders. There is no assurance that AxoGen will be able to secure funding on terms acceptable to it, or at all. The increasing need for capital could also make it more difficult to obtain funding through either equity or debt. Should additional capital not become available to AxoGen as needed, AxoGen may be required to take certain action, such as, slowing sales and marketing expansion, delaying regulatory approvals or reducing headcount.

During the year ended December 31, 2014, the Company had a net decrease in cash and cash equivalents of approximately $11,854,000 as compared to a net increase of cash and cash equivalents of approximately $6,162,000 in the year ended December 31, 2013. The Company's principal sources and uses of funds are explained below:

Net Cash used in operating activities

AxoGen used approximately $10,451,000 of cash for operating activities in 2014, as compared to using approximately $10,445,000 of cash for operating activities in 2013. This increase in cash used in operating activities is primarily attributed to the net loss generated in 2014, net of significant non-cash interest added to the note payable, an increase in the stock based compensation along with a write off of deferred financing costs.

Net Cash used in investing activities

Investing activities for 2014 used approximately $594,000 of cash as compared to 2013 which used approximately $244,000. This increase in use is principally attributable to the purchase of certain fixed assets for the expansion of the headquarters office and the opening of the worldwide distribution facility in Burleson, Texas.

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Net Cash provided by financing activities

Financing activities in 2014 used approximately $809,000 of cash as compared to providing approximately $16,851,000 of cash in 2013. The cash use increased in 2014 as a result of the $1,750,000 of cash used as part of the final payment to fully repay the Royalty Contract with PDL. In addition, in the PDL Equity Sale, we sold an aggregate offering price of $1.75 million of registered common shares to PDL in November 2014 and we intend to use the proceeds for general corporate purposes.

The cash provided in 2013 is primarily attributed to approximately $16,778,000 as a result of the sale of Common Stock.

On February 10, 2015, we completed an underwritten public offering pursuant to an Underwriting Agreement (the "Underwriting Agreement") dated February 5, 2015 with Wedbush Securities Inc., as underwriter (the "Underwriter"), of 5,437,200 of our common shares (including 709,200 shares issued under an over-allotment option) at a price to the public of $2.75 per share. We intend to use the net proceeds of approximately $13.6 million from this offering for continued expansion of our sales force and surgeon education and general corporate purposes.

Off-Balance Sheet Arrangements

AxoGen does not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

In May 2014, the FASB issued a new standard on revenue recognition which outlines a single comprehensive model to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The core principle of the revenue model is that an entity should recognize revenue to depict the transfer of promised goods

or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is designed to create greater comparability for financial statement users across industries and jurisdictions and also requires enhanced disclosures. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is not permitted. We are currently evaluating the impact of the adoption of this standard on our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of AxoGen, Inc. and subsidiary as of December 31, 2014 and 2013, and the related consolidated statements of operations, shareholders' equity (deficit), and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of AxoGen, Inc. and subsidiary as of December 31, 2014 and 2013, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ LURIE BESIKOF LAPIDUS & COMPANY, LLP

Minneapolis, Minnesota
March 5, 2015

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AXOGEN, INC.
CONSOLIDATED BALANCE SHEETS
December 31, 2014 and 2013

	December 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 8,215,791	$ 20,069,750
Accounts receivable, net of allowance for doubtful accounts of approximately $94,000 and $58,000, respectively	2,872,308	1,893,699
Inventory	3,213,620	3,398,438
Prepaid expenses and other	109,369	296,719
Total current assets	14,411,088	25,658,606
Property and equipment, net	619,028	381,689
Intangible assets	577,174	570,396
Deferred financing costs	793,499	1,073,579
	$ 16,400,789	$ 27,684,270
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,431,194	$ 2,083,942
Current deferred revenue	14,118	14,118
Total current liabilities	2,445,312	2,098,060
Note Payable	25,085,777	25,363,695
Long Term Deferred Revenue	115,380	85,882
Total liabilities	27,646,469	27,547,637
Shareholders' equity (deficit):		
Common stock, $.01 par value; 50,000,000 shares authorized; 19,488,814 and 17,339,561 shares issued and outstanding	194,888	173,395
Additional paid-in capital	78,675,686	72,369,016
Accumulated deficit	(90,116,254)	(72,405,778)
Total shareholders' equity (deficit)	(11,245,680)	136,633
	$ 16,400,789	$ 27,684,270

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, 2014 and 2013

	2014	2013
Revenues	$ 16,817,403	$ 10,947,361
Cost of goods sold	3,442,183	2,439,818
Gross profit	13,375,220	8,507,543
Costs and expenses:		
Sales and marketing	13,193,795	10,259,153
Research and development	3,033,325	2,125,476
General and administrative	6,948,890	5,715,119
Total costs and expenses	23,176,010	18,099,748
Loss from operations	(9,800,790)	(9,592,205)
Other income (expense):		
Interest expense	(6,812,315)	(4,819,708)
Interest expense — deferred financing costs	(1,100,520)	(178,864)

Other income	3,149	33,892
Total other income (expense)	(7,909,686)	(4,964,680)
Net Loss	(17,710,476)	(14,556,885)
Weighted Average Common Shares outstanding — basic and diluted	17,721,742	13,499,793
Loss Per Common share — basic and diluted	$ (0.99)	$ (1.08)

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

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AXOGEN, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
Years ended December 31, 2014 and 2013

	Common Stock		Additional Paid-in	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Deficit	Equity/(Deficit)
Balance, December 31, 2012	11,122,573	$ 111,226	$ 54,908,226	$ (57,848,893)	$ (2,829,441)
Stock-based compensation	—	—	671,887	—	671,887
Exercise of stock options	32,656	326	73,000	—	73,326
Issuance of common shares	6,184,332	61,843	16,715,903	—	16,777,746
Net loss	—	—	—	(14,556,885)	(14,556,885)
Balance, December 31, 2013	17,339,561	173,395	72,369,016	(72,405,778)	136,633
Stock-based compensation	—	—	956,449	—	956,449
Exercise of stock options	117,402	1,174	134,666	—	135,840
Issuance of common shares	2,031,851	20,319	5,215,555	—	5,235,874
Net loss	—	—	—	(17,710,476)	(17,710,476)
Balance, December 31, 2014	19,488,814	194,888	78,675,686	(90,116,254)	(11,245,680)

