

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**Form 10-K**

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(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, 2012**

Or

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

For the transition period from \_\_\_\_\_ TO \_\_\_\_\_

Commission File Number: **0-16159**

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**AXOGEN, INC.**

(Exact name of registrant as specified in its charter)

**MINNESOTA**

(State or other jurisdiction of  
incorporation or organization)

**41-1301878**

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

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

(Address of principal executive offices)

**32615**

(Zip Code)

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

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

**Securities registered pursuant to Section 12(g) of the Act:**

**Common Stock, par value \$0.01 per share**

(Title of class)

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

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

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

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

As of June 29, 2012, the value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$29,987,223 based upon the last reported sale price of the Common Stock at that date by the Over-the-Counter Bulletin Board.

The number of shares outstanding of the registrant's Common Stock as of March 11, 2013 was 11,127,869 shares.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

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**FORWARD-LOOKING STATEMENTS**

From time to time, in reports filed with the Securities and Exchange Commission (including this Form 10-K), in press releases, and in other communications to shareholders or the investment community, the Company may provide forward-looking statements concerning possible or anticipated future results of operations or business developments. These statements are based on management's current expectations or predictions of future conditions, events or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as "expects", "anticipates", "intends", "plans", "believes", "seeks", "estimates", "projects", "forecasts", "may", "should", variations of such words and similar expressions are intended to identify such forward-looking statements. The forward-looking statements may include, without limitation, statements regarding product development, product potential, regulatory environment, sales and marketing strategies, capital resources or operating performance. The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the statements. Forward-looking statements in this Form 10-K should be evaluated together with the many uncertainties that affect the Company's business and its market, particularly those discussed in the risk factors and cautionary statements in the Company's filings with the Securities and Exchange Commission, including as described in "Risk Factors" included in Item 1A of this Form 10-K. Forward-looking statements are not guarantees of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made, and the Company assumes no responsibility to update any forward-looking statements, whether as a result of new information, future events or otherwise.

**PART I**

**ITEM 1. BUSINESS**

**General**

The Company is a leading regenerative medicine company dedicated to advancing the science and commercialization of peripheral nerve repair solutions. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body and their damage can result in the loss of function and feeling. In order to improve surgical reconstruction and regeneration of peripheral nerves, the Company has developed and licensed patented and patent pending technologies. The Company's innovative approach to regenerative medicine has resulted in first-in-class products that will define their product categories. AxoGen's products offer a full suite of surgical nerve reconstruction solutions including Avance® Nerve Graft, the only commercially available processed nerve allograft for bridging severed nerves without the comorbidities associated with a second surgical site, AxoGuard® Nerve Connector, a porcine submucosa ExtraCellular Matrix ("ECM") coaptation aid for tensionless repair of severed nerves, and AxoGuard® Nerve Protector, a porcine submucosa ECM product used to wrap and protect injured peripheral nerves and reinforce coaptation sites while preventing soft tissue attachments.

AxoGen's products are used by surgeons during surgical interventions to repair a wide variety of traumatic nerve injuries ranging from a simple laceration of a finger to a complex brachial plexus case. The Avance® Nerve Graft, unlike hollow-tube conduits, provides surgeons with the essential three-dimensional structure of a natural nerve for bridging nerve discontinuities without the complication, expense and morbidity of harvesting peripheral nerve from the patient (nerve autograft). Additionally, the Avance® Nerve Graft has product and sales synergies with the AxoGuard® Nerve Protector and AxoGuard® Nerve Connector. AxoGuard® products provide the unique features of pliability, suturability, and translucence for visualization of the underlying nerve, while also allowing the patient's own cells to incorporate into the extracellular matrix to remodel and form a tissue similar to the nerve epineurium.

***Regenerative Medical Products Industry***

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

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

Regenerative medicine products typically consist of:

- 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.

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AxoGen provides a simple solution for the reconstruction of peripheral nerves; its products are scaffolds, and the patients' own body provides the cells to regenerate or recellularize these scaffolds.

### ***Peripheral Nerves and Their Regeneration***

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

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

### ***Peripheral Nerve Regeneration Market Overview***

Everyday patients suffer traumatic wounds to peripheral nerves severe enough to require surgical treatment, including injuries from motor vehicle accidents, collisions, gun wounds, dislocations, fractures, lacerations, or other forms of penetrating trauma. Specifically, military service men and women may suffer severe wounds from explosions and other military-related injuries. The peripheral nerves commonly injured from these traumas include the digital, median, ulnar, radial, facial, spinal accessory and brachial plexus nerves. Based upon epidemiological studies regarding the number of trauma patients and incidence of peripheral nerve injury in the population, , each year in the U.S. more than 1.3 million people suffer traumatic injuries to peripheral nerves resulting in at least 400,000 nerve repair procedures in the U.S. annually. ("Health", United States, 2011, Publication of US Department of Health & Human Services; Noble, et al. J of Trauma Injury Infection and Critical Care 1998).

Beyond traumatic injury to nerves, nerve damage also occurs due to surgical intervention. Some of these nerve cases occur after dental or oral surgery when patients lose sensory and taste function in the mouth, including complications from third molar extractions and dental implants. Also, nerves that support erectile function may be injured or removed following a surgical prostatectomy to remove prostate cancer. Further, breast cancer patients may have reduced sensation in the tissue used to reconstruct the breast after mastectomy. Finally, nerves are also damaged or compromised due to repetitive stress or compression injuries. For instance, severe and recurrent carpal tunnel cases may result in complications and damage to the nerve that requires further surgical intervention and protection of the nerve.

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

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In the cases where a nerve is severed, if the gap between the two ends of the nerve is extremely small, the surgeon can reconnect the nerve without tension through direct suturing. Because a tension-free repair is important, when the gap is more than a few millimeters in length, the surgeon typically needs to bridge the gap between the nerve ends. Historically, to repair a severed nerve gap, surgeons have relied on an autotransplantation (autologous grafting or autograft). In autograft procedures, surgeons remove nerve from another part of the patient's body, frequently from the back of the lower leg, to repair the damaged nerve. Autografting is often effective in repairing a damaged peripheral nerve, but it presents a tradeoff — fix the damaged nerve while creating a nerve deficit. For example, a patient may opt to get movement and feeling back in their finger while losing some sensation in their foot. Additionally, the secondary surgery to obtain the needed autograft also increases operating time, and thus medical expenses, and increases the risk of surgical infection and other complications. In the case of extreme trauma where multiple nerves need to be repaired, it may not be possible to recover enough nerve from the patient to complete the repair.

Drawbacks of repair with autograft eventually led to the development of hollow-tube conduits, or hollow-tube nerve cuffs, for peripheral nerve repair made of, for instance, bovine collagen or polyglycolic acid. The nerve cuff is typically an absorbable hollow tube that, unlike natural nerve, does not have basal lamina tubes to support regenerating axons; as a result, it is deficient in the qualities that natural nerve possesses to support nerve regeneration. Hollow-tube conduits may also lack pliability and structural integrity needed when used around joints and may be difficult to use in a confined space. Additionally, hollow-tube conduits do not provide familiar handling characteristics to the surgeon and in some instances are contraindicated for use in infected wound beds. Clinical data has demonstrated that conduits are most effective only when used in very short gaps and the reliability of successful nerve recovery diminishes as gap length increases. However, with surgeons seeking alternatives to autografts, the annual number of procedures using hollow-tube conduits has grown. AxoGen believes this demand has resulted in hollow-tube conduits being used for gap lengths where their likelihood of effectiveness is greatly diminished.

The growth of hollow-tube conduit use demonstrates there is market demand for products that do not have the drawbacks of autografting. However, as stated above, the shortcomings of conduits limit where they may be used effectively. Thus, the nerve repair market needs an alternative off-the-shelf product that provides the natural ECM scaffold and three-dimensional structure of a typical nerve for bridging nerve discontinuities without the complication, expense and morbidity of autografting a nerve. AxoGen believes its product portfolio meets this market need.


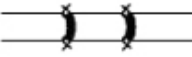

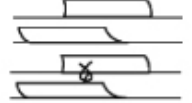

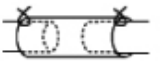
### **AxoGen's Product Portfolio**

#### ***Overview of AxoGen's Products***

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

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

Length of Nerve Injury	0 mm 5 mm 10 mm 15 mm 20 mm 25 mm 30 mm 35 mm 40 mm 45 mm 50 mm 55 mm 60 mm 65 mm 70 mm																
																	<ul style="list-style-type: none"> <li>• Bridge gaps up to 70 mm</li> <li>• Cable grafting (alone or in combination with autograft)</li> <li>• Bridge a partially severed nerve</li> </ul>
																	<ul style="list-style-type: none"> <li>• Wrap injured nerves up to 40 mm</li> <li>• Minimize risk of entrapment</li> <li>• Protect partially severed nerves</li> <li>• Reinforce coaptation site</li> </ul>
																	<ul style="list-style-type: none"> <li>• Bridge gaps up to 5 mm</li> <li>• Coaptation aid for direct repair, grafting, or cable grafting</li> <li>• Reinforce coaptation site</li> </ul>

**Avance® Nerve Graft**

Avance® Nerve Graft is intended for the surgical repair of peripheral nerve discontinuities (a gap created when the nerve is severed) to support regeneration across defects of 5mm to 70mm in length. 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 a proprietary method for processing recovered human peripheral nerve tissue in a manner that preserves the essential structure of the ECM while cleansing away cellular and noncellular debris. Avance® Nerve Graft provides the natural nerve structure of an autograft and the ease and availability of an off-the-shelf product. AxoGen believes that Avance® Nerve Graft is the first and only commercially available allograft nerve for bridging nerve discontinuities. The Avance® Nerve Graft is comprised of bundles of small diameter endoneurial tubes that are held together by an outer sheath called the epineurium. Avance® Nerve Graft has been processed to remove cellular and noncellular factors such as cells, fat, blood, axonal debris and chondroitin sulfate proteoglycans, (“CSPG”), while preserving the three-dimensional scaffold, basal lamina tubular structure, epineurium and microvasculature of the peripheral nerve. After processing, Avance® Nerve Graft is flexible and pliable, and its epineurium can be sutured in place allowing for tension-free approximation of the proximal and distal peripheral nerve stumps. The design results in a product that has clean and clear pathways for the regenerating axons to grow through. During the healing process, the body revascularizes and gradually remodels the graft into the patient’s own tissue while allowing the processed nerve allograft to physically support axonal regeneration across the nerve discontinuity.

Avance® Nerve Graft provides the natural nerve structure of an autograft and the ease and availability of an off-the-shelf product. AxoGen believes that Avance® Nerve Graft is the only commercially available processed nerve allograft for bridging nerve discontinuities.

With lengths up to 70 mm and diameters up to 5 mm, the Avance® Nerve Graft allows surgeons to choose the correct length for the relevant nerve gap for repairs up to 70 mm, as well as to match the diameter to the proximal and distal end of the severed nerve. The Avance® Nerve Graft is stored frozen and utilizes packaging

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that maintains the graft in a sterile condition. The packaging is typical for medical products so the surgical staff is familiar with opening the package for transfer of the Avance® Nerve Graft into the sterile surgical field. Such packaging also provides protection during shipment and storage and a reservoir for the addition of sterile fluid to aid in thawing the product. The Avance® Nerve Graft thaws in less than 10 minutes, and once thawed, it is ready for implantation.

The Avance® Nerve Graft provides the following key advantages:

- Provides a three-dimensional bioscaffold for bridging a nerve gap;
- No patient donor-nerve surgery, therefore no loss of donor nerve function;
- Available in a variety of diameters, 1-2 mm to 4-5mm, to meet a range of anatomical needs
- Available in a variety of lengths, 15mm 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 porcine submucosa ECM coaptation aid for tensionless repair of severed nerves. AxoGuard® Nerve Connector is a tubular, multilaminar extracellular matrix with an open lumen where the severed nerve ends are placed. Typically, the AxoGuard® Nerve Connector is used to align and connect nerves with less than a 5mm gap between the severed nerve ends. The AxoGuard® Nerve Connector material allows the body's natural healing process to repair the nerve by isolating and protecting it during the healing process. The patient's own cells incorporate into the extracellular matrix to remodel and form a tissue similar to the nerve epineurium. AxoGuard® Nerve Connector is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs.

AxoGuard® Nerve Connector can be used to:

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

AxoGuard® Nerve Connector has the following advantages:

- Only porcine submucosa extra-cellular matrix coaptation product to bridge gaps up to 5 mm;
- Alleviates tension at the repair site;
- Reduces the number of required sutures (versus direct repair);
- Moves location of sutures away from the coaptation face;
- Reduces potential for fascicular mismatch;
- Allows visualization of underlying nerve;
- Strong and flexible, easy to suture; and
- Stored at room temperature with an 18 month shelf life.



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### ***AxoGuard® Nerve Protector***

The AxoGuard® Nerve Protector is a porcine submucosa ECM product used to wrap and protect injured peripheral nerves and reinforce coaptation sites while preventing soft tissue attachments surgical implant that provides protection for peripheral nerves. It is designed to protect and isolate the nerve during the healing process after surgery. AxoGuard® is a multilaminar extracellular matrix that separates and protects the nerve from the surrounding tissues during the healing process. The patient's own cells incorporate into the extracellular matrix to remodel and form a tissue similar to the nerve epineurium. AxoGuard® Nerve Protector is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs.

AxoGuard® Nerve Protector can be used to:

- Wrap injured nerves;
- Minimize risk of entrapment in compressed nerves;
- Protect partially severed nerves;
- Protect nerves in a traumatized wound bed; and
- Reinforce a coaptation site.

AxoGuard® Nerve Protector has the following advantages:

- Only porcine submucosa bioscaffold used to reinforce a coaptation site, wrap a partially severed nerve or protect nerve tissue;
- Isolates and protects the nerve in a traumatized wound bed;
- Easily conforms and wraps the injured nerve;
- Minimizes the potential for soft tissue attachments and nerve entrapment by physically isolating the nerve during the healing process;
- Allows nerve gliding;
- Strong and flexible, plus easy to suture;
- Stored at room temperature with an 18 month shelf life.