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, 2014 and 2013

	2014	2013
Cash flows from operating activities:		
Net loss	$ (17,710,476)	$ (14,556,885)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	153,670	79,232
Amortization of intangible assets	45,224	59,100
Loss on impairment	—	9,424
Amortization of deferred financing costs	199,328	178,864
Write off of deferred financing costs	901,192	—
Provision for bad debt	35,478	58,617
Stock-based compensation	956,449	671,887
Stock grant for service	60,125	—
Interest added to note payable	5,022,082	3,783,443
Change in assets and liabilities:		
Accounts receivable	(1,014,087)	(902,227)
Inventory	184,818	(247,329)
Prepaid expenses and other	187,350	(109,463)
Accounts payable and accrued expenses	498,290	430,579
Deferred revenue	29,498	100,000
Net cash used for operating activities	(10,451,059)	(10,444,758)

Cash flows from investing activities:		
Purchase of property and equipment	(542,045)	(178,776)
Acquisition of intangible assets	(52,002)	(65,189)
Net cash used for investing activities	(594,047)	(243,965)
Cash flows from financing activities:		
Proceeds from issuance of common stock	1,625,748	16,777,746
Repayments of long-term debt	(1,750,000)	—
Debt issuance costs	(820,441)	—
Proceeds from exercise of stock options	135,840	73,326
Net cash (used) / provided by financing activities	(808,853)	16,851,072
Net (decrease) / increase in cash and cash equivalents	(11,853,959)	6,162,349
Cash and cash equivalents, beginning of year	20,069,750	13,907,401
Cash and cash equivalents, end of period	$ 8,215,791	$ 20,069,750
Supplemental disclosures of cash flow activity:		
Cash paid for interest	$ 3,912,463	$ 1,030,219
Supplemental disclosure of non-cash investing and financing activities:		
Payments of fixed assets in accounts payable	$ 22,575	$ 173,611
Payments of long term debt with proceeds from note payable of $25,000,000 and issuance of shares of $3,550,000	28,550,000	—

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

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AXOGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2014 and 2013

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, 2014 and December 31, 2013 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

AxoGen is a leading medical technology company dedicated to peripheral nerve repair. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body and their damage can result in the loss of function and feeling. In order to improve surgical repair and regeneration of peripheral nerves, AxoGen has developed and licensed regenerative medicine technologies. AxoGen's innovative approach to regenerative medicine has resulted in first-in-class products that it believes are redefining the peripheral nerve repair market. AxoGen's products offer a full suite of surgical nerve repair solutions including Avance® Nerve Graft, a proprietary off-the-shelf processed nerve allograft (human nerve tissue obtained from a donor) used for bridging severed nerves without the comorbidities associated with a nerve autograft additional surgical site, AxoGuard® Nerve Connector, a porcine submucosa ExtraCellular Matrix ("ECM") coaptation aid for tensionless repair of severed nerves, and AxoGuard® Nerve Protector, a porcine submucosa ECM product used to wrap and protect injured peripheral nerves and reinforce coaptation sites while preventing soft tissue attachments. AxoGen also sells AxoTouch™ Two Point Discriminator, a measurement tool for determining innervation density and sensory function.

3. Summary of Significant Accounting Policies

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. Revenues for manufactured products and products sold to a customer or under a distribution agreement are recognized when the product is delivered to the customer or distributor, at which time title passes to the customer or distributor, provided, however, that in the case of revenues from consigned sales delivery is determined when the product is

utilized in a surgical procedure. Once a product is delivered, the Company has no further performance obligations. Delivery is defined as delivery to a customer location or segregation of product into a contracted distribution location. At such time, this product cannot be sold to any other customer. Fees charged to customers for shipping are recognized as revenues when products are shipped to the customer, distributor or end user. Revenues from research grants are recognized in the period the associated costs are incurred.

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 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.

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In 2013, we established a reserve for doubtful accounts as we did have some accounts deemed uncollectible. We regularly review all accounts that exceed 60 days from the invoice date and based on an assessment of current credit worthiness, estimate the portion, if any, of the balance that will not be collected. The analysis excludes certain government related receivables due to our past successful experience in collectability. Specific accounts that are deemed uncollectible are reserved at 100% of their outstanding balance. The remaining balances outstanding over 60 days have a percentage applied by aging category (5% for balances 61-90 days and 20% for balances over 90 days aged), based on a historical valuation that allows us to calculate the total reserve required. The reserve balance was determined by applying a percentage to the cumulative balance between 60 and 90 days and a higher percentage to the balance over 90 days. In the event that we exhaust all collection efforts and deem an account uncollectible, we would subsequently write off the account. The write off process involves approval by senior management based on the write off amount. The allowance for doubtful accounts reserve balance was approximately $94,000 and $58,000 at December 31, 2014 and 2013, respectively.

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

Inventories

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

	December 31, 2014	December 31, 2013
Finished goods	$ 2,072,235	$ 2,131,336
Work in process	331,891	235,966
Raw materials	809,494	1,031,136
	$ 3,213,620	$ 3,398,438

Inventories are net of reserve of approximately $404,000 and $383,000 at December 31, 2014 and 2013, 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 5 and other costs related to the license agreements, including patent prosecution and protection costs. Such costs are capitalized and amortized on a straight-line basis over the underlying terms of the license agreements or estimated useful life of patents, ranging from 5 to 20 years.

Impairment of Long-lived Assets, Including License Agreements

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be

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generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. For the years ended December 31, 2014 and 2013, the Company recorded an impairment loss of $0 and $9,424, respectively.

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.

Effective Interest Rate on Note payable

The PDL Royalty Contract was accounted for as long-term debt. AxoGen recorded interest using its best estimate of the effective interest rate. This estimate took into account both the internal rate of return (IRR) of the PDL agreement and the rate of return as the result of exercise of the put option. The IRR of the PDL Royalty Contract was based on the actual payments to date, projected future revenues and required minimum payments, and was calculated at 20.535%. The PDL Royalty Contract Put option provided PDL a 20% return, if exercised. As a result of the return of the Put option being higher than the IRR of the PDL agreement, management believed the best estimate of the effective interest rate on this instrument would be the Put rate. As a result, AxoGen was accruing interest using the specified internal rate of return for the Put which was 20%. The PDL Royalty Contract was paid in full on November 12, 2014. The Company has no further obligation under the PDL Royalty Contract.

The Term Loan Agreement and Revenue interest Agreement are used in calculating the effective interest rate. AxoGen records interest using its best estimate of the effective interest rate. This estimate takes into account both the rate on the Term Loan Agreement and the rate associated with the 10 year Revenue Interest Agreement with Three Peaks. The effective interest rate is based on actual payments to date, projected future revenues and the projected royalty payments and the quarterly interest payments due on the Term Loan Agreement. From time to time, AxoGen will reevaluate the expected cash flows and may adjust the effective interest rate. Determining the effective interest rate requires judgment and is based on significant assumptions related to estimates of the amounts and timing of future revenue streams. Determination of these assumptions is highly subjective and different assumptions could lead to materially different outcomes.

Advertising

Advertising costs are expensed as incurred. Advertising costs were $8,000 and $37,000 for the years ended December 31, 2014 and 2013, respectively, and are included in sales and marketing expense on the accompanying consolidated statements of operations.

Research and Development Costs

Research and Development costs are expensed as incurred and were approximately $3,033,000 and $2,125,000 for the years ended December 31, 2014 and 2013, respectively.

Income Taxes

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

The Company identifies and evaluates uncertain tax positions, if any, and recognizes the impact of uncertain tax positions for which there is a less than more-likely-than-not probability of the position being upheld when reviewed by the relevant taxing authority. Such positions are deemed to be unrecognized tax benefits and a corresponding liability is established on the balance sheet. The Company has not recognized a liability for uncertain tax positions. If there were an unrecognized tax benefit, the Company would recognize interest accrued related to unrecognized tax benefits in interest expense and penalties in operating expenses. The Company's remaining open tax years subject to examination by the Internal Revenue Service include the years ended December 31, 2010 through 2014; there currently are no examinations in process.

Fair Value of Financial Instruments

The respective carrying value of certain on-balance-sheet financial instruments approximated their fair values due to the short-term nature of these instruments. These financial instruments include cash, accounts receivable, accounts payable and accrued expenses. The fair value of

the Company's long-term debt approximates its carrying value based upon current rates available to the Company.

Stock-Based Compensation

Stock-based compensation cost related to stock options granted under the AC 2002 Stock Option Plan and AxoGen 2010 Stock Incentive Plan (see Note 10) is measured at grant date, based on the fair value of the award, and is recognized as an expense over the employee's requisite service period. The Company estimates the fair value of each option award issued under the Plan on the date of grant using a Black-Scholes-Merton option-pricing model that uses the assumptions noted in the table below. The Company estimates the volatility of its common stock at the date of grant based on the volatility of comparable peer companies which are publicly traded, for the periods prior to the merger, and based on the Company's common stock for periods subsequent to the merger. The Company determines the expected life based on historical experience with similar awards, giving consideration to the contractual terms, vesting schedules and post-vesting forfeitures. The Company uses the risk-free interest rate on the

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implied yield currently available on U.S. Treasury issues with an equivalent remaining term approximately equal to the expected life of the award. The Company has never paid any cash dividends on its common stock and does not anticipate paying any cash dividends in the foreseeable future. The Company used the following weighted-average assumptions for options granted during the year ended December 31:

Years ended December 31,	2014	2013
Expected term (in years)	4.0	4.0
Expected volatility	78.31%	83.15%
Risk free rate	1.26%	0.79%
Expected dividends	0.0%	0.0%

The Company estimates forfeitures when recognizing compensation expense and this estimate of forfeitures is adjusted over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative catch-up adjustment, which is recognized in the period of change, and also impact the amount of unamortized compensation expense to be recognized in future periods. The Company did not apply a forfeiture allocation to its unvested options outstanding during the years ended December 31, 2014 and 2013 as they were deemed insignificant.

Earnings (Loss) Per Common Share

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

There were no dilutive instruments as of December 31, 2014 and 2013. The basic and diluted weighted average shares outstanding were 17,721,742 and 13,499,793 for the years ended December 31, 2014 and 2013.

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 May 2014, the FASB issued a new standard on revenue recognition which outlines a single comprehensive model to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The core principle of the revenue model is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is designed to create greater comparability for financial statement users across industries and jurisdictions and also requires enhanced disclosures. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is not permitted. We are currently evaluating the impact of the adoption of this standard on our consolidated financial statements.

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

4. Property and Equipment

Property and equipment consist of the following:

	December 31, 2014	December 31, 2013
Furniture and equipment	$ 873,824	$ 893,973

Leasehold improvements	285,697	53,864
Processing equipment	1,194,712	1,015,388
Less: accumulated depreciation and amortization	(1,735,205)	(1,581,536)
Property and equipment	$ 619,028	$ 381,689

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5. Intangible Assets

The Company's intangible assets consist of the following:

	December 31, 2014	December 31, 2013
License agreements	$ 850,859	$ 816,300
Patents	79,996	62,553
Less: accumulated amortization	(353,681)	(308,457)
Intangible assets, net	$ 577,174	$ 570,396

License agreements are being amortized over periods ranging from 17-20 years. Patent costs were being amortized over three years. As of December 31, 2014, the patents were fully amortized, the remaining patents of $79,996 are pending patent costs and are not amortizable. Amortization expense for 2014 and 2013 was approximately $45,000 and $59,000, respectively. As of December 31, 2014, future amortization of license agreements is expected to be $47,000 for 2015 through 2019.