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

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

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

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

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

AxoGen partners with FDA registered tissue establishments and AATB accredited recovery agencies or recovery agencies in compliance with AATB standards to recover human peripheral nerve tissue for Avance® Nerve Graft processing. After consent for donation is obtained, donations are screened and tested in detail for safety in compliance with the federal regulations and AATB standards on communicable disease transmission. AxoGen 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 returned to AxoGen's headquarters in Alachua, Florida. There, the product receives its final labels and is released following a final stringent technical and quality review. Orders for Avance® Nerve Graft are placed with AxoGen's customer care team and product is shipped from the distribution facilities.

### ***Avance® Nerve Graft Product Release***

The AxoGen Quality System meets the requirements set forth under 21 CFR § 1271 for Human Cells, Tissues and Cellular and Tissue-Based Products, including Good Tissue Practices ("GTP") and is compliant with the 21 CFR § 820 Quality System Regulations ("QSR"). AxoGen has established quality procedures for review of tissue recovery, relevant donor medical record review and release to processing that meet or exceed FDA requirements as defined in 21 CFR §1271, state regulations, international regulations and AATB standards. Furthermore, AxoGen utilizes validated processes for the handling of raw material components, environmental control, processing, packaging and terminal sterilization. In addition to ongoing monitoring activities for product conformity to specifications and sterility, product biocompatibility, shipping methods and shelf life have been validated in accordance with applicable industry standards.

### ***Manufacturing for the AxoGuard® Product Line***

AxoGuard® is manufactured by Cook Biotech Incorporated, 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, suturable, translucent and allows the patient's own cells to incorporate into the extracellular matrix to remodel and form a tissue similar to the nerve's epineurium. In August 2008, Cook Biotech entered into an agreement with AxoGen to distribute its product worldwide in the field of peripheral nerve repair, and the parties subsequently amended the agreement in March, 2012. The agreement has an initial seven-year term from the date of the original agreement and following such initial term, the agreement automatically renews for an additional seven (7) year period provided that the parties agree to meet at least ninety (90) days before the end of such initial term to review whether the purchase price of the products obtained from Cook Biotech need to be

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adjusted and reasonably agree to such adjustment in writing, where such agreement shall not be unreasonably withheld. The Cook Biotech agreement also requires certain minimum purchases, although through mutual agreement the parties have not established such minimums and to date have not enforce 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 reconstruction needs. AxoGen is focused on the developing market of peripheral nerve reconstruction and regeneration and is committed to improving awareness of new peripheral nerve reconstruction options, as well as building additional scientific and clinical data to assist surgeons and patients in making informed choices. AxoGen believes this approach will solidify its position as a leader in the field of products for peripheral nerve injuries. The following provides the key elements of AxoGen's sales and marketing strategy.

#### *Increase Awareness of AxoGen's Products Bridging Nerve Gaps*

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

AxoGen intends to increase market share by improving awareness of its products through the use of educational conferences and presentations, surgical resident and fellow training, scientific publications, and a knowledgeable and professional sales team. AxoGen expects to increase usage with existing customers as well as expand the overall customer base. Initially, AxoGen will focus on plastic reconstructive surgeons and orthopedic and plastic surgeons who perform surgeries on patients suffering traumatic nerve injuries and who perform hand reconstructive surgeries. In select hospital accounts, AxoGen is also expanding into the market for the reconstruction of nerve injuries in oral surgery.

#### *Expand Clinical and Scientific Data Regarding the Performance of AxoGen Products*

Data will be a mainstay of AxoGen's marketing strategy. AxoGen will continue to accept patients in its RANGER® clinical study (defined below in "Government Regulations"), a utilization registry of Avance® Nerve Graft. A multicenter prospective randomized comparative pilot study of hollow tube conduits and Avance® Nerve Graft is in process. A case series in digital nerve repair has already been published and other studies have been completed. Case series in brachial plexus, military trauma, prostate cancer 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 for National Coverage*

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

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### ***AxoGen Strengths***

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

#### Established Nerve Repair Reconstruction and Regeneration Expertise

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

#### Surgical Implant Commercialization Experience

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

### ***Avance® Nerve Graft Performance***

AxoGen has worked with leading institutions, researchers and surgeons to support innovation in the field of peripheral nerve reconstruction. To date, AxoGen's RANGER® study (defined below in "Government Regulations") is the largest multi-center clinical study conducted in peripheral nerve gap repair. AxoGen's RECON study will also continue AxoGen's clinical work, providing a new multi-center, prospective, randomized, clinical study on the Avance® Nerve Graft. The January, 2012 edition of *Microsurgery* and November 2012 edition of *The Journal of Hand Surgery* each contain an article summarizing the RANGER® study results. To date the use of Avance®, Nerve Graft has been associated with meaningful motor and sensory recovery ranging from 80% to 86% in nerve discontinuities between 5 and 50 mm in the upper extremity. Additionally no implant related adverse events have been reported. (Brooks, D. N., Weber, R. V., Chao, J. D., Rinker, B. D., Zoldos, J., Robichaux, M. R., Ruggeri, S. B., Anderson, K. A., Bonatz, E. E., Wisotsky, S. M., Cho, M. S., Wilson, C., Cooper, E. O., Ingari, J. V., Safa, B., Parrett, B. M. and Buncke, G. M. (2012), Processed nerve allografts for peripheral nerve reconstruction: A multicenter study of utilization and outcomes in sensory, mixed, and motor nerve reconstructions. *Microsurgery*, 32: 1–14. doi: 10.1002/micr.20975 and Cho, et al. 2012, *J Hand Surg Am* 37(11):2340-9). A meta-analysis of available clinical outcomes data from published papers on the leading synthetic collagen conduit showed meaningful improvement in only 53% of cases bridging a gap in the nerve.

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

AxoGen currently focuses on the U.S. market, with additional Avance® Nerve Graft foreign sales in Canada, Italy, Austria and Switzerland. The need for reconstruction of injured nerves is a global issue. Through its foreign sales, AxoGen has shown the capability to take its current product offering into new geographical markets. AxoGen does not currently have EU-wide approval for the Avance® Nerve Graft or the AxoGuard® products, but has a regulatory strategy for Europe and certain other international regions.

### **Research and Development**

AxoGen believes it provides the most extensive product portfolio for peripheral nerve repair available. Our current development focus is to expand clinical data in both traumatic nerve repair and other surgical applications. Additional product line extensions of the Avance® and AxoGuard® products may be developed. AxoGen's current intention is to spend limited direct resources on extensive research into new unmet peripheral nerve needs. AxoGen does, however, work with academic intuitions in the expansion of treatments for peripheral nerve. For the years ended December 31, 2012 and 2011, AxoGen spent \$1,427,211, and \$697,355, respectively, on research and development expenses.

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### **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 autograft and hollow-tube conduits based on product features and performance, price, surgical application, ease of use and healthcare provider education. AxoGen's major competitors for off-the-shelf repair option in hollow-tube conduits are the following companies:

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

AxoGen believes that surgeons use Avance® Nerve Graft because, unlike hollow-tube conduits, it provides them with the natural three-dimensional structure of a typical nerve for bridging nerve discontinuities (severed nerves) without the complications, expense and morbidity of autografting a nerve. AxoGuard® Nerve Protector and AxoGuard® Nerve Connector provide the unique features of pliability, suturability, and translucence for visualization of the underlying nerve while also allowing the patient's own cells to incorporate into the extracellular matrix to remodel and form a tissue similar to the nerve epineurium.

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

### **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

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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, five pending U.S. patent applications, three issued international patents and nine pending international patent applications with regard to its peripheral nerve products. In Mexican cases PA/A/2004/001334, 2007/012379, 2007/012380, and 2007/012382, Notices of Allowance have been issued, and the four patents are awaiting issuance. Additionally, the granted European Patent No. EP1425390 is in the process of being validated in France, Germany, Italy, Spain, Sweden, Switzerland, and the United Kingdom. The following table illustrates the issued patents owned or licensed by AxoGen with regard to its peripheral nerve products, including the patent number, a description of each patent, and the estimated expiration date of each patent.

<b>Patent No.</b>	<b>Description</b>	<b>Estimated expiration date</b>
US 6,972,168	Materials and Methods for Nerve Grafting, Selection of Nerve Grafts, and in vitro Nerve Tissue Culture	August 13, 2021
US 7,402,319	Cell Free Tissue Replacement for Tissue Engineering	September 26, 2023
US 7,732,200	Materials and Methods for Nerve Grafting, Selection of Nerve Grafts, and in vitro Nerve Tissue Culture	December 21, 2022
US 6,696,575	Biodegradable, electrically conducting polymer for tissue engineering applications	March 27, 2021
US 7,851,447	Materials and Methods for Nerve Repair	November 18, 2023
US 7,772,185	Materials and Methods for Promotion of Nerve Regeneration	November 18, 2023
Japan No. 4,749,667	Materials and Methods to Promote Repair of Nerve Tissue	August 13, 2022
Europe No. EP1425390	Materials and Methods to Promote Repair of Nerve Tissue	August 12, 2022
Japan No. 4,773,976	Materials and Methods for Promotion of Nerve Regeneration	January 31, 2025

Additionally, AxoGen entered into an exclusive distribution agreement with Cook Biotech in August 2008, as subsequently amended in March 2012, to distribute its ECM technology in the form of the Surgisis® Nerve Cuff, the form of a nerve wrap or patch, or the form of any other mutually- agreed-to configuration in the field of peripheral nervous system and central nervous system use. AxoGen has subsequently rebranded the Surgisis products under the AxoGuard® name. Cook Biotech holds multiple issued and pending U.S. and international

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patents covering its ECM technology. The following table illustrates the two non-licensed U.S. patents held by Cook Biotech that are specifically identified on AxoGen's AxoGuard® Nerve Connector and AxoGuard® Nerve Protector product labeling. The table includes the U.S. Patent number, a description of each patent, and the estimated expiration date of each patent.

U.S. Patent No.	Description	Estimated expiration date
6,206,931	Graft Prosthesis Material	August 23, 2016
6,241,981	Composition and Method for Repairing Neurological Tissue	September 16, 2016

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

Finally, AxoGen continues to hold IP, including patents, related to LecTec's original hydrogel patch technology and hand sanitizer patch. AxoGen has not been able to monetize the IP regarding the hand sanitizer patch and issues regarding the enforceability of such IP has resulted in AxoGen determining that it has no future value. AxoGen continues to take all action necessary to maintain relevant patents licensed to Novartis Consumer Health, Inc., however, Novartis has discontinued sale of products related to the license in certain countries and as such AxoGen has determined that the value of the Novartis license has been impaired.

### ***Trademarks, Trade Secrets, Copyrights and Domain Names***

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

## **Government Regulations**

### ***U.S. Government Regulation Overview***

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

AxoGen distributes for Cook Biotech the AxoGuard® product line and Cook Biotech is responsible for the regulatory compliance of the AxoGuard product line. AxoGuard® products are regulated as medical devices and subject to 21 CFR § 820 ("Quality System Regulation") and related laws and regulations. Cook Biotech has obtained a 510(k) marketing clearance from the FDA for porcine small intestine submucosa for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. AxoGuard® products represent the product for which 510(k) clearance was obtained.



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In 2007, AxoGen began to process and distribute its Avance® Nerve Graft pursuant to section 361 of the Public Health Service Act and 21 CFR § 1271 Human Cell & Tissue Products (“HCT/P”) controls. Such action was based on AxoGen’s good faith belief that the Avance® Nerve Graft product was a 361 HCT/P tissue product. From October 2008 through early 2010, AxoGen was in communication with the FDA concerning the regulatory status of the Avance® Nerve Graft product. In April 2010, in response to a Request For Designation (“RFD”) filed by AxoGen, the FDA determined that the Avance® Nerve Graft was a biological product that would be reviewed and regulated by Center for Biologics Evaluation and Research (“CBER”) under the biologics licensing provision of the Public Health Service Act (the “PHS Act”).

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

- AxoGen transitions to compliance with the Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the “FD&C Act”), the current good manufacturing practice regulations in 21 CFR § 210 and 211 and the applicable regulations and standards in 21 CFR § 600-610 prior to initiation of a phase 3 clinical trial;
- AxoGen conduct a phase 3 clinical trial to demonstrate safety, purity and potency of the Avance® Nerve Graft under a Special Protocol Assessment; and
- AxoGen continues to comply with the regulations and standard for 21 CFR § 1271 and exercises due diligence in executing the transition.

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

The BLA application and commercial distribution of the Avance® Nerve Graft, if approved, will require a potentially substantial user fee payment to the FDA, although certain exemptions, waivers and discounts of the user fees may apply, including certain waivers or discounts for small businesses. AxoGen has continued to communicate with CBER since the acceptance of the transition plan on clinical trial design and Chemistry, Manufacturing, and Controls (“CMC”) and continues to move with diligence toward the completion of the BLA. A Special Protocol Assessment has been submitted, reviewed and approved by CBER. In compliance with the transition plan established by the FDA, AxoGen is able to continue to distribute the Avance® Nerve Graft.

### ***FDA — General***

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

- product design, development and manufacture;
- product safety, testing, labeling and storage;
- pre-clinical testing in animals and in the laboratory;
- clinical investigations in humans;
- premarketing clearance or approval and licensing;
- record-keeping and document-retention procedures;
- advertising and promotion;



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- the import and export of products;
- product marketing, sales and distribution;
- post-marketing surveillance and medical device reporting, including reporting of deaths, serious injuries, communicable diseases, device malfunctions or other adverse events; and
- corrective actions, removals and recalls.

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

### ***FDA's Premarket Clearance and Approval Requirements — Medical Devices***

Unless an exemption applies, each medical device distributed commercially in the U.S. requires either prior 510(k) clearance or approval of a PMA from the FDA. Medical devices are classified into one of three classes — Class I, Class II, or Class III — depending on the degree of risk and the level of control necessary to assure the safety and effectiveness of each medical device. Medical devices deemed to pose lower risks are generally placed in either Class I or II. Pre-market review and clearance by the FDA for Class I and II medical devices is accomplished through the 510(k) pre-market notification procedure, unless the device is exempt. Most Class I medical devices are exempt from the 510(k) premarket notification requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device are generally placed in Class III. Class III devices requiring an approved PMA to be marketed are devices that were regulated as new drugs prior to May 28, 1976 (transitional devices), devices not found substantially equivalent to a predicate device, and Class III pre-amendment devices that by regulation require pre-market approval. A PMA must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction, the safety and effectiveness of the device.