In 2014 and 2013, the Company performed an evaluation of certain patents and determined that the carrying value of such patents were not recoverable and exceeded their estimated fair value. As a result, the Company recorded in the year ended December 31, 2014 and 2013 an impairment loss of $0 and $9,424, respectively, to reduce these patents to their estimated fair value.

License Agreements

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

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

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

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

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

Royalty fees were approximately $329,000 and $230,000 during 2014 and 2013 and are included in sales and marketing expense on the accompanying consolidated statements of operations.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consists of the following:

	December 31, 2014	December 31, 2013
Accounts payable	$ 1,160,859	$ 1,181,375
Miscellaneous Accruals	105,315	152,239
Accrued Compensation	1,165,020	750,328
Accounts Payable and Accrued Expenses	$ 2,431,194	$ 2,083,942

7. Note Payable

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

	December 31, 2014	December 31, 2013
Revenue Interest Purchase Agreement with PDL BioPharma, Inc. ("PDL") for aggregate of $20,800,000 with amounts payable monthly at 9.95% of Net Revenues through September 2014; and the greater of (i) 9.95% of product revenue or (ii) specific quarterly amounts varying from approximately $1.3 million to $2.5 million per quarter through September 2020. The minimum annual payment amounts were as follows: 2014 - $1,250,805, 2015 - $6,781,440, 2016 - $9,232,642, 2017 and 2018 - $9,000,000, 2019 - $9,063,000 and 2020 - $6,939,000.	—	$ 25,363,695
Term Loan and Revenue Interest Agreement with Three Peaks Capital S.a.r.l. ("Three Peaks") for a total term loan amount of $25,000,000 which has a six year term and requires interest only payments and a final principal payment due at the end of the term. Interest is payable quarterly at 9.00% per annum plus the greater of LIBOR or 1.0% which as of November 13, 2014 ("the Initial Closing Date") and December 31, 2014 resulted in a 10% rate. The Revenue Interest Agreement is for a period of ten years. Royalty payments are based on a royalty rate of 3.75% of revenues up to a maximum of $30 million in revenues in any 12 month period.	$ 25,085,777	—
Long-term portion	$ 25,085,777	$ 25,363,695

Note Payable

On October 5, 2012, AxoGen entered into a Revenue Interests Purchase Agreement (the "Royalty Contract") with PDL BioPharma, Inc. ("PDL"), pursuant to which the Company sold to PDL the right to receive royalties equal to 9.95% of the Company's Net Revenues (as defined in the Royalty Contract) generated by the sale, distribution or other use of AxoGen's products Avance® Nerve Graft, AxoGuard® Nerve Connector and AxoGuard® Nerve Protector. The Royalty Contract had a term of eight years. Under the Royalty Contract, PDL received royalty payments based on a royalty rate of 9.95% of the Company's Net Revenues, subject to certain agreed upon minimum payment requirements, which were anticipated to be approximately $1.3 to $2.5 million per quarter tobegin in the fourth quarter of 2014 through the third quarter of 2020 as provided in the Royalty Contract. The Company recorded interest using its best estimate of the effective interest rate accruing interest using the specified

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internal rate of return of the Put Option of 20%. The total consideration PDL paid to the Company was $20,800,000 (the "Funded Amount"), which included $19,050,000 PDL paid to the Company on October 5, 2012, and $1,750,000 PDL paid to the Company on August 14, 2012 pursuant to an Interim Revenue Interest Purchase Agreement between the Company and PDL, dated August 14, 2012 (the "Interim Royalty Contract"). Upon the closing (the "Closing") of PDL's purchase of the specified royalties described above, which was concurrent with the execution of the Royalty Contract, the Interim Royalty Contract was terminated. On November 12, 2014, the Company paid PDL $30.3 million to fully extinguish the Royalty Contract. The Company has no further obligations under the Royalty Contract.

As a result of the accounting treatment for the Three Peaks transaction, interest expense for 2014 included approximately $86,000 of non-cash expense that is expected to be paid in the future based upon the terms of the Three Peaks transaction and increases in AxoGen revenues. The $86,000 of non-cash expense was derived from taking the imputed interest for 2014 on the Three Peaks agreement less the actual cash payment made to Three Peaks for the year. Other than the $86,000 non-cash expense, the remaining $6,724,000 in interest expense for 2014 is related to cash paid for interest on the note payable with PDL and the interest paid on the Term Loan with Three Peaks.

On November 12, 2014, the Company sold 643,382 shares of common stock for a total of $1.75 million to PDL ("PDL Equity Sale") at a price of $2.72 per share pursuant to a Securities Purchase Agreement by and between the Company and PDL. The Company intends to use the proceeds from the PDL Equity Sale for general corporate purposes.

Term Loan Agreement and Revenue Interest Agreement

On November 12, 2014, (the "Signing Date"), AxoGen, as borrower, and AC, as guarantor, entered into a term loan agreement (the "Term Loan Agreement") with the lenders party thereto and Three Peaks Capital S.a.r.l. ("Three Peaks"), an indirect wholly-owned subsidiary of Oberland Capital Healthcare Master Fund LP ("Oberland"), as administrative and collateral agent for the lenders. Under the Term Loan Agreement, Three Peaks has agreed to lend to AxoGen a term loan of $25 million (the "Initial Term Loan") which has a six year term and requires interest only payments and a final principal payment due at the end of the term. Interest is payable quarterly at 9.00% per annum plus the greater of LIBOR or 1.0% which as of November 13, 2014 ("the Initial Closing Date") resulted in a 10% rate. Under certain conditions, AxoGen has the option to draw an additional $7 million ("Subsequent Borrowing" and, together with the Initial Term Loan, (the "Term Loan") during the period of April 1, 2016 through June 29, 2016 (the closing date of each such Subsequent Borrowing, a ("Subsequent Closing Date" and, together with the Initial Closing Date, the "Closing Dates") under similar terms and conditions. AxoGen has to maintain certain covenants including limiting new indebtedness, restriction of the payment of dividends and maintain certain levels of revenue. Three Peaks has a first perfected security interest in the assets of AxoGen.

In addition, AxoGen entered into a 10 year Revenue Interest Agreement ("Revenue Interest Agreement") with Three Peaks. Royalty payments are based on a royalty rate of 3.75% of AxoGen's revenues up to a maximum of $30 million in revenues in any 12 month period. In the event the Subsequent Borrowing is drawn, the royalty rate increases proportionally up to a maximum of 4.80%. AxoGen has to maintain certain covenants including those covenants under the Term Loan.

Under the Term Loan Agreement, AxoGen has the option at any time to prepay the Term Loan, in whole or in part, and the Royalty Interest Agreement, defined below, by making the following payment, and Three Peaks has the right to demand the following payment upon a change of control of AxoGen, sale of the majority of AxoGen's assets or a material adverse change to AxoGen: (i) on or prior to the first anniversary of the applicable Closing Date, 120% of the outstanding principal amount of the Term Loan or any portion being prepaid; (ii) after the first anniversary but no later than the second anniversary of the applicable Closing Date, 135% of the outstanding principal amount of the Term Loan or any portion being prepaid ; (iii)) after the second anniversary but no later than the third anniversary of the applicable Closing Date, 150% of the outstanding principal amount of the Term Loan or any portion being prepaid; or (iv)) after the third anniversary of the applicable Closing Date, an amount generating an Internal Rate of Return of 16.25% of the outstanding principal amount of the Term Loan or any portion being prepaid. In all cases, the amount due is reduced by the sum of interest and principal previously paid and all amounts received under the Revenue Interest Agreement. In each such case AxoGen will also owe an additional 3% of the originally advanced Term Loan amount. Upon payment to Three Peaks, AxoGen would have no further obligations to Three Peaks under the Term Loan or the Revenue Interest Agreement.

In connection with the Term Loan Agreement, on the Signing Date, the Company and its wholly owned subsidiary, AC entered into a Security Agreement (the "Security Agreement") with Three Peaks, pursuant to which each of the Company and AC grants to Three Peaks a security interest in certain collateral as specified in the Security Agreement to guarantee the payment in full when due of the Secured Obligations.

Also in connection with the above transaction, the Company sold 1,375,969 shares of common stock to Three Peaks for a total of $3.55 million ("Three Peaks Equity Sale") at a price of $2.58 per share. Pursuant to the equity purchase provisions in the Three Peaks Term Loan Agreement, in the event that we sell prior to November 12, 2016 our securities at a lower price per share than the $2.58 per share paid by Three Peaks, or where the terms of such subsequent sale are otherwise more favorable, then in such case we have agreed to match the more favorable terms of such subsequent sale with respect to the shares purchased by Three Peaks. A subsequent sale does not include the issuance of securities or options to our employees, officers, directors or consultants pursuant to our

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approved employee option pool or any other employee stock purchase or option plan existing as of November 12, 2014.

The Company records interest using its best estimate of the effective interest rate. This estimate takes into account both the rate on the Term Loan Agreement and the rate associated with the 10 year Revenue Interest Agreement with Three Peaks. The effective interest rate is based on actual payments to date, projected future revenues and the projected royalty payments and the quarterly interest payments due on the Term Loan Agreement. From time to time, AxoGen will reevaluate the expected cash flows and may adjust the effective interest rate. Determining the effective interest rate requires judgment and is based on significant assumptions related to estimates of the amounts and timing of future revenue streams. Determination of these assumptions is highly subjective and different assumptions could lead to materially different outcomes.

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.

Warrants

Pursuant to a retired financing agreement, certain lenders received a ten-year warrant to purchase 89,686 shares of AxoGen's common

stock at $2.23 per share. The warrants have an effective date of September 30, 2011.

9. Stock 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, AxoGen, Inc., formerly LecTec Corporation, 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. At the 2014 Annual Meeting of Shareholders the AxoGen Plan was amended and restated to, among other things, increase the number of shares of common stock authorized for issuance under the plan by 750,000 shares so that the total number of shares authorized for issuance under the AxoGen Plan is 3,500,000 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 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 $956,449 and $671,887 for 2014 and 2013, respectively.

The following is a summary of stock option activity:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term(Years)
Outstanding at December 31, 2012:	1,799,991	2.54	7.66
Granted	261,000	3.72	
Forfeited	(58,843)	(3.48)	
Exercised	(32,656)	(2.25)	
Outstanding at December 31, 2013:	1,969,492	2.68	6.61
Granted	935,750	3.57	
Forfeited	(44,023)	(3.78)	
Exercised	(117,401)	(1.16)	
Outstanding at December 31, 2014	2,743,818	3.03	5.94
Exercisable at December 31, 2014	1,584,326	2.78	5.57

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The average fair value of options granted at market during 2014 and 2013 was $3.57 and $3.72 per option, respectively.

The intrinsic value of options exercised during the years ended December 31, 2014 and 2013 was approximately $266,000 and $48,000, respectively. The intrinsic value of options outstanding at December 31, 2014 and 2013 was approximately $1,535,000 and $3,571,000, respectively. The intrinsic value of options exercisable at December 31, 2014 and 2013 was approximately $1,278,000 and $2,487,000, respectively.

Total future compensation expense related to nonvested awards is expected to be approximately $2,120,000 at December 31, 2014 which is expected to be recognized over a weighted average period of 2.19 years. The following table represents non-vested share-based payment activity with employees for the years ended December 31, 2014 and 2013:

	Number of Options	Weighted Average Exercise Price
Nonvested options - December 31, 2012:	858,115	2.36
Granted	261,000	3.72
Vested	(385,076)	(2.22)
Forfeited	(58,843)	(3.48)
Nonvested options - December 31, 2013:	675,196	2.88
Granted	935,750	3.57
Vested	(407,437)	(3.03)
Forfeited	(44,023)	(3.78)
Nonvested options - December 31, 2014	1,159,486	3.37

10. Income Taxes

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

December 31	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	$ 29,263,100	$ 23,075,700
Charitable contributions	500	500
Inventory Reserves	152,000	144,000
Stock-based compensation	107,900	101,500
Total deferred tax assets	29,523,500	23,321,700
Deferred tax liabilities:		
Depreciation	(85,700)	(84,100)
Amortization	123,500	121,000
Total deferred tax assets (liabilities)	37,800	36,900
Net deferred tax assets	29,561,300	23,358,600
Valuation allowance	(29,561,300)	(23,358,600)

As of December 31, 2014, the Company had net operating loss carry forwards of approximately $77.8 million to offset future taxable income which expire in various years through 2034. 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, 2014 and 2013. The valuation allowance increased by $6,202,700 and $4,962,500 during 2014 and 2013, respectively.