### ***FDA's Premarket Clearance and Approval Requirements — Biologic Products***

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

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

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

- completion of preclinical laboratory tests, animal studies and formulation studies under the FDA's good laboratory practices regulations;
- submission to the FDA of an Investigational New Drug Application ("IND"), for human clinical testing, which must become effective before human clinical trials may begin and which must include independent Institutional Review Board (IRB), approval at each clinical site before the trials may be initiated;

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

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

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

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

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

### Post-Approval Requirements

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

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

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

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

### Clinical Trials

Clinical trials are required to support a BLA and are sometimes required for 510(k) clearance. Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under strict requirements to ensure the protection of human subjects participating in the trial and under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring and safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND or IDE. In addition, an IRB at each site at which the study is conducted must approve the protocol, subject consent form and any amendments. All research subjects must be informed, among other things, about the risks and benefits of the investigational product and provide their informed consent in writing.

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

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

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

### Investigational New Drug (IND) Application

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

- **Animal Pharmacology and Toxicology Studies** — Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experiences with the product in humans (often foreign use).
- **Manufacturing Information** — Information pertaining to the composition, manufacturer, stability, and controls used for manufacturing of the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.
- **Clinical Protocols and Investigator Information** — Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators — professionals (generally physicians) who oversee the administration of the experimental compound — to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an IRB, and to adhere to the investigational new drug regulations.

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

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

Clinical trials are subject to extensive recordkeeping and reporting requirements. AxoGen's clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. AxoGen is also required to obtain the patients' written informed consent in form and substance that complies with both FDA requirements

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and state and federal privacy and human subject protection regulations. AxoGen, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the U.S. Similarly, in Europe, the clinical study must be approved by a local ethics committee and, in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

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

#### Educational Grants

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

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

- whether the intent of the funded activity is to present clearly defined educational content, free from commercial influence or bias;
- whether the third-party grant recipient and not the manufacturer has maintained control over selecting the faculty, speakers, audience, program content and materials;
- whether the program focuses on a single product of the manufacturer without a discussion of other relevant existing competitive products or treatment options;
- whether there was meaningful disclosure to the audience, at the time of the program, regarding the manufacturer's funding of the program, any significant relationships between the provider, presenters, or speakers and the supporting manufacturer; whether any unapproved uses will be discussed;
- whether there are legal, business, or other relationships between the supporting manufacturer and provider or its employees that could permit the supporting manufacturer to exert influence over the content of the program
- whether the individuals employed by the provider and involved in designing or conducting the educational activities are also involved in advising or assisting the company with respect to sales or marketing; and
- whether the information about the company's products is further disseminated after the initial program, by or at the direction of the company, other than in response to an unsolicited request or through an independent provider.

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

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### Pervasive and Continuing Regulation

There are numerous regulatory requirements that apply after a product is cleared or approved. These include: the FDA's Quality System Regulation (QSR) per 21 CFR § 820 for medical devices, the FDA's Good Tissue Practices (GTP) per 21 CFR §1271 for HCT/P tissue products and the FDA's Good Manufacturing Practices (GMP) per 21 CFR § 210, 211, and 600 for biologic products. These regulations require manufacturers, including third-party manufacturers:

- to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- to comply with labeling regulations and FDA prohibitions against the false or misleading promotion or the promotion of products for uncleared, unapproved or off-label use or indication;
- to comply with requirements to obtain clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use;
- to report to the FDA certain adverse events, adverse reactions and deviations: (a) for medical devices, a report to FDA is required if the device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; (b) for biologics, a deviation from current good manufacturing practice or an unexpected or unforeseeable event that may affect the safety, purity, or potency of the product must be reported; and (c) for 361 HCT/P tissue products, FDA requires reporting of certain adverse reactions involving a communicable disease related to an HCT/P that the company made available for distribution;
- to comply with post-approval restrictions or conditions, including post-approval study commitments;
- to follow post-market surveillance regulations that may apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and
- to follow requirements to issue notices of correction or removal, or conduct market withdrawals or recalls where quality or other issues arise.

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

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

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

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

### Fraud, Abuse and False Claims

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

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

AdvaMed is one of the primary voluntary U.S. trade associations for medical device manufacturers. This association has established guidelines and protocols for medical device manufacturers in their relationships with healthcare professionals on matters including research and development, product training and education, grants and charitable contributions, support of third-party educational conferences, and consulting arrangements. Adoption of the AdvaMed Code by a medical device manufacturer is voluntary, and while the OIG and other



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federal and state healthcare regulatory agencies encourage its adoption and may look to the AdvaMed Code, they do not view adoption of the AdvaMed Code as proof of compliance with applicable laws. AxoGen has incorporated the principles of the AdvaMed Code in its standard operating procedures, sales force training programs, and relationships with doctors. Key to the underlying principles of the AdvaMed Code is the need to focus the relationships between manufacturers and healthcare professionals on matters of training, education and scientific research, and limit payments between manufacturers and healthcare professionals to fair market value for legitimate services provided and payment of modest meal, travel and other expenses for a healthcare professional under limited circumstances. AxoGen has incorporated these principles into its relationships with healthcare professionals under its consulting agreements, payment of travel and lodging expenses, research and educational grant procedures and sponsorship of third-party conferences. In addition, AxoGen has conducted training sessions on these principles. However, AxoGen cannot provide any assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws.

### ***Regulation Outside of the United States***

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

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

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



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### ***Tissue products are not currently regulated under the CE Mark***

Although some standards of harmonization exist, each country in which AxoGen conducts business has its own specific regulatory requirements. AxoGen procures and processes its tissue products in the U.S., and markets in the U.S., Canada, Switzerland, Austria and Italy under compliance with the individual country regulations. These requirements are dynamic in nature and, as such, are continually changing. New regulations may be promulgated at any time and with limited notice. 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.

### **LecTec Corporation Merger**

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

### **PDL BioPharma, Inc. Revenue Interests Purchase Agreement**

#### *General*

On October 5, 2012, AxoGen entered into a Revenue Interests Purchase Agreement (the "Royalty Contract") with PDL BioPharma, Inc. ("PDL"), pursuant to which the Company sold to PDL the right to receive specified royalties on 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

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AxoGuard® Nerve Protector. The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments based on a high single digit royalty rate of the Company's Net Revenues, subject to certain agreed upon minimum payment requirements which begin in the fourth quarter of 2014 as provided in the Royalty Contract. The total consideration PDL paid to the Company was \$20,800,000 (the "Funded Amount"), including \$19,050,000 PDL paid to the Company on October 5, 2012, and \$1,750,000 PDL paid to the Company on August 14, 2012 pursuant to an Interim Revenue Interest Purchase Agreement between the Company and PDL, dated August 14, 2012 (the "Interim Royalty Contract"). Upon the closing (the "Closing") of PDL's purchase of the specified royalties described above, which was concurrent with the execution of the Royalty Contract, the Interim Royalty Contract was terminated.

### *Put Option*

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

### *Change of Control; Call Option*

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

### *Board Designee*

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

### *Preemptive Rights*

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

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### *Restriction on Dividends*

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

### *Guarantee and Collateral Agreement*

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

### **Employees**

At December 31, 2012, the Company had 57 full time employees which included 10 in administration, information technology and finance, 14 in manufacturing and quality control, 7 in research and development and regulatory and 26 in sales and marketing. As of the date of this 10-K AxoGen has not had a work stoppage and no employees are represented by a labor union. AxoGen believes its relationship with its employees is satisfactory.

### **Executive Officers of the Registrant**

Prior to the Merger, Mr. Gregory Freitag was LecTec's only executive officer serving as CEO and CFO. The following table, except as noted, lists the names and positions of the individuals who have served since the completion of the Merger, and who are, as of March 12, 2013, executive officers the Company:

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

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

*Karen Zaderej, President, Chief Executive Officer and Director (Age 51)*

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

*Gregory G. Freitag, J.D., CPA, Chief Financial Officer, General Counsel and Director (Age 51)*

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

*John P. Engels, Vice President (Age 41)*

Mr. Engels has served as AxoGen's Vice President since September, 2011. He is a co-founder of AC and has served as AC's Vice President since June 2006, providing operational and financial leadership and managing AxoGen's strategic and product development partnerships. From 1999 to 2002, Mr. Engels worked as a consultant for the University of Florida, Saffron Hill Ventures and PA Early Stage Partners, among other companies. From 1993 to 1997, Mr. Engels was an analyst and associate at CACM, a boutique investment banking firm. Mr. Engels is currently a member of the board of directors of Oxicool, Inc., a privately-held company developing new cooling technologies. Mr. Engels holds a MBA in Management and Operations from the Wharton School of Business at the University of Pennsylvania, and a BA from the University of Chicago.

*Jill F. Schiaparelli, Senior Vice President, Business Strategy & Marketing (Age 47)*

Ms. Schiaparelli has served as AxoGen's Senior Vice President, Business Strategy & Marketing since February 2012. From January 2011 to February 2012 and from June, 2007 to December 2008, Ms. Schiaparelli was employed by JS Strategic Partners, LLC, a consulting firm she founded to provide business strategy, commercialization and marketing services to biotechnology companies and health care providers. From December 2008 to December 2010, Ms. Schiaparelli was the Vice President, Commercial Strategy & Business Development for ApaTech, a venture-back global orthopedic graft company based in the UK that was later acquired by Baxter Healthcare. From 1996 to 2007, Ms. Schiaparelli was employed by Johnson & Johnson family of companies where she held several senior positions in strategic marketing, marketing, sales operations

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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 55)*

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

### *David Hansen, Corporate Controller (Age 52)*

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

### *Shawn McCarrey, Vice President of Sales (Age 55)*

Mr. McCarrey has served as AxoGen's Senior Vice President of Sales since February, 2013. Mr. McCarrey was Executive Vice President of North American Cardiovascular Sales at Bayer Interventional/MEDRAD Interventional from January, 2009 to May 2012. Bayer HealthCare, a subgroup of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry. Bayer Interventional, now doing business as part of Bayer Medical Care's Radiology and Interventional business, is the Interventional franchise formerly operated under Bayer's MEDRAD brand. From 1998 to 2009, Mr. Carrey 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 of 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.

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

**ITEM 1A. RISK FACTORS**

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

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

AxoGen has historically operated with negative cash flow from its operations. As of December 31, 2012, AxoGen had an accumulated deficit of approximately \$58 million. If AxoGen product sales do not increase as anticipated, then it will continue to experience negative cash flows and adverse operating conditions. AxoGen's continuing capital needs and other factors, could cause the Company to raise additional funds through public or private equity offerings, debt financings or from other sources. The sale of additional equity may result in dilution to AxoGen's shareholders. There is no assurance that AxoGen will be able to secure funding on terms acceptable to it, or at all.

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

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

***AxoGen's revenue depends solely on three products.***

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

The AxoGuard® products are only available through an exclusive distribution agreement with Cook Biotech Incorporated. Such contract is for an initial seven year term and following such initial term, the agreement automatically renews for an additional seven (7) year period provided that the parties agree to meet at least ninety (90) days before the end of such initial term to review whether the purchase price of the products obtained from Cook Biotech need to be adjusted and reasonably agree to such adjustment in writing, where such agreement shall not be unreasonably withheld. However, there are conditions for continuation of the agreement, including payment terms and minimum purchase requirements, that if breached could result in an earlier termination of the agreement; except that through mutual agreement the parties have not established such minimums and to date have not enforce such minimum purchase provision. Although there are products that AxoGen believes it could develop or obtain that would replace the AxoGuard® products, the loss of the ability to sell the AxoGuard® products could have a material adverse effect on AxoGen's business until other replacement products are available.



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

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

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

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

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

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

### ***AxoGen must maintain high quality manufacturing and processing.***

AxoGen's Avance® Nerve Graft product requires careful calibration and precise, high-quality processing and manufacturing. Achieving precision and quality control requires skill and diligence by its personnel. If it fails to achieve and maintain these high quality controls, processing and manufacturing standards, including avoidance of manufacturing errors, defects or product failures, AxoGen could experience recalls or withdrawals of its product, delays in delivery, cost overruns or other problems that would adversely affect its business. AxoGen cannot completely eliminate the risk of errors, defects or failures. In addition, AxoGen may experience

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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.***

Although most of the raw materials used in the production of Avance® Nerve Graft are available from more than one supplier, AxoGen currently obtains one of the chemicals it uses in the manufacture of Avance® Nerve Graft from only one supplier. Some of the test results and reagents AxoGen uses in its manufacturing process are also obtained from single suppliers. FDA approval of a new supplier may be required if these materials become unavailable from AxoGen's current suppliers. Although there may be other suppliers that have equivalent materials that would be available to AxoGen, FDA approval of any alternate suppliers if required could take several months or years to obtain, if able to be obtained at all. Any delay, interruption or cessation of production by AxoGen's third-party suppliers of important materials, or any delay in qualifying new materials, if necessary, would prevent or delay AxoGen's ability to manufacture products. In addition, an uncorrected impurity, a supplier's variation in a raw material or testing, either unknown to AxoGen or incompatible with its manufacturing process, or any other problem with AxoGen's materials, testing or components, would prevent or delay its ability to manufacture products. These delays may limit AxoGen's ability to meet demand for its products and delay its clinical trial, which would have a material adverse impact on its business, results of operations and financial condition.

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

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

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

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

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

AxoGen's future success 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.



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

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

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

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

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

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

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

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

### ***Technological change could reduce demand for AxoGen's products.***

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

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

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

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

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

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

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

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

Many factors affect the efficient use and planning of product inventory, such as effectiveness of predicting demand, effectiveness of preparing manufacturing to meet demand, 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 efficiently, or keep sufficient product on hand to meet demand, and AxoGen can provide no assurance that it can keep inventory costs within its target levels. Failing to do so may require AxoGen to raise additional cash resources or may harm long term growth prospects.