The Company had no income tax expense or income tax benefit for 2013 and 2014 due to incurrence of net operating losses. The Company does not believe there are any additional tax refund opportunities currently available.

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11. Employee Benefit Plan

The Company adopted the AxoGen Simple IRA plan in 2007. All full-time employees who have attained the age of 18 are eligible to participate in the Plan. Eligibility is immediate upon employment and enrollment is available any time during employment. Participating employees may make annual pretax contributions to their accounts up to a maximum amount as limited by law. The simple IRA plan requires the Company to make matching contributions of between 1% and 3% of the employee's annual salary as long as the employee participates in the Plan. Additionally, the matching has to be at least 3% for three of the first five years of the Plan. Both employee contributions and Company contributions vest immediately. In 2014 and 2013, the Company match was 3% of the participating employee's annual salary. The Company contributed $146,681 and $126,322 in matching funds during 2014 and 2013, respectively.

12. Commitments and Contingencies

Operating Leases

On November 12, 2013, AxoGen entered into the Third Amendment to Lease with SNH Medical Office Properties Trust ("SNH"). SNH was the landlord of AxoGen's corporate headquarters leased facility in Alachua, Florida and AxoGen and SNH agreed to the amendment by which AxoGen relocated and expanded its corporate headquarters to a new space owned by SNH within the same office park. The lease amendment provides for 11,761 square feet of office space until October 31, 2018, renewable thereafter by agreement of the parties, subject to AxoGen's right to earlier termination after three years from the effective date of the lease. AxoGen's annual cost of such property ranges from approximately $194,000 to $206,000 per year.

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

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

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

Year ending December 31	Amount
2015	$ 243,000
2016	244,000
2017	206,000
2018	194,000
2019	—
TOTAL	$ 887,000

Total rent expense for the Company's leased office and lab space for the years ended December 31, 2014 and 2013 was approximately $288,000 and $197,000, respectively.

Service Agreements

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

In August 2008, the Company entered into an agreement to distribute the AxoGuard® product worldwide in the field of peripheral nerve repair, and the parties subsequently amended the agreement in March, 2012. The agreement has an initial seven-year term from the date of the original agreement and following such initial term, the agreement automatically renews for an additional seven (7) year period pursuant to AxoGen's and Cook's agreement as to meeting the parameters for such renewal. AxoGen and Cook Biotech have agreed that the parameters for renewal have been met and the contract will automatically renew for the additional seven (7) year period. The Cook Biotech agreement also requires certain minimum purchases, although through mutual agreement the parties have not established such minimums and to date have not enforced such provision, and establishes a formula for the transfer

cost of the AxoGuard® products. Under the agreement, AxoGen provides purchase orders to Cook Biotech, and Cook Biotech fulfills the purchase orders.

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

Certain executive officers of the Company are parties to employment contracts. All such contracts have severance payments for certain conditions including change of control.

Concentrations

Vendor

All of AxoGen's revenue is currently derived from three products, Avance® Nerve Graft, AxoGuard® Nerve Protector and AxoGuard® Nerve Connector. AxoGen has an exclusive distribution agreement with Cook Biotech for the purchase of AxoGuard®. AxoGen and Cook Biotech have agreed that the parameters for renewal have been met and the contract will automatically renew for the additional seven (7) year period from August 2015. The Cook Biotech agreement also requires certain minimum purchases, although through mutual agreement the parties have not established such minimums and to date have not enforced such provision, and establishes a formula for the transfer cost of the AxoGuard® products.

The agreement allows for termination provisions for both parties. Although there are products that AxoGen believes it could develop or obtain that would replace the AxoGuard® products, the loss of the ability to sell the AxoGuard® products could have a material adverse effect on AxoGen's business until other replacement products would be available.

Processor

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

13. Subsequent Events

Public Offering of Common Stock

On February 5, 2015, AxoGen entered into the Underwriting Agreement with the Underwriter, in connection with the offering, issuance and sale (the "Offering") of 4,728,000 shares of the Company's common shares, par value $0.01 per share (the "Common Shares"), at a price to the public of $2.75 per share. The Company also granted to the Underwriter a 30-day option to purchase up to an aggregate of 709,200 additional Common Shares to cover over-allotments, if any.

The Offering was made pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-195588) previously filed with the Securities and Exchange Commission, and pursuant to the prospectus supplement and the accompanying prospectus describing the terms of the Offering, dated February 5, 2015.

As of February 13, 2015, the Offering was completed with the sale of 5,437,200 Common Shares, which included the exercise of the over-allotment option, at $2.75 per share resulting in gross proceeds to AxoGen from the Offering of approximately $15.0 million, before deducting underwriting discounts and commissions and other

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estimated offering expenses payable by AxoGen estimated at approximately $1.4 million. The Common Shares were listed on the NASDAQ Capital Market.

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, 2014 and concluded that our disclosure controls and procedures were effective as of December 31, 2014.

MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

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

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

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

Based on its evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2014 based on the criteria in Internal Control-Integrated Framework (2013) issued by the COSO.

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

CHANGES IN INTERNAL CONTROLS OVER FINANCIAL REPORTING

During the year ended December 31, 2014, there were no changes in the Company's internal control over financial reporting (as defined in Rule 13a-15(f) and 15d—15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Information required by this item concerning our directors will be set forth under the caption "Election of Directors" in our definitive proxy statement for our 2015 annual meeting, and is incorporated herein by reference.