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

On October 5, 2012, AxoGen entered into the Royalty Contract with PDL, pursuant to which AxoGen sold to PDL the right to receive specified royalties on AxoGen's Net Revenues generated by the sale, distribution or other use of AxoGen's products Avance® Nerve Graft, AxoGuard® Nerve Protector and AxoGuard® Nerve Connector. The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments, currently paid weekly, based on a high single digit royalty rate of AxoGen's Net Revenues, subject to certain agreed upon minimum payment requirements which begin in the fourth quarter of 2014 as provided in the Royalty Contract. Further, on October 1, 2016, or in the event of the occurrence of a material adverse event or AxoGen's bankruptcy or material breach of the Royalty Contract, PDL may require AxoGen to repurchase the Assigned Interests at the "Put Price." The Put Price is equal to the sum of (i) an amount that, when paid to PDL, would generate a specified internal rate of return to PDL on the Funded Amount, taking into consideration payments made to PDL by AxoGen, and (ii) any "Delinquent Assigned Interests Payment" (as defined in the Royalty Contract) AxoGen owed to PDL.

During 2012, AxoGen's monthly expenses exceeded its revenues and thus it operated at a cash loss. Royalty payments to PDL are owed without consideration to any negative affect it has on AxoGen's cash or loss position. In addition, minimum payments under the Royalty Contract start in October 2014 and if AxoGen is required to pay an amount greater than the royalty fee, AxoGen would have an even greater cash burden. Finally, there is no assurance that AxoGen will have sufficient capital to pay the Put Price if it was exercised. If AxoGen does not have sufficient cash to pay PDL, AxoGen would need to raise additional capital. The sale of additional equity to further finance the company may result in dilution to AxoGen's shareholders. There is no assurance that if AxoGen is required to secure funding it can do so on terms acceptable to it, or at all.

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

In the event of a "Change of Control" (as defined in the Royalty Contract), AxoGen must repurchase the Assigned Interests from PDL for a repurchase price equal to the "Change of Control Price" on or prior to the third business day after the occurrence of the Change of Control. The Change of Control Price is an amount that, when paid to PDL, would generate a specified internal rate of return to PDL on the Funded Amount, taking into consideration payments made to PDL by the Company. Payment of the Change of Control Price could materially reduce the consideration to be received by AxoGen shareholders.

### ***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.

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

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

- trading of AxoGen common stock on the OTCBB;
- limited daily trading volume resulting in the lack of a liquid market;
- fluctuations in price and volume due to investor speculation and other factors that may not be tied to the financial performance of AxoGen;

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- performance by AxoGen in the execution of its business plan;
- financial viability;
- regulatory developments in both the United States and foreign countries;
- performance of products sold and advertised by licensees in the marketplace;
- economic and other external factors; and
- period-to-period fluctuations in financial results.

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

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

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

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

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

AxoGen's Avance® Nerve Graft product is currently allowed to be sold pursuant to a transition plan with the FDA See "Business — Government Regulations — U.S. Government Regulation Review." AxoGen is continuing to communicate with CBER since the acceptance of the transition plan on clinical trial design and CMC for the Avance® Nerve Graft. Until final action on the Avance® Nerve Graft premarket submission, if AxoGen remains in compliance with the transition plan, it is able to continue to provide the Avance® Nerve Graft for sale. In the event that the FDA changed its position regarding its use of enforcement discretion to permit AxoGen to provide the Avance® Nerve Graft product in accordance with the transition plan, AxoGen would no longer be able to sell the Avance® Nerve Graft product, which would have a material adverse effect on AxoGen's operations and financial viability. In addition, if AxoGen fails to comply with applicable regulatory requirements or fails to comply with the ongoing requirements of the premarket submission to become a biological product, the FDA could deny approval of the premarket application, or impose civil penalties, including fines, product seizures or product recalls and, in extreme cases, criminal sanctions.

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

AxoGen's AxoGuard® product line is regulated as a medical device under the FD&C Act and subject to 21 CFR Part 820 (Quality System Regulation) and other FDA regulations. AxoGen distributes for Cook Biotech Incorporated the AxoGuard® product line and Cook Biotech is responsible for the regulatory compliance of the AxoGuard® product line. Cook Biotech has obtained a 510(k) marketing clearance from the FDA for porcine small intestine submucosa for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. If AxoGen or Cook Biotech Incorporated fails to comply with applicable regulatory requirements the FDA could deny marketing clearance or approval, withdraw approvals, or impose civil penalties, including fines, product seizures or product recalls and, in extreme cases, criminal sanctions.

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

AxoGen is subject to extensive regulation. Its products are subject to regulation by the FDA in the U.S., the Center for Medicare Services of the U.S. Department of Health and Human Services and other federal governmental agencies and, in some jurisdictions, by state and foreign governmental authorities. The FDA regulates the development, distribution, manufacturing, labeling, and record-keeping procedures for human tissue for transplantation such as that of AxoGen's Avance® Nerve Graft product. The FDA also regulates medical devices, such as the AxoGuard® products. The process of obtaining marketing clearance from the FDA for new products and new applications for existing products can be time consuming and expensive. Some of the future products and enhancements to such products that AxoGen expects to develop and market may require marketing clearance or approval from the FDA. There can be no assurance, however, that clearance or approval will be granted with respect to any of AxoGen's products or enhancements or that FDA review will not involve delays that would adversely affect AxoGen's ability to market such products or enhancements. In addition, there can be no assurance that AxoGen products or enhancements will not be subject to a lengthy and expensive approval process with the FDA.

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

The use, misuse or off-label use of AxoGen's products may harm its reputation or the image of its products in the marketplace, or result in injuries that lead to product liability suits, which could be costly to AxoGen's business or result in FDA sanctions if they are deemed to have engaged in off-label promotion. AxoGen is seeking FDA approval for Avance® Nerve Graft under specific circumstances. Its promotional materials and training methods must comply with FDA requirements and other applicable laws and regulations, including the prohibition on the promotion of a medical device for an indication that has not been approved or cleared by the FDA, or an off-label use. The FDA does not restrict or regulate a physician's use of a medical device within the practice of medicine, and AxoGen cannot prevent a physician from using its products for an off-label use. However, the FD&C Act and the FDA's regulations restrict the kind of communications that may be made about AxoGen's products and if the FDA determines that its promotional or training materials constitute the unlawful promotion of an off-label use, it could request that AxoGen modify its training or promotional materials or subject it to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, civil money penalties, criminal fines and penalties, and exclusion from participation in federal health programs. Other federal, state or foreign governmental authorities might also take action if they consider AxoGen promotion or training materials to constitute promotion of an uncleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, AxoGen's reputation could be damaged and the use of its products in the marketplace could be impaired.

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

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use improper techniques if they are not adequately trained in the particular use, potentially leading to injury and an increased risk of product liability. Product liability claims are expensive to defend and could divert management's attention from its primary business and result in substantial damage awards against AxoGen. Any of these events could harm AxoGen's business, results of operations and financial condition.

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

If AxoGen's products are defective or otherwise pose safety risks, the FDA could require their recall, or AxoGen may initiate a voluntary recall of its products. The FDA may require recall of a marketed product in the event that it determines that due to material deficiencies or defects that use of the product poses an unacceptable risk to health. In addition, manufacturers may, on their own initiative, recall a product to remove or correct a deficiency or to remedy a violation of the Federal Food, Drug, and Cosmetic Act that may pose a risk to health. A government-mandated or a voluntary recall could occur as a result of an unacceptable risk to health, failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls, corrections or removals of any of AxoGen's products would divert managerial and financial resources and have an adverse effect on its business, results of operations and financial condition. A recall could harm AxoGen's reputation with customers and negatively affect its sales. AxoGen may initiate removals involving some of its products in the future that it determines do not require notification of the FDA. If the FDA were to disagree with AxoGen's determinations, it could request that it report those actions as recalls, and take regulatory or enforcement action relating to the product.

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

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

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

Sales of AxoGen products outside the U.S. are subject to foreign regulatory requirements that vary from country to country. In the European Union (the "EU") regulations, if applicable, differ from one EU member state to the next. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the EU, as well as for other countries, the approval process for human derived cell or tissue based medical products may be extensive, lengthy, expensive and unpredictable. AxoGen products will be subject to EU member states' regulations that govern the donation, procurement, testing, coding,

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traceability, processing, preservation, storage, and distribution of human tissues and cells and cellular or tissue-based products. In addition, some EU member states have their own tissue banking regulations. The inability to meet foreign regulatory requirements could materially affect AxoGen's future growth and compliance with such requirements could place a significant financial burden on AxoGen.

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

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

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

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

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

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



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

Human tissues intended for transplantation have been regulated by the FDA since 1993. In May 2005, three new comprehensive regulations went into effect that address manufacturing activities associated with HCT/Ps. The first requires that companies that produce and distribute HCT/Ps register with the FDA. The second provides criteria that must be met for donors to be eligible to donate tissues and is referred to as the "Donor Eligibility" rule. The third rule governs the processing and distribution of the tissues and is often referred to as the Current Good Tissue Practices rule. The Current Good Tissue Practices rule covers all stages of allograft processing, from procurement of tissue to distribution of final allografts. Together, they are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients. These regulations increased regulatory scrutiny within the industry in which AxoGen operates and have led to increased enforcement action, which affects the conduct of its business. See "Business — Government Regulations." In addition, these regulations can increase the cost of tissue recovery activities. Additionally, the Avance® Nerve Graft is subjected to certain state and local regulations, as well as compliance to the standards of the tissue bank industry's accrediting organization, the AATB.

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

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

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

### ***Healthcare policy changes 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



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way healthcare is financed by both governmental and private insurers, and encourages improvements in the quality of healthcare items and services. This Act significantly impacts the biotechnology and medical device industries and could have a material adverse impact on numerous aspects of AxoGen's business.

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

- a 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the U.S., with limited exceptions, beginning in 2013;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research;
- new reporting and disclosure requirements on healthcare manufacturers for any "transfer of value" made or distributed to physicians and teaching hospitals, as well as reporting of certain physician ownership interests, with the first of such reports due March 31, 2013 for calendar year 2012 ("Sunshine Act");
- payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models, beginning on or before January 1, 2013;
- an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate; and
- a new abbreviated pathway for the licensure of biologic products that are demonstrated to be biosimilar or interchangeable with a licensed biologic product.

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

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

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

### ***Risks Related to AxoGen's Intellectual Property***

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

AxoGen's success will depend, to a large extent, on its ability to successfully obtain and maintain patents, prevent misappropriation or infringement of IP, maintain trade secret protection, and conduct operations without violating or infringing on the IP rights of third parties. See "Business — Intellectual Property." There can be no assurance that AxoGen's patented and patent-pending technologies will provide it with a competitive advantage, that AxoGen will be able to develop or acquire additional technology that is patentable, or that third parties will

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not develop and offer technologies which are similar to AxoGen's. Moreover, AxoGen can provide no assurance that confidentiality agreements with its employees, consultants and other parties, trade secrecy agreements or similar agreements intended to protect unpatented technology will provide the intended protection. IP litigation is extremely expensive and time-consuming, and it is often difficult, if not impossible, to predict the outcome of such litigation. A failure by AxoGen to protect its IP could have a materially adverse effect on its business and operating results and its ability to successfully compete in its industry.

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

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

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

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

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

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

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

*AxoGen depends on maintenance of exclusive licenses.*

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

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

Not applicable.

### **ITEM 2. PROPERTIES**

AxoGen's corporate headquarters are currently located in Alachua, Florida, in a facility with a lease for 4,742 square feet of office space until April 2014. AxoGen also leases 2,224 square feet of laboratory and distribution space in University of Florida's Sid Martin Biotechnology Incubator in Alachua, Florida under a one-year lease until September 2013 and leases space and maintains records at certain facilities, which includes the Company's prior corporate headquarters at 1407 South Kings Highway, Texarkana, Texas 75501. The Company's aggregate cost of such properties is approximately \$176,000 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, although AxoGen will likely require additional space in the future to accommodate its expansion.

### **ITEM 3. LEGAL PROCEEDINGS**

On July 25, 2008, LecTec filed a complaint for patent infringement (the "Complaint") against five companies, including Chattem, Inc. (Ticker: CHTT), Endo Pharmaceuticals, Inc. (Ticker: ENDP), Johnson & Johnson Consumer Company, Inc. (Ticker: JNJ), The Mentholatum Company, Inc. (Division of Rohto

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Pharmaceuticals, Ticker RPHCF.PK), and Prince of Peace Enterprises, Inc. (Private Company) (collectively, the “Defendants”) in the U.S. District Court for the Eastern District of Texas. The Complaint alleged, among other things, that the Defendants infringed two of LecTec’s patents (the “Patents-In-Suit”), which related to LecTec’s medicated patch technology. LecTec sought to enjoin the Defendants from infringing the Patents-In-Suit and to recover monetary damages related to such infringement, as well as interest and litigation costs.

As of December 31, 2010, LecTec had settlement with Endo Pharmaceuticals, Inc., Johnson & Johnson Consumer Company, Inc. and The Mentholatum Company. On March 23, 2011, LecTec entered into a Confidential Settlement Agreement and Mutual Release (the “Chattem Settlement Agreement”) with Chattem to settle LecTec’s claims against Chattem that Chattem infringed the Patents-In-Suit. Pursuant to the Chattem Settlement Agreement, Chattem paid a one-time sum of \$3,600,000 to LecTec. and LecTec granted to Chattem a fully paid-up, world-wide, non-exclusive and irrevocable license to (a) the Patents-In-Suit, (b) any patent that claims priority, directly or indirectly, from the Patents-In-Suit (the “Family Patents”) and (c) any foreign counterparts of the Family Patents, for use in connection with any product or process sold or used by Chattem, other than products covered by exclusive licenses previously granted to other companies. Such settlement proceeds were before payment of contingent legal fees and any applicable taxes. In addition, under the Chattem Settlement Agreement, LecTec and Chattem entered into mutual releases of all claims.

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

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

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

Not applicable

**PART II**

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

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

The following table sets forth, for each of the calendar periods indicated, the quarterly high and low closing bid prices for the Company's common stock quoted on the OTC Bulletin Board. The prices in the table represent prices between dealers and do not include adjustments for retail mark-up, markdown or commission and may not represent actual transactions.

	Year Ended December 31, 2012		Year Ended December 31, 2011	
	High	Low	High	Low
First Quarter	\$ 3.49	\$ 2.60	\$ 4.00	\$ 2.75
Second Quarter	\$ 3.99	\$ 2.51	\$ 3.37	\$ 2.17
Third Quarter	\$ 3.25	\$ 2.50	\$ 3.00	\$ 2.00
Fourth Quarter	\$ 3.10	\$ 2.25	\$ 3.10	\$ 2.05

**Dividend Policy**

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

**Shareholders**

As of December 31, 2012, the Company had 11,122,573 shares of common stock outstanding, and approximately 342 common shareholders of record, based upon information received from our stock transfer agent. However, this number does not include beneficial owners whose shares were held of record by nominees or broker dealers. The Company estimates that there are approximately less than 850 individual owners.

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

We did not repurchase any of our securities during the year of 2012.

**Recent Sales of Unregistered Securities**

We had no sales of unregistered securities during 2012 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 I 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**

On September 30, 2011, LecTec completed its business combination with AC in accordance with the terms of the Merger Agreement. Pursuant to the Merger Agreement, Merger Sub merged with and into AC, with AC continuing after the Merger as the surviving corporation and a wholly owned subsidiary of LecTec. Immediately following the Merger, LecTec changed its name to AxoGen, Inc. In October 2011, AxoGen, Inc. moved its corporate headquarter facilities (principal executive office) from Texarkana, Texas to 13859 Progress Blvd., Suite 100, Alachua, Florida 32615.

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

AxoGen is a leading regenerative medicine company dedicated to advancing the science and commercialization of peripheral nerve repair solutions. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body and their damage can result in the loss of function and feeling. In order to improve surgical reconstruction and regeneration of peripheral nerves, AxoGen has developed and licensed patented and patent pending technologies. AxoGen's innovative approach to regenerative medicine has resulted in first-in-class products that will define their product categories. AxoGen's products offer a full suite of surgical nerve reconstruction solutions including Avance® Nerve Graft, the only commercially available processed nerve allograft for bridging severed nerves without the comorbidities associated with a second surgical site, AxoGuard® Nerve Connector, a porcine submucosa ExtraCellular Matrix ("ECM") coaptation aid for tensionless repair of severed nerves, and AxoGuard® Nerve Protector, a porcine submucosa ECM product used to wrap and protect injured peripheral nerves and reinforce coaptation sites while preventing soft tissue attachments.

Revenue from the distribution of these products is the main contributor to AxoGen's total reported sales and has been the key component of its growth to date. AxoGen revenues increased in the fourth quarter and the twelve months of 2012 compared to the fourth quarter and the twelve months of 2011, respectively, as a result of increased usage in the number of accounts utilizing our products. AxoGen has continued to broaden its sales and marketing focus which is expected to have a positive contribution to its revenue growth in the long term, even though in the near term revenue growth may lag behind expense increase.

From May 2009 to December 2010, AxoGen temporarily stopped the manufacturing of Avance® Nerve Graft due to adequate inventory. In December 2010, AxoGen resumed the manufacturing of Avance® Nerve Graft, and as a result incurred higher processing and testing fees, travel costs and temporary labor costs in 2011

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compared to 2012. In 2011 AxoGen reviewed inventory expiration and wrote off inventory for products manufactured in early 2009. Additionally AxoGen reviewed and adjusted inventories and established reserves to adequately reflect inventory value in 2011. AxoGen believes that such actions will not be required in the future and that it has the necessary inventories, inventory reserves and manufacturing capabilities for its anticipated sales growth.

### **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.

Our significant accounting policies are described in Note 3 to the consolidated financial statements contained in Item 8 of this Report. The most significant estimates include allowance for doubtful accounts, valuation of goodwill, effective interest rate on the note payable, and the provision for income taxes.

#### **Comparison of the Years Ended December 31, 2012 and 2011**

##### Revenues

Revenues for the year ended December 31, 2012 increased 59% to approximately \$7,692,000 as compared to approximately \$4,849,000 for the year ended December 31, 2011 principally due to a greater number of customers utilizing AxoGen products.

##### Gross Profit

Gross profit for the year ended December 31, 2012 increased 136% to approximately \$5,730,000 as compared to approximately \$2,423,000 for the year ended December 31, 2011. This increase was primarily attributable to the increased revenues and gross margin in 2012 and not incurring inventory write-offs such as that of \$614,000 for expiring inventory and \$214,000 for raw material obsolescence in 2011 or higher processing and testing fees, travel costs and temporary labor costs due to the resumption of the manufacturing of Avance® Nerve Graft in 2011.

##### Costs and Expenses

Total cost and expenses increased 44% to approximately \$13,532,000 for the year ended December 31, 2012 as compared to approximately \$9,392,000 for the year ended December 31, 2011. These increases were primarily due to increasing sales and marketing activities, increases in research and development in preparation for the Company's Investigational New Drug (IND) Application with the FDA and subsequent start of its phase 3 trial and increases in salaries as AxoGen hires to meet growth needs, offset by decreases in certain professional services and financing costs.

As a percentage of revenues, total operating expenses were 175.9% for the year ended December 31, 2012 compared to 193.7% for the year ended December 31, 2011. Such lower total costs and expenses as a percentage of revenue were a result of increased expenses in 2012 being absorbed by increased revenues.



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Sales and marketing expenses increased 57.2% to approximately \$6,884,000 for the year ended December 31, 2012 as compared to approximately \$4,379,000 for the year ended December 31, 2011. This increase was primarily due to an increase in sales and marketing activity as the Company expands support for both its direct sales force and independent distributors and increasing the number of its direct sales representatives. As a percentage of revenues, sales and marketing expenses were 89.4% for the year ended December 31, 2012 compared to 90.3% for the year ended December 31, 2011. Sales and marketing expenses as a percentage of revenue remaining flat between periods was primarily a result of 2012 revenue increases being offset by increased costs associated with new sales representatives and marketing and educational resources in 2012.

General and administrative expenses increased 21.0% to approximately \$5,221,000 for the year ended December 31, 2012 as compared to approximately \$4,316,000 for the year ended December 31, 2011. As a percentage of revenues, general and administrative expenses were 67.9% for the year ended December 31, 2012 compared to 89.0% the year ended December 31, 2011. The increase in aggregate dollars spent were a result of hiring and costs related to being a public company, offset by a savings in certain professional fees and finance costs. As a percentage of revenue, general and administrative expenses decreased as the increase in aggregate dollars spent were absorbed by the increase in revenues.

Research and development expenses increased 104.7% to approximately \$1,427,000 in the year ended December 31, 2012 as compared to approximately \$697,000 for the year ended December 31, 2011. Development includes AxoGen's clinical efforts and a large portion of the increase in research and development expenses from 2011 to 2012 related to expenditures for such clinical activity. Because AxoGen's products are developed for sale in their current use, it conducts limited direct research and product development, but intends to pursue new products and new applications for existing products in the future that may result in increased spending.

### Other Income and Expenses

Interest expense increased 27% to approximately \$1,391,000 in 2012 as compared to approximately \$1,095,000 for the year ended December 31, 2011. This increase was a result of the interest expense related to the PDL transaction. As a result of the accounting treatment for the PDL transaction, interest expense included approximately \$780,000 of non-cash expense that is expected to be paid in the future based upon the terms of the PDL transaction and increases in AxoGen revenues. Excluding this non-cash component, cash paid for interest decreased in 2012 by approximately \$483,000 compared to 2011 as a result of accrued interest on convertible debt and an increased interest rate on borrowed money in 2011 not recurring in 2012.

Interest expense — deferred financing costs decreased 19.3% to approximately \$987,000 for the year ended December 31, 2012 as compared to approximately \$1,223,000 for the year ended December 31, 2011. This decrease is primarily due to certain deferred financing costs associated with warrants issued as consideration for several amendments executed during 2010 related to the Loan and Security agreement originally entered into in April 2008 becoming fully amortized by March 31, 2011.

Change in fair value of warrant liability decreased 100% to \$0 in the year ended December 31, 2012 as compared to approximately \$62,000 for the year ended December 31, 2011.

### Income Taxes

Income tax benefit of approximately \$738,000 for 2012 was the result of the Company's ability to utilize net operating losses and franchise tax adjustments which resulted in tax refunds. The company had no income tax expense or income tax benefit for 2011 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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### **Effect of Inflation**

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

### **Liquidity and Capital Resources**

#### *Long-Term Debt / Note Payable*

On October 5, 2012, AxoGen entered into the Royalty Contract with PDL. Proceeds from the PDL transaction were used to fully repay the MidCap Loan and extinguish AxoGen's long-term debt obligations thereunder. When the Company entered into the Royalty Contract with PDL, pursuant to which the Company sold to PDL the right to receive specified royalties on the Company's Net Revenues (as defined in the Royalty Contract) generated by the sale, distribution or other use of the Company's products Avance® Nerve Graft, AxoGuard® Nerve Protector and AxoGuard® Nerve Connector (the "Acquired Revenues"). The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments currently paid weekly based on a high single digit royalty rate of the Company's Net Revenues (the "Assigned Interests"), subject to certain agreed upon minimum payment requirements which begin in the fourth quarter of 2014 as provided in the Royalty Contract. The total consideration PDL paid to the Company was \$20,800,000 (the "Funded Amount"), including \$19,050,000 PDL paid to the Company on October 5, 2012, and \$1,750,000 PDL paid to the Company on August 14, 2012 pursuant to the Interim Royalty Contract. Upon the closing of PDL's purchase of the specified royalties described above, which was concurrent with the execution of the Royalty Contract, the Interim Royalty Contract was terminated. There are no financial covenants or other restrictions on the use of capital by AxoGen as a result of the Royalty Contract, however, PDL has a first perfected security interest in the Assigned Interests.

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

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

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

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

On June 11, 2010, AxoGen entered into Convertible Debt Agreements for an aggregate principal amount of \$3.7 million with 8% interest and principal and interest payable in full on June 30, 2013, as amended. The Convertible Debt Agreements were collateralized by a third lien on certain property and were subordinated to the

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2008 Loan and Security Agreement. Immediately prior to the closing of the Merger, the Convertible Debt Agreements pursuant to their terms automatically converted into AC common stock which was then exchanged for Company common stock pursuant to the terms of the Merger Agreement.

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

The Company had no material commitments for capital expenditures at December 31, 2012 or 2011.

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

On October 5, 2012, AxoGen entered into the Royalty Contract with PDL. Under the Royalty Contract, the Company sold to PDL the Acquired Revenues. The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive the Assigned Interests, i.e., a royalty payment based on a high single digit royalty rate of the Company's Net Revenues, subject to certain agreed upon minimum payment requirements beginning in the fourth quarter of 2014 as provided in the Royalty Contract. The total consideration PDL paid to the Company was \$20,800,000, including \$19,050,000 PDL paid to the Company on October 5, 2012, and \$1,750,000 PDL paid to the Company on August 14, 2012, pursuant to the Interim Royalty Contract. Upon the closing of PDL's purchase of the specified royalties under the Royalty contract, which was concurrent with its execution, the Interim Royalty Contract was terminated. Proceeds from the PDL Royalty Contract transaction were used to fully repay the MidCap Loan and extinguish AxoGen's obligations thereunder. There are no financial covenants or other restrictions on the use of capital by AxoGen as a result of the Royalty Contract, however, PDL has a first perfected security interest in the Assigned Interests.

The Company currently has sufficient capital to maintain its operations for more than 12 months. If future capital is necessary, the Company may raise additional funds through public or private equity offerings, debt financings or from other sources. The sale of additional equity may result in dilution to AxoGen's shareholders. There is no assurance that, if necessary, AxoGen will be able to secure additional funding on terms acceptable to it, or at all. Should additional capital not become available to AxoGen, if needed, AxoGen may be required to take certain action, such as, slowing sales and marketing expansion, delaying certain regulatory activities or reducing headcount.

AxoGen had working capital of approximately \$16.8 million and a current ratio of 12.4 at December 31, 2012, compared to a working capital of \$8.8 and a current ratio of 5.4 at December 31, 2011. The increase in working capital and the current ratio at December 31, 2012, compared to December 31, 2011, was primarily due to the Royalty Contract with PDL.

The Company believes it has sufficient cash resources to meet its liquidity requirements for the next 12 months. AxoGen's future capital requirements depend on a number of factors, including, without limitation, revenue increases consistent with its business plan, cost of products, acquisition and/or development of new products and payments pursuant to the PDL transaction. If the Company requires additional capital it could seek 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. 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.

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During 2012, the Company had a net increase in cash and cash equivalents of \$5,717,000 as compared to a net increase of cash and cash equivalents of \$6,392,000 in 2011. The Company's principal sources and uses of funds are explained below:

### Net Cash used in operating activities

The Company used approximately \$8,662,000 of cash for operating activities in 2012, as compared to using approximately \$7,079,000 of cash for operating activities in 2011. This increase in cash used in operating activities is primarily attributed to the increase in net loss before income taxes in 2012, as well as cash used for inventory purchases.

### Net Cash provided by for investing activities

Investing activities for 2012 used approximately \$127,000 of cash as compared to 2011 which provided approximately \$7,112,000. This decrease in cash provided is attributable to cash acquired in 2011 as a result of the Merger.

### Net Cash provided by financing activities

Financing activities in 2012 provided approximately \$14,506,000 of cash as compared to approximately \$6,359,000 of cash in 2011. This increase in cash provided is primarily attributed to issuance of \$20,800,000 of additional debt, partially offset by the repayment of approximately \$5,000,000 of debt (of which approximately \$4.8 million is non-cash proceeds and payments) during 2012 and fees associated therewith.

## **Off-Balance Sheet Arrangements**

AxoGen does not have any off-balance sheet arrangements.

## **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Not applicable

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**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of AxoGen, Inc. as of December 31, 2012 and 2011, 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 audit.