Information required by this item concerning compliance with Section 16(a) of the Exchange Act, as amended, will be set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for our 2015 annual meeting, and is incorporated herein by reference.

Information required by this item concerning the audit committee of the Company, the audit committee financial expert of the Company and any material changes to the way in which security holders may recommend nominees to the Company's Board of Directors will be set forth under the caption "Corporate Governance" in our definitive proxy statement for our 2015 annual meeting, and is incorporated herein by reference.

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

ITEM 11. EXECUTIVE COMPENSATION.

Information required by this item will be set forth under the caption "Executive Compensation" in our definitive proxy statement for our 2015 annual meeting, and is incorporated herein by reference.

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

Information required by this item concerning ownership will be set forth under the caption "Security Ownership of Certain Beneficial Owners", "Security Ownership of Directors and Executive Officers" and " Equity Compensation Plan Information" in our definitive proxy statement for our 2015 annual meeting, and is incorporated herein by reference.

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

Information required by this item concerning ownership will be set forth under the caption "Corporate Governance — Director Independence" and "Certain Relationships and Related Transactions" in our definitive proxy statement for our 2015 annual meeting, and is incorporated herein by reference.

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ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information required by this item concerning ownership will be set forth under the caption "Proposal 2 — Ratification of Appointment of Independent Registered Public Accounting Firm" in our definitive proxy statement for our 2015 annual meeting, and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this Report

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

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

(3) Exhibits

Exhibit Number	Description
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 filed on October 6, 2011)

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**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 to Amended and Restated Nerve Tissue Processing Agreement, dated as of March 12, 2012, by and between AxoGen Corporation and LifeNet Health (incorporated by reference to the Company's Annual Report on Form 10-K filed for the year ended December 31, 2011)
**10.4.4	Fourth Amendment to Amended and Restated Nerve Tissue Processing Agreement, dated as of September 8, 2014, by and between AxoGen Corporation and LifeNet Health (incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014)
**10.5.1	Distribution Agreement, dated as of August 27, 2008, by and between AxoGen, Inc. and Cook Biotech Incorporated (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
10.5.2	Amendment dated March 14, 2012 to Distribution Agreement, dated as of August 27, 2008, by and between AxoGen, Inc. and Cook Biotech Incorporated (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2011)
**10.6.1	Revenue Interests Purchase Agreement, dated as of October 5, 2012, by and among AxoGen, Inc. and PDL BioPharma, Inc. (incorporated by reference to the Company's Amendment No. 1 on Form 10-K/A filed on August 7, 2013 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012)
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10.6.3	Interim Revenue Interests Purchase Agreement dated August 14, 2012, by and between AxoGen, Inc. and PDL BioPharma, Inc. (incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012)

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10.7	LecTec Corporation 2010 Stock Incentive Plan, Amended and Restated on September 27, 2011 (incorporated by reference to Appendix E to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
***10.8.1	Executive Employment Agreement, effective as of October 15, 2007, by and between AxoGen Corporation and Karen Zaderej (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
***10.8.2	Amendment to Executive Employment Agreement, effective as of September 29, 2011, by and between AxoGen Corporation and Karen Zaderej (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
***10.9.1	Executive Employment Agreement, effective as of May 6, 2003, by and between AxoGen Corporation and John P. Engels (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
***10.9.2	Amendment to Executive Employment Agreement, effective as of September 29, 2011, by and between AxoGen Corporation and John P. Engels (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
10.10.1	Lease dated as of February 6, 2007, by and between AxoGen Corporation and WIGSHAW, LLC, its successors and assigns (incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on November 14, 2011)
10.10.2	Second Amendment dated February 27, 2013 to lease dated as of February 6, 2007, by and between AxoGen Corporation and WIGSHAW, LLC, its successors and assigns (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2012)
10.10.3	Third Amendment dated November 12, 2013 to lease dated as of February 6, 2007, by and between AxoGen Corporation and SHN Medical Office Properties, its successors and assigns (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2013)

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***10.15	Form of Employee Incentive Stock Option Agreement (incorporated by reference to the Company's Current Report on Form 8-K filed on September 26, 2007)
***10.16	Executive Employment Agreement, effective as of October 1, 2011, by and between AxoGen, Inc. and Gregory G. Freitag (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2011)
***10.16.1	Amendment to Executive Employment Agreement, effective as of May 11, 2014, by and between AxoGen, Inc. and Greg Freitag (incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on August 4, 2014)
***10.17	Executive Employment Agreement, effective as of February 27, by and between AxoGen, Inc. and Jill Schiaparelli (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2011)
10.18	Commercial Lease dated October 25, 2013 by and between AxoGen Corporation and Ja-Cole, as amended December 10, 2013. (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2013)
10.19.1	Loan and Security Agreement, dated as of September 30, 2011, by and among AxoGen, Inc. and AxoGen Corporation, as borrower, Midcap Financial SBIC, LP, as administrative agent, and the Lenders listed on Schedule 1 thereto (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
10.19.2	First Amendment to Loan and Security Agreement dated August 14, 2012, by and between AxoGen, Inc. and Midcap Financial SBIC, LP. (incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012)
10.19.3	Subordination and Intercreditor Agreement dated August 14, 2012, by and between AxoGen, Inc., PDL BioPharma, Inc. and Midcap Financial SBIC, LP. (incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012)
***10.20	Executive Employment Agreement, effective as of February 25, 2013, by and between AxoGen, Inc. and Shawn McCarrey (incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013)
***10.21	Executive Employment Agreement, dated May 12, 2014, between Lee R. Johnston, Jr. and AxoGen Corporation, a wholly owned subsidiary of AxoGen, Inc. (incorporated by reference to the Company's Quarterly Report on Form 10-Q

filed on August 4, 2014)