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. as of December 31, 2012 and 2011, 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 12, 2013

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**AXOGEN, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**December 31, 2012 and 2011**

	December 31, 2012	December 31, 2011
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 13,907,401	\$ 8,190,781
Accounts receivable	1,050,089	797,654
Inventory	3,151,109	1,760,540
Prepaid expenses and other	187,256	133,500
<b>Total current assets</b>	<b>18,295,855</b>	<b>10,882,475</b>
<b>Property and equipment, net</b>	<b>108,534</b>	<b>247,824</b>
<b>Goodwill</b>	<b>—</b>	<b>169,987</b>
<b>Intangible assets</b>	<b>573,731</b>	<b>899,480</b>
<b>Deferred financing costs</b>	<b>1,252,443</b>	<b>295,276</b>
	<b><u>\$ 20,230,563</u></b>	<b><u>\$ 12,495,042</u></b>
<b>Liabilities and Shareholders' Equity (Deficit)</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 1,479,752	\$ 1,585,100
Current portion of long-term debt	—	434,734
<b>Total current liabilities</b>	<b>1,479,752</b>	<b>2,019,834</b>
<b>Long-term debt</b>	<b>—</b>	<b>4,403,737</b>
<b>Note Payable — Revenue Interest Purchase Agreement</b>	<b>21,580,252</b>	<b>—</b>
<b>Total liabilities</b>	<b><u>23,060,004</u></b>	<b><u>6,423,571</u></b>
<b>Shareholders' equity (deficit):</b>		
Common stock, \$.01 par value; 50,000,000 shares authorized; 11,122,573 and 11,062,188 shares issued and outstanding	111,226	110,622
Additional paid-in capital	54,908,226	54,391,784
Accumulated deficit	(57,848,893)	(48,430,935)
<b>Total shareholders' equity (deficit)</b>	<b><u>(2,829,441)</u></b>	<b><u>6,071,471</u></b>
	<b><u>\$ 20,230,563</u></b>	<b><u>\$ 12,495,042</u></b>

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



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**AXOGEN, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**Years ended December 31, 2012 and 2011**

	2012	2011
<b>Revenues</b>	\$ 7,691,704	\$ 4,849,470
<b>Cost of goods sold</b>	1,961,877	2,426,544
<b>Gross profit</b>	5,729,827	2,422,926
<b>Costs and expenses:</b>		
Sales and marketing	6,883,953	4,378,694
Research and development	1,427,211	697,355
General and administrative	5,220,599	4,315,604
<b>Total costs and expenses</b>	13,531,763	9,391,653
<b>Loss from operations</b>	(7,801,936)	(6,968,727)
<b>Other income (expense):</b>		
Interest expense	(1,391,342)	(1,094,657)
Interest expense — deferred financing costs	(986,844)	(1,223,126)
Change in fair value of warrant liability	—	62,305
Other income	23,972	4,985
<b>Total other income (expense)</b>	(2,354,214)	(2,250,493)
<b>Loss before income taxes</b>	(10,156,150)	(9,219,220)
<b>Income tax benefit</b>	738,192	—
<b>Net Loss</b>	(9,417,958)	(9,219,220)
Preferred Stock dividends (assumes all paid)	—	(1,028,351)
Net loss available to common shareholders	\$ (9,417,958)	\$ (10,247,571)
Weighted Average Common Shares outstanding — basic and diluted	11,089,425	3,697,390
Loss Per Common share — basic and diluted	\$ (0.85)	\$ (2.77)

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, 2012 and 2011**

	<i>Series A Convertible Preferred Stock</i>		<i>Common Stock</i>		<i>Additional Paid-in Capital</i>	<i>Accumulated Deficit</i>	<i>Total Stockholders' Deficit</i>
	<i>Shares</i>	<i>Amount</i>	<i>Shares</i>	<i>Amount</i>			
<b>Balance, December 31, 2010</b>	2,544,750	\$ 1,125,000	1,205,624	\$ 12,056	9,934,980	\$(38,183,364)	\$(27,111,328)
Stock-based compensation	—	—	—	—	250,044	—	250,044
Exercise of stock options	—	—	98,700	987	25,493	—	26,480
Director Stock Compensation	—	—	27,275	273	74,727	—	75,000
Conversion of preferred stock, debt, and accrued interest into Common Stock and shares exchange in Merger	(2,544,750)	(1,125,000)	5,001,854	50,019	21,447,936	—	20,372,955
Preferred Stock dividend payable forfeited	—	—	—	—	7,076,729	—	7,076,729
Warrant Liability forfeited	—	—	—	—	2,607,510	—	2,607,510
Merger Closing — LecTec shares	—	—	4,305,026	43,050	11,804,866	—	11,847,916
Issuance of common stock	—	—	423,709	4,237	995,763	—	1,000,000
Issuance of warrants	—	—	—	—	173,736	—	173,736
Series B preferred stock dividends	—	—	—	—	—	(292,330)	(292,330)
Series C preferred stock dividends	—	—	—	—	—	(515,577)	(515,577)
Series D preferred stock dividends	—	—	—	—	—	(220,444)	(220,444)
Net loss	—	—	—	—	—	(9,219,220)	(9,219,220)
<b>Balance, December 31, 2011</b>	—	—	11,062,188	\$110,622	\$54,391,784	\$(48,430,935)	\$ 6,071,471
Stock-based compensation	—	—	—	—	495,077	—	495,077
Exercise of stock options	—	—	58,340	583	15,069	—	15,652
Stock Grant for Services	—	—	7,500	75	21,300	—	21,375
Cancellation of shares	—	—	(5,455)	(54)	(14,946)	—	(14,999)
Merger Closing — Fractional shares	—	—	—	—	(58)	—	(58)
Net loss	—	—	—	—	—	(9,417,958)	(9,417,958)
<b>Balance, December 31, 2012</b>	—	—	11,122,573	\$111,226	\$54,908,226	\$(57,848,893)	\$ (2,829,441)

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, 2012 and 2011**

	2012	2011
<b>Cash flows from operating activities:</b>		
Net loss	\$ (9,417,958)	\$ (9,219,220)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	187,749	273,528
Amortization of intangible assets	127,080	67,147
Loss on impairment	299,654	—
Loss on abandonment of license	147,826	—
Amortization of deferred financing costs	352,667	1,223,126
Amortization of debt discount	161,529	23,643
Stock-based compensation	495,077	250,044
Directors Stock Compensation	—	15,000
Stock grant for service	21,375	—
Cancellation of shares	(14,999)	—
Change in fair value of warrant liability	—	(62,305)
Interest added to note payable	780,252	55,562
Change in assets and liabilities:		
Accounts receivable	(252,435)	(368,954)
Inventory	(1,390,570)	142,249
Prepaid expenses and other	(53,757)	20,070
Accounts payable and accrued expenses	(105,348)	500,820
<b>Net cash used for operating activities</b>	<b><u>(8,661,858)</u></b>	<b><u>(7,079,290)</u></b>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(48,459)	(20,610)
Acquisition of intangible assets	(78,825)	(68,856)
Cash acquired with Merger	—	7,201,638
<b>Net cash (used for) provided by investing activities</b>	<b><u>(127,284)</u></b>	<b><u>7,112,172</u></b>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of long-term debt	—	10,500,000
Proceeds from issuance of note payable	15,961,294	—
Proceeds from issuance of common stock	—	1,000,000
Repayments of long-term debt	(161,292)	(4,732,857)
Debt issuance costs	(1,309,834)	(434,772)
Proceeds from exercise of stock options	15,652	26,480
Merger	(58)	—
<b>Net cash provided by financing activities</b>	<b><u>14,505,762</u></b>	<b><u>6,358,851</u></b>
Net increase in cash and cash equivalents	5,716,620	6,391,733
<b>Cash and cash equivalents, beginning of year</b>	<b><u>8,190,781</u></b>	<b><u>1,799,048</u></b>
<b>Cash and cash equivalents, end of period</b>	<b><u>\$13,907,401</u></b>	<b><u>\$ 8,190,781</u></b>
<b>Supplemental disclosures of cash flow activity:</b>		
Cash paid for interest	\$ 649,108	\$ 1,029,753
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Payments of long term debt with proceeds from note payable	\$ 4,838,706	\$ —
Conversion of preferred stock, convertible debt and accrued interest into common stock	—	21,497,955
Accretion of dividends of Series B preferred stock	—	292,330
Accretion of dividends of Series C preferred stock	—	515,577
Accretion of dividends of Series D preferred stock	—	220,444
Preferred stock dividend payable forfeited with the Merger	—	7,076,729
Warrant Liability forfeited with the Merger	—	2,607,510
Debt discount related to warrants issued with debt	—	173,736
Net assets acquired on Merger	—	11,847,916
Note and accrued interest retired with the Merger	—	4,555,562
Directors stock compensation included in prepaid expenses	—	60,000

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

**AXOGEN, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2012 and 2011**

**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, 2012 and December 31, 2011 and the years then ended. The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. All significant intercompany accounts and transactions have been eliminated in consolidation.

**2. Organization and Business**

**Business Summary**

On September 30, 2011, LecTec Corporation ("LecTec") completed its business combination with AC in accordance with the terms of an Agreement and Plan of Merger, dated as of May 31, 2011, by and among LecTec, Nerve Merger Sub Corp., a subsidiary of LecTec ("Merger Sub"), and AC, which the parties amended on September 30, 2011 and August 9, 2011 (as amended, the "Merger Agreement"). Pursuant to the Merger Agreement, Merger Sub merged with and into AC, with AC continuing after the merger as the surviving corporation and a wholly owned subsidiary of LecTec (the "Merger"). Immediately following the Merger, LecTec changed its name to AxoGen, Inc. In October 2011, the Company moved its corporate headquarter facilities (principal executive office) from Texarkana, Texas to 13859 Progress Blvd., Suite 100, Alachua, Florida 32615.

In connection with the Merger,

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

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

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

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

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

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

The Company is a regenerative medicine company with a portfolio of proprietary products and technologies for peripheral nerve reconstruction and regeneration. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body and their damage can result in the loss of function and feeling. In order to improve surgical reconstruction and regeneration of peripheral nerves, the Company has developed and licensed technologies which are used in its products. Its product portfolio includes Avance® Nerve Graft, which the Company believes is the first and only commercially available allograft nerve for bridging nerve discontinuities (a gap created when the nerve is severed), AxoGuard® Nerve Connector, a coaptation aid allowing for close approximation of severed nerves, and AxoGuard® Nerve Protector that protects nerves during the body's healing process after surgery.

### **3. Summary of Significant Accounting Policies**

#### **Revenue Recognition**

Revenue is recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. Revenues for products are recognized when the tissue is delivered to the customer, at which time title passes to the customer. Once product is delivered, the Company has no further performance obligations. Delivery is defined as delivery to a customer location or segregation of product into a contracted distribution location. At such time, this product cannot be sold to any other customer. Fees charged to customers for storage and shipping of products are recognized as revenues when processed tissue is shipped to the customer or end user.

#### **Cash and Cash Equivalents and Concentration**

For purposes of the statement of cash flows, the Company considers all highly liquid debt instruments purchased with a maturity of three months or less to be cash equivalents. Cash and cash equivalents are maintained at financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances and does not believe it is not 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. As of December 31, 2012 and December 31, 2011, there were no amounts deemed uncollectible and there was no allowance for doubtful accounts recorded.

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

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### Inventories

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

	December 31, 2012	December 31, 2011
Finished goods	\$2,143,176	\$1,374,817
Work in process	145,156	145,300
Raw materials	862,777	240,423
	<u>\$3,151,109</u>	<u>\$1,760,540</u>

Inventories are net of reserve of \$537,798 and \$433,706 at December 31, 2012 and 2011, respectively

### Property and Equipment

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

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

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

### Intangible Assets

Intangible assets consist primarily of license agreements for exclusive rights to use various patented and patent-pending technologies described in Note 6 and other costs related to the license agreements, including patent prosecution and protection costs. Such costs are capitalized and amortized on a straight-line basis over the underlying terms of the license agreements or estimated useful life of patents, ranging from 5 to 20 years.

### Impairment of Long-lived Assets, Including License Agreements

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. For the year ended December 31, 2012, the Company recorded an impairment loss of \$129,667; there was no impairment for the year ended December 31, 2011.

### Goodwill

Goodwill represents the excess of the purchase price over the fair value of net assets acquired. Goodwill is not amortized, but is tested for impairment annually. The Company utilizes the income approach in estimating fair value. The Company's 2012 annual goodwill impairment analysis indicated a significant decrease in the carrying value of goodwill, due to declines in the associated revenues, resulting in a \$169,887 impairment loss being recorded for the year ended December 31, 2012; there was no impairment for the year ended December 31, 2011.

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### **Deferred Financing Costs**

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

### **Advertising**

Advertising costs are expensed as incurred. Advertising costs were approximately \$56,000 and \$17,000 for 2012 and 2011, respectively, and are included in sales and marketing expense on the accompanying consolidated statements of operations.

### **Research and Development Costs**

Research and Development costs are expensed as incurred.

### **Income Taxes**

The Company has not recorded current income tax expense due to the generation of net operating losses. Deferred income taxes are accounted for using the balance sheet approach which requires recognition of deferred tax assets and liabilities for the expected future consequences of temporary differences between the financial reporting basis and the tax basis of assets and liabilities. A valuation allowance is provided when it is more likely than not that a deferred tax asset will not be realized. A full valuation allowance has been established on the deferred tax asset as it is more likely than not that future tax benefit will not be realized. 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, 2009 through 2012; there currently are no examinations in process.

### **Preferred Stock**

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

Prior to conversion in connection with the Merger, all or any number of the Series B, Series C, and Series D preferred stock was originally redeemable by a majority of preferred shareholder approval at any time after January 7, 2015 at a redemption price determined in accordance with the Company's Certificate of Incorporation, plus accrued and unpaid dividends. The Company has determined that its Series B, Series C, and Series D preferred stock required temporary equity classification as its obligation to redeem these instruments were outside the control of the Company. Permanent equity classification was not currently applicable as the preferred stock was not currently redeemable but may become so in the future.



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### **Fair Value of Financial Instruments**

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

### **Stock-Based Compensation**

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

<u>Years ended December 31,</u>	<u>2012</u>	<u>2011</u>
Expected term (in years)	4.0	4.0
Expected volatility	117.2%	90.9%
Risk free rate	0.61%	1.27%
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, 2012 and 2011 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.

The basic loss attributable to common stockholders was computed as follows:

	<u>Years Ended December 31,</u>	
	<u>2012</u>	<u>2011</u>
Net loss	<u>\$(9,417,958)</u>	<u>\$ (9,219,220)</u>
Less preferred dividends	(—)	(1,028,351)
Net loss attributable to common stockholders	<u>\$(9,417,958)</u>	<u>\$(10,247,571)</u>

There were no dilutive instruments as of December 31, 2012 and 2011. The basic and diluted weighted average shares outstanding were 11,089,425 and 3,697,390 for the years ended December 31, 2012 and 2011.

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### **Use of Estimates**

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

### **Recent Accounting Pronouncements**

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

## **4. Merger**

On September 30, 2011, LecTec completed its business combination with AC pursuant to the terms of the Merger Agreement (see Note 2).

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

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

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

	Year Ended December 31, 2011
Revenues	\$ 4,914,938
Net Loss	\$ (8,610,775)
Basic and diluted net loss per common share	\$ (0.79)
Weighted average shares — basic and diluted	10,957,705

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### 5. Property and Equipment

Property and equipment consist of the following:

	December 31, 2012	December 31, 2011
Furniture and equipment	\$ 572,459	\$ 535,183
Leasehold improvements	42,564	42,564
Processing equipment	995,815	988,716
Less: accumulated depreciation and amortization	(1,502,304)	(1,318,639)
Property and equipment	<u>\$ 108,534</u>	<u>\$ 247,824</u>

### 6. Intangible Assets

The Company's intangible assets consist of the following:

	December 31, 2012	December 31, 2011
License agreements	\$ 772,230	\$ 899,231
Patents	63,429	291,907
Less: accumulated amortization	(261,928)	(291,658)
<b>Intangible assets, net</b>	<u>\$ 573,731</u>	<u>\$ 899,480</u>

License agreements are being amortized over periods ranging from 17-20 years. Patent costs are being amortized over three years. Pending patent costs are not amortizable. Amortization expense for 2012 and 2011 was approximately \$127,000 and \$67,000, respectively. As of December 31, 2012, future amortization of license and patent agreements is expected to be \$58,400 for 2013 \$55,300 for 2014, \$46,000 for 2015, 2016 and 2017.

In 2012 the Company determined that the carrying value of certain patents were not recoverable and exceeded their estimated fair value. As a result, the Company recorded an impairment loss of \$129,667 to reduce these patents to their estimated fair value.

#### License Agreements

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

- AxoGen pays royalty fees ranging from 1% to 3% under the License Agreements based on net sales of licensed products. One of the agreements also contains a minimum royalty of \$12,500 per quarter, which may include a credit in future quarters in the same calendar year for the amount the minimum royalty exceeds the royalty fees. Also, when AxoGen pays royalties to more than one licensor for sales of the same product, a royalty stack cap applies, capping total royalties at 3.75%;
- Under one of the agreements, if AxoGen does not achieve certain regulatory milestones, which AxoGen has not achieved, AxoGen would owe an annual license maintenance fee starting on August 31, 2012 of \$120,000, escalating to \$240,000 on August 31, 2013 and August 31, 2014. In 2012, AxoGen decided to abandon the license and as a result recorded a \$147,826 loss on abandonment of license.

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- If AxoGen sublicenses technologies covered by the License Agreements to third parties, AxoGen would pay a percentage of sublicense fees received from the third party to the licensor. Currently, AxoGen does not sublicense any technologies covered by License Agreements. The Company is not considered a sub-licensee under the License Agreements and does not owe any sublicensee fees for its own use of the technologies;
- AxoGen reimburses the licensors for certain legal expenses incurred for patent prosecution and defense of the technologies covered by the License Agreements; and
- Currently, under one of the License Agreements, AxoGen would owe a \$15,000 milestone fee upon receiving a Phase II Small Business Innovation Research or Phase II Small Business Technology Transfer grant involving the licensed technology. The Company has not received either grant and does not owe such a milestone fee. Other milestone fees are due if AxoGen develops certain pharmaceutical or medical device products under the License Agreements. No such products are currently under development.

Royalty fees were approximately \$167,000 and \$115,000 during 2012 and 2011 and are included in sales and marketing expense on the accompanying consolidated statements of operations.

### **7. Long-Term Debt / Note Payable**

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

	December 31, 2012	December 31, 2011
Loan and Security Agreement with financial institutions for aggregate of \$5,000,000 with 9.9% interest payable monthly through September 2012; principal and interest payable monthly for the 30 months thereafter maturing on April 1, 2015, collateralized by all the assets of the Company and subject to certain financial covenant restrictions including minimum revenue requirements	\$ —	\$5,000,000
Revenue Interest Purchase Agreement with PDL BioPharma, Inc. (“PDL”) for aggregate of \$20,800,000 with amounts payable monthly at a high single digit percentage based on the Net Revenues through September 2014; and the greater of (i) high single digit percentage of product revenue or (ii) specific quarterly amounts varying from approximately \$1.3 million to \$2.5 million per quarter through September 2020.	21,580,252	—
<b>Total debt</b>	<b>21,580,252</b>	<b>5,000,000</b>
Less unamortized debt discount	—	(161,529)
Less current portion	—	(434,734)
<b>Long-term portion</b>	<b>\$21,580,252</b>	<b>\$4,403,737</b>

### **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 specified royalties on 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 has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments based on a high single digit royalty rate of the Company’s Net Revenues, subject to certain agreed upon minimum payment requirements of approximately \$1.3 to \$2.5 million per quarter which begin in the fourth quarter of 2014 through the third quarter of 2020 as provided in the Royalty Contract. The total consideration PDL paid to the Company was \$20,800,000 (the “Funded Amount”), including \$19,050,000 PDL paid to the Company on October 5, 2012, and \$1,750,000 PDL paid to the Company on August 14, 2012 pursuant to an Interim Revenue Interest Purchase Agreement between the Company and PDL, dated August 14,

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2012 (the “Interim Royalty Contract”). Upon the closing (the “Closing”) of PDL’s purchase of the specified royalties described above, which was concurrent with the execution of the Royalty Contract, the Interim Royalty Contract was terminated.

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

### *Put Option*

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

### *Change of Control; Call Option*

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

### *Board Designee*

Under the Royalty Contract, during the term of the Royalty Contract, PDL is entitled to designate, and AxoGen shall appoint an individual designated by PDL, who shall serve on the Board of Directors of the Company (the “Board”) until the Company’s 2013 Annual Meeting of Shareholders (the “2013 Annual Meeting”). For the 2013 Annual Meeting and each annual meeting thereafter during the term of the Royalty Contract, the Board shall nominate and recommend the PDL designee as a director nominee to serve on the Board until the next annual meeting and shall include such nomination in AxoGen’s proxy statement for the 2013 Annual Meeting and each annual meeting thereafter, provided that the election of the PDL designee is subject to shareholders’ approval. Should at any time there become a vacancy on the Board as a result of (i) the resignation, death or removal of the PDL designee or (ii) such PDL designee failing to obtain the requisite approval of the Company’s shareholders at any annual or special meeting of the Company’s shareholders and where no other individual is elected to such vacancy, PDL shall have the right to designate an individual to fill such vacancy, and AxoGen shall take such actions necessary to appoint, such individual to the Board.

### *Preemptive Rights*

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

### *Restriction on Dividends*

Under the Royalty Contract, during the period from the October 5, 2012 to December 4, 2016 (or the payment of the Put Price in the event PDL exercises its put option on or prior to December 4, 2016), AxoGen

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

### *Guarantee and Collateral Agreement*

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

The minimum contractual payments related to the note payable — revenue royalty are 2013- a high single digit royalty rate applied to net revenues as defined in the agreement, 2014- a high single digit royalty rate applied to net revenues for the first three quarters plus \$1,250,805 in the fourth quarter of 2014, 2015-\$6,781,440, 2016-\$9,232,642, \$9,000,000 in 2017 and \$25,002,000 thereafter.

### **Long-Term Debt**

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

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

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

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

In conjunction with the 2008 Loan and Security Agreement, the Company also issued warrants to purchase a combined 280,803 shares of the Company’s Series C Preferred Stock, immediately exercisable at \$0.7345 per share, expiring on May 1, 2018. The fair value of the warrants was recorded as debt discount and was being amortized through interest expense using the effective interest method over the term of the debt. Amortization of this debt discount was \$11,436 during 2011.

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

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

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

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

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

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

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



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### **2011 Convertible Debt**

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

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

The \$4,500,000 notes to LecTec were retired on September 30, 2011 after the closing of the Merger. The \$1,000,000 notes to certain AC shareholders were converted into 423,709 shares of AxoGen, Inc.'s common stock using the \$0.088 conversion price and 0.03727336 exchange ratio.

### **8. Stockholders' Equity (Deficit) and Temporary Equity**

#### **AxoGen, Inc. Classes of Stock**

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

In connection with the Merger, 32,709,676 shares of AC common stock were converted into 1,219,199 shares of AxoGen, Inc.'s common stock using the 0.03727336 exchange ratio.

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

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

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

##### *General*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

On January 7, 2010, AC issued 39,156,876 shares of Series D Preferred Stock ("Series D") at \$0.1198 per share for an aggregate price of \$4,661,326, net of issuance costs of \$29,667. Of the total shares issued, 16,694,489 shares were issued for \$2,000,000 in cash. The remaining 22,462,387 shares were issued in conjunction with the conversion of \$2,617,000 of principal and \$73,994 of accrued and unpaid interest under the 2009 Convertible Debt (see Note 7). The holders of the Series D are entitled to receive a cash dividend in preference over all other shareholders of AC at a rate of 8% of the issued price, per annum. Upon liquidation, the Series D holders have preference to any distributions of any of AC's assets equal to the Preferred Original Issue Price plus any unpaid dividends. At any time on or after January 7, 2015, the Series D shareholders have the right to redeem shares equal to the redemption price upon written request of at least 66 2/3% of the holders of Series D. Each share of Series D is convertible into AC common stock at any time at the option of the holder by dividing the Preferred Original Issue Price by the Conversion Price at the time of conversion, which as of December 31, 2010 is equal to the purchase price of \$0.1198. The conversion price is subject to adjustment, as defined. The holders of a majority of the Series B, C and D have the right to elect three directors to the Board. Also, Series B, C and D will vote together with Series A and AC common shareholders to elect two directors to the Board. Each share of Series B, C and D has voting rights equal to the number of AC common shares as if converted.

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

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

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

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### 9. Preferred Stock Warrants and Warrant Liability

#### **Preferred Stock Warrants**

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

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

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

#### **Warrant Liability**

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

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

	<b>2011</b>
Exercise price	\$0.1198 – \$0.7345
Market value of stock at end of period	\$0.01
Expected dividend rate	0.00%
Expected volatility	33.47% – 62.86%
Risk-free interest rate	0.03% – 3.18%
Expected life in years	3.40 – 9.90
Shares underlying warrants outstanding classified as liabilities	41,558,259

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

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### 10. Stock Options

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

AxoGen, Inc. has a AxoGen 2010 Stock Incentive Plan (the “AxoGen Plan”), which allows for issuance of incentive stock options and non-qualified stock options to employees, directors and consultants at an exercise price equal to or greater than fair market value. On September 27, 2011, LecTec amended and restated the AxoGen Plan to, among other things, increase the number of shares of common stock authorized for issuance under the plan by 2,300,000 shares. The total number of shares authorized for issuance under the AxoGen Plan is 2,750,000 shares. As a result of the Merger, options granted under the AC Plan were assumed by the Company so that each stock option pursuant to the AC Plan so assumed continued to have, and be subject to, the same terms and conditions of such stock option immediately prior to the Merger, except that (i) each AC Plan stock option is exercisable for that number of shares of Company common stock equal to the product of the number of shares of AC common stock that were issuable upon exercise of such stock option immediately prior to the Merger multiplied by the Closing Ratio (“as defined in the Merger Agreement”) and (ii) the per share exercise price for the shares of Company common stock issuable upon the exercise of such assumed stock option will be equal to the quotient determined by dividing the exercise price per share of AC common stock at which such stock option was exercisable immediately prior to the Merger by the Closing Ratio. The options to employees typically vest 12.5% every six months over a four-year period and those to directors and certain executive officers have vested 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 \$495,077 and \$250,044 for 2012 and 2011, 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, 2010:	447,659	\$ 0.27	8.62
Granted	1,141,952	2.61	
LecTec stock option from Merger	464,000	3.48	
Forfeited	(9,223)	(0.06)	
Exercised	(98,700)	(0.27)	
Outstanding at December 31, 2011:	1,945,688	2.41	7.35
Granted	267,576	2.99	
Forfeited	(354,932)	(2.48)	
Exercised	(58,341)	(0.27)	
Outstanding at December 31, 2012	1,799,991	2.54	7.66
Exercisable at December 31, 2012	941,876	2.71	7.11

The average fair value of options granted at market during 2012 and 2011 was \$2.99 and \$0.42 per option, respectively.

The intrinsic value of options exercised during the years ended December 31, 2012 and 2011 was approximately \$173,000 and \$190,000, respectively. The intrinsic value of options outstanding at December 31, 2012 and 2011 was approximately \$288,000 and \$1,126,000, respectively. The intrinsic value of options exercisable at December 31, 2012 and 2011 was approximately \$0 and \$391,000, respectively.

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In connection with the Merger, all outstanding options to purchase shares of AC Common Stock were exchanged for options to purchase shares of AxoGen, Inc. common stock at a ratio of one to 0.03727336. The Company recorded \$19,769 and \$38,521 incremental cost in 2012 and 2011, respectively, related to this modification.

Total future compensation expense related to nonvested awards is expected to be approximately \$1,405,000 at December 31, 2012 which is expected to be recognized over a weighted average period of 3.04 years. The following table represents non-vested share-based payment activity with employees for the year ended December 31, 2012 and 2011:

	Number of Options	Weighted Average Grant Date Fair Value
Nonvested options — December 31, 2010:	325,575	0.27
Granted	1,141,952	0.42
Vested	(195,099)	(0.87)
Forfeited	<u>(9,223)</u>	(0.004)
Nonvested options — December 31, 2011:	1,263,205	1.41
Granted	267,576	2.99
Vested	(317,734)	(1.92)
Forfeited	<u>(354,932)</u>	(2.48)
Nonvested options — December 31, 2012	<u>858,115</u>	2.36

## 11. Income Taxes

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

December 31	2012	2011
<b>Deferred tax assets:</b>	\$	\$
Net operating loss carryforwards	18,182,000	15,065,000
Charitable contributions	2,800	3,000
Inventory Reserves	365,600	163,000
Stock-based compensation	<u>52,300</u>	<u>361,000</u>
Total deferred tax assets	<u>18,602,700</u>	<u>15,592,000</u>
<b>Deferred tax liabilities:</b>		
Depreciation	(154,900)	(160,000)
Amortization	<u>(51,700)</u>	<u>(51,000)</u>
Total deferred tax liabilities	<u>(206,600)</u>	<u>(211,000)</u>
Net deferred tax assets	<u>18,396,100</u>	<u>15,381,000</u>
Valuation allowance	<u>(18,396,100)</u>	<u>(15,381,000)</u>

As of December 31, 2012, the Company had net operating loss carry forwards of approximately \$48.3 million to offset future taxable income which expire in various years through 2031. 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, 2012 and 2011. The valuation allowance increased by \$3,015,100 and \$3,572,000 during 2012 and 2011, respectively.