*10.22	Term Loan Agreement dated as of November 12, 2014 among AxoGen, Inc. as Borrower, AxoGen Corporation, as Guarantor, the Lenders party hereto and Three Peaks Capital S.a.r.l., as Administrative Agent and Collateral Agent (incorporated by reference to Amendment No. 1 on Form 8-K/A (to the Company's Current Report on Form 8-K filed on November 13, 2014) filed on February 4, 2015)
10.23	Revenue Interest Agreement dated as of November 12, 2014 among AxoGen, Inc., AxoGen Corporation and Three Peaks Capital S.a.r.l. (incorporated by reference to Amendment No. 1 on Form 8-K/A (to the Company's Current Report on Form 8-K filed on November 13, 2014) filed on February 4, 2015)
10.24	Security Agreement dated as of November 12, 2014 among AxoGen, Inc., AxoGen Corporation and Three Peaks Capital S.a.r.l. (incorporated by reference to Amendment No. 1 on Form 8-K/A (to the Company's Current Report on Form 8-K filed on November 13, 2014) filed on February 4, 2015)
10.25	Securities Purchase Agreement dated as of November 12, 2014, between AxoGen, Inc., and PDL BioPharma, Inc. (incorporated by reference to Amendment No. 1 on Form 8-K/A (to the Company's Current Report on Form 8-K filed on November 13, 2014) filed on February 4, 2015)
+21.1	Subsidiary of the Registrant
+23.1	Consent of Lurie Besikof Lapidus & Company, LLP
++24.1	Power of Attorney
+31.1	Certification of Principal Executive Officer
+31.2	Certification of Principal Financial Officer
+++32.1	Chief Executive Officer Certification Pursuant to 18 U.S.C. 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
+101.INS	XBRL Instance Document.
+101.SCH	XBRL Taxonomy Extension Schema Document.
+101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
+101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
+101.LAB	XBRL Extension Labels Linkbase.
+101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

* Confidential treatment has been 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.

+++ Furnished herewith.

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SIGNATURES

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

AXOGEN, INC

/s/ Karen Zaderej
Karen Zaderej
Chief Executive Officer

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

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

/s/ Karen Zaderej Karen Zaderej Chief Executive Officer and Director (Principal Executive Officer)	March 5, 2015
/s/Lee Robert Johnston, Jr. Lee Robert Johnston, Jr. (Principal Financial Officer) (Principal Accounting Officer)	March 5, 2015
/s/ Greg Freitag Greg Freitag, General Counsel, SVP Business Development Director	March 5, 2015
/s/ Jamie Grooms Jamie Grooms Director	March 5, 2015
/s/ Robert Rudelius Robert Rudelius Director	March 5, 2015
/s/ Dr. Mark Gold Mark Gold, M.D. Director	March 5, 2015
/s/ John Harper John Harper Director	March 5, 2015
/s/ Joe Mandato Joe Mandato Director	March 5, 2015

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EXHIBIT INDEX

Exhibit Number	Description
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 filed on October 6, 2011)
**10.4.2	Second Amendment to Amended and Restated Nerve Tissue Processing Agreement, dated as of August 9, 2011, by and between AxoGen Corporation and LifeNet Health (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
**10.4.3	Third Amendment to Amended and Restated Nerve Tissue Processing Agreement, dated as of March 12, 2012, by and between AxoGen Corporation and LifeNet Health (incorporated by reference to the Company's Annual Report on Form 10-K filed for the year ended December 31, 2011)
**10.4.4	Fourth Amendment to Amended and Restated Nerve Tissue Processing Agreement, dated as of September 8, 2014, by and between AxoGen Corporation and LifeNet Health (incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014)
**10.5.1	Distribution Agreement, dated as of August 27, 2008, by and between AxoGen, Inc. and Cook Biotech Incorporated (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
10.5.2	Amendment dated March 14, 2012 to Distribution Agreement, dated as of August 27, 2008, by and between AxoGen, Inc. and Cook Biotech Incorporated (incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2011)
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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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assigns (incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on November 14, 2011)

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+21.1	Subsidiary of the Registrant
+23.1	Consent of Lurie Besikof Lapidus & Company, LLP

++24.1	Power of Attorney
+31.1	Certification of Principal Executive Officer
+31.2	Certification of Principal Financial Officer
+++32.1	Chief Executive Officer Certification Pursuant to 18 U.S.C. 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
+101.INS	XBRL Instance Document.
+101.SCH	XBRL Taxonomy Extension Schema Document.
+101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
+101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
+101.LAB	XBRL Extension Labels Linkbase.
+101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

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

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*** Management contract or compensatory plan or arrangement.

+ Filed herewith.

++ Included on signature page.

+++ Furnished herewith.

EXHIBIT 21.1

SUBSIDIARY OF AXOGEN, INC.

As of December 31, 2014, AxoGen Inc.'s sole subsidiary was AxoGen Corporation, a Delaware corporation.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of AxoGen, Inc. on Form S-3 (File No. 333-195588) and Form S-8 (File Nos. 333-201238 and 333-177980) of our report dated March 5, 2015, appearing in this annual report on form 10-K of AxoGen, Inc. as of and for the years ended December 31, 2014 and 2013.

/s/ LURIE BESIKOF LAPIDUS & COMPANY, LLP

Minneapolis, Minnesota
March 5, 2015

EXHIBIT 31.1

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

I, Karen Zaderej, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 5, 2015

/s/ Karen Zaderej
Karen Zaderej
Chief Executive Officer

EXHIBIT 31.2

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

I, Lee Robert Johnston, Jr., 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 5, 2015

/s/ Lee Robert Johnston, Jr.
Lee Robert Johnston, Jr.
Chief Financial Officer

EXHIBIT 32.1

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

In connection with the Annual Report of AxoGen, Inc. (the "Company") on Form 10-K for the year ended December 31, 2014 as filed with the Securities and Exchange Commission (the "Report"), I, Karen Zaderej, Chief Executive Officer and Lee Robert Johnston, Jr., 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 5, 2015

/s/ Lee Robert Johnston, Jr.
Lee Robert Johnston, Jr.
Chief Financial Officer
March 5, 2015