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The net income tax benefit of approximately \$738,000 for 2012 was the result of the Company's ability to utilize net operating losses and franchise tax adjustments which resulted in tax refunds. The Company had no income tax expense or income tax benefit for 2011 due to incurrence of net operating losses. The Company does not believe there are any additional tax refund opportunities currently available.

### **12. Employee Benefit Plan**

The Company adopted the AxoGen Simple IRA plan in 2007. All full-time employees who have attained the age of 18 are eligible to participate in the Plan. Eligibility is immediate upon employment and enrollment is available any time during employment. Participating employees may make annual pretax contributions to their accounts up to a maximum amount as limited by law. The simple IRA plan requires the Company to make matching contributions of between 1% and 3% of the employee's annual salary as long as the employee participates in the Plan. Additionally, the matching has to be at least 3% for three of the first five years of the Plan. Both employee contributions and Company contributions vest immediately. In 2012 and 2011, the Company match was 3% of the participating employee's annual salary. The Company contributed \$102,189 and \$66,687 in matching funds during 2012 and 2011, respectively.

### **13. Commitments and Contingencies Operating Leases**

#### **Operating Leases**

The Company leases its lab space under one-year lease agreements, currently expiring in September 2013.

Its corporate office space lease agreement expires in April 2014. Estimated future minimum rental payments on the leases are as follows:

Year ending December 31	
2013	\$145,964
2014	<u>34,015</u>
TOTAL	<u>\$179,979</u>

Total rent expense for the Company's leased office and lab space for the years ended December 31, 2012 and 2011 was approximately \$176,000 and \$171,000, respectively.

#### **Service Agreements**

In 2008, the Company entered into a biostorage and management services agreement with a vendor. The agreement specifies monthly administration fees, storage fees based on volume, and retrieval fees per specimen based on lead times. The agreement can be terminated with 90 days written notice.

In 2009, the Company also entered into a two-year tissue processing agreement with another vendor. Tissue processing fees are based on a per donor batch rate. The agreement requires minimum annual purchases of \$160,000 and either party may terminate this agreement with six month written notice. In 2011 and 2012, the parties agreed to an extension for an additional twelve months and amended the agreement to provide for automatic twelve month renewals.

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

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

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



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

Not Applicable.

**ITEM 9A. CONTROLS AND PROCEDURES**

**EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES**

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

Our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2011 and concluded that our disclosure controls and procedures were ineffective as of December 31, 2011. Actions were taken in 2012 to correct such situation and our management believes as of December 31, 2012 the design and operation of our disclosure controls and procedures were effective.

**MANAGEMENT’S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

Our management is responsible for establishing and maintaining internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. The Company’s internal control system is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes, in accordance with generally accepted accounting principles. Because of inherent limitations, a system of internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate due to change in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has excluded AC from its assessment of internal control over financial reporting as of December 31, 2011 because it was acquired in a business combination that was accounted for as a reverse merger at the end of the third quarter of 2011. AC’s total assets and total revenues represents 34% and 99%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2011.

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

Subsequent to December 31, 2011, we became aware of an instance in which the accounting for a contract was inappropriately treated as an expense as opposed to a prepaid asset. Specifically, an effective control was not operating to ensure that accounting for the contract was completely and accurately recorded during the 4th quarter of 2011. This control deficiency could have resulted in misstatement of net loss that would not have been prevented or detected. Accordingly, we determined that this control deficiency constituted a material weakness.

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

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

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

Based on its evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2012.

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

### **CHANGES IN INTERNAL CONTROLS OVER FINANCIAL REPORTING**

During the quarter ended December 31, 2012, 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.**

**Executive Officers and Directors**

At the Company's 2012 annual meeting of shareholders (the "Annual Meeting"), Greg Freitag, Mark Gold, M.D., Jamie M. Grooms, John Harper, Joe Mandato, Karen Zaderej and Robert Rudelius were nominated for re-election to AxoGen's Board of Directors (the "Board") and the AxoGen shareholders approved their election.

On October 5, 2012, the AxoGen Board approved the increase in its size from seven directors to eight directors, and Mr. McLaughlin, a PDL designee, was elected to the Board to serve until the 2013 Annual Meeting. See "Business — PDL BioPharma, Inc. Revenue Interest Purchase Agreement — Board Designee."

Each elected director was to hold office for a term of one year and until their successors are duly elected and qualified (except in the case of earlier death, resignation or removal). The following table lists the names, age and positions of the individuals who serve on the Board of Directors of the Company as of March 12, 2013,

<u>Name</u>	<u>Age</u>	<u>Title</u>
Karen Zaderej	51	Chief Executive Officer and Director
Gregory Freitag	51	Chief Financial Officer, General Counsel and Director
Jamie M. Grooms	53	Director, Chairman of the Board of Directors
Mark Gold, M.D.	63	Director
John Harper	62	Director
Joe Mandato	68	Director
Robert Rudelius	57	Director
John P. McLaughlin	61	Director

*Karen Zaderej, President, Chief Executive Officer and Director (Age 51)*

Ms. Zaderej's biographical information is provided above under "Business — Executive Officers of the Registrant."

*Gregory G. Freitag, Chief Financial Officer and Director (Age 51)*

Mr. Freitag's biographical information is provided above under "Business — Executive Officers of the Registrant."

*Jamie M. Grooms, Chairman and Director (Age 53)*

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

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### *Mark Gold, MD, Director (Age 63)*

Dr. Gold has served as a member of the Company's board of directors since September 30, 2011 and AC's board of directors since July 2007. Since 1991, Dr. Gold has been a Professor at the University of Florida College of Medicine's McKnight Brain Institute. Dr. Gold has taught medical neuroscience for four decades and has been a pioneer in translational neuroscience research for over three decades. Dr. Gold was also a Founder of Somerset Valley Bank and served on its board of directors from its formation through its initial public offering to its acquisition by Fulton Financial Corporation, a publicly-traded financial holding company. Dr. Gold has consulted for many major global pharmaceutical companies as well as firms such as the Carlyle Group and Cressey & Company. Dr. Gold has authored hundreds of scientific research articles, chapters, and abstracts on a wide variety of research subjects and is frequently interviewed for comment by the Wall Street Journal, CNN and other major business and national publications concerned with the strengths and limitations of new technology and treatments.

### *John Harper, Director (Age 62)*

Mr. Harper has served as a member of the Company's board of directors since September 30, 2011 and AC's board of directors since June 2006. From January 2012 until present, Mr. Harper has been Executive Chairman of Xhale, Inc., a company that provides patient-centric monitoring solutions, from patient monitoring to medication adherence to anesthesia monitoring. From June 2005 to January 2006, Mr. Harper was the Entrepreneur-in-Residence at The Innovation Factory, a medical device incubator. From August 2000 to October 2001, Mr. Harper served as President and Chief Executive Officer of ATI Medical, Inc. and from February 1998 to May 1999, he served as Executive Chairman of Meretek Diagnostics, Inc., which was acquired by American Standard Companies. From November 1995 to March 1997, Mr. Harper served as President and Chief Executive Officer of Indigo Medical, Inc., which merged with Johnson & Johnson. Mr. Harper also served as Vice President of Sales and Marketing, and then President and Chief Executive Officer, of Menlo Care, Inc. from June 1989 to June 1995. Menlo Care, Inc. merged with Johnson & Johnson in 1995. Mr. Harper has served on the board of directors for a number of medical device and biotechnology companies since 1999. He received his BA in Economics from Davidson College in 1971.

### *Joe Mandato, Director (Age 68)*

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

### *Robert J. Rudelius, Director (Age 57)*

Mr. Rudelius has served as a member of the Board of Directors since September 2010. Since 2003, Mr. Rudelius has been the Managing Director and Chief Executive Officer of Noble Ventures, LLC, a company he founded that provides advisory and consulting services to early-stage companies in the information technology, renewable energy and loyalty marketing fields. Mr. Rudelius is also the Managing Director and Chief Executive Officer of Noble Logistics, LLC, a holding company he founded in 2002 to create, acquire and

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grow a variety of businesses in the freight management, logistics and information technology industries. From April 1999 through May 2001, when it was acquired by StarNet L.P., Mr. Rudelius was the founder and Chief Executive Officer of Media DVX, Inc., a start-up business that provided a satellite-based, IP-multicasting alternative to transmitting television commercials via analog videotapes to television stations, networks and cable television operators throughout North America. Mr. Rudelius assisted StarNet L.P. with the transition and integration of the Media DVX, Inc. business through January 2002. From April 1998 to April 1999, Mr. Rudelius was the President and Chief Operating Officer of Control Data Systems, Inc., during which time Mr. Rudelius reorganized and repositioned the software company as a professional services company, which resulted in the successful sale of Control Data Systems, Inc. to Syntegra, British Telecom's systems integration subsidiary. From October 1995 through April 1998, Mr. Rudelius was the founding Managing Partner of AT&T Solution's Media, Entertainment & Communications industry group. From January 1990 through September 1995, Mr. Rudelius was a partner in McKinsey & Company's Information, Technology and Systems practice group, during which time he headed the practice group in Tokyo and co-lead the practice group in London. Mr. Rudelius is currently a member of the Board of Directors of ProUroCare Medical, Inc., a publicly-held medical device company that develops and markets prostate imaging systems.

### *Mr. McLaughlin, Director (age 61)*

Mr. McLaughlin has served as a member of the Board of Directors since October 2012. Mr. McLaughlin has been PDL's President and Chief Executive Officer since December 18, 2008, when PDL spun-off Facet Biotech Corporation and was elected a director of PDL in October 2008. From November 6, 2008, until the spinoff, he served as a Senior Advisor to PDL. From January 2000 to June 2008, Mr. McLaughlin was the Chief Executive Officer and a director of Anesiva, Inc., formerly known as Corgentech, Inc., a publicly-traded biopharmaceutical company. From December 1997 to September 1999, Mr. McLaughlin was President of Tularik Inc., a biopharmaceutical company. From September 1987 to December 1997, Mr. McLaughlin held a number of senior management positions at Genentech, Inc., a biopharmaceutical company, including Executive Vice President and General Counsel. From January 1985 to September 1987, Mr. McLaughlin was a partner at a Washington, D.C. law firm specializing in food and drug law. Prior to that, Mr. McLaughlin served as counsel to various subcommittees in the United States House of Representatives, where he drafted numerous measures that became FDA laws. Mr. McLaughlin co-founded and served as Chairman of the Board of Directors of Eyetech Pharmaceuticals, Inc., a publicly-traded biopharmaceutical company subsequently bought by OSI Pharmaceuticals, Inc., and co-founded and served as a director of Peak Surgical, Inc., a private medical device company, until it was acquired by Medtronic in 2011. Mr. McLaughlin currently serves as a director of Seattle Genetics, Inc., a publicly-traded biopharmaceutical company. He received a B.A. from the University of Notre Dame and a J.D. from Catholic University of America.

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

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

Based solely on a review of the copies of such reports furnished to us and representations from the executive officers and directors, we believe that all Section 16(a) filing requirements applicable to our executive officers, directors and greater than 10% beneficial owners during 2012 have been satisfied, except that one report on Form 4 was inadvertently filed late for David Hansen, the Company's Corporate Controller, reporting the receipt of an employee stock option and one report on Form 4 was inadvertently filed late by Dr. Mark Gold, a Company director, reporting the exercise of vested portions of certain stock options.

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### **Code of Ethics**

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

### **Director Independence**

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

### **Board Committees**

The standing committees of AxoGen's Board of Directors include an Audit Committee, a Compensation Committee and a Governance and Nominating Committees. Messrs. Rudelius (Chairman), McLaughlin and Harper are the members of the Audit Committee. Messrs. Harper (Chairman), Rudelius and Mandato and Dr. Gold are members of the Compensation Committee. Dr. Gold (Chairman) and Messrs. Grooms and Harper are members of the Nominating and Governance Committees. The Charters of each of the Audit Committee, the Compensation, and Governance and Nominating Committee can be found on our website under "About AxoGen — Investors — Corporate Governance."

#### ***Audit Committee***

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

#### ***Compensation Committee***

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

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

The Governance and Nominating Committee is responsible to provide oversight in relation to the corporate governance of AxoGen and also identifies director nominees for election to fill vacancies on the AxoGen Board of Directors. Nominees are approved by the AxoGen Board of Directors on recommendation of the Governance and Nominating Committee. In evaluating nominees, the Governance and Nominating Committee particularly seeks candidates of high ethical character with significant business experience at the senior management level who have the time and energy to attend to board responsibilities. Candidates should also satisfy such other

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particular requirements that the Governance and Nominating Committee may consider important to AxoGen's business at the time. When a vacancy occurs on the AxoGen Board of Directors, the Governance and Nominating Committee will consider nominees from all sources, including shareholders, nominees recommended by other parties, and candidates known to the directors or AxoGen's management. The best candidate from all evaluated will be recommended to the AxoGen Board of Directors to consider for nomination.

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

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**ITEM 11. EXECUTIVE COMPENSATION.**

**Executive Compensation**

The following table sets forth the cash and non-cash compensation for the fiscal years 2012 and 2011 for: (i) each individual serving as the Company's Chief Executive Officer ("CEO") or acting in a similar capacity during any part of such fiscal years; and (ii) the other two most highly paid executive officers who were serving as executive officers during such periods (our "named executive officers").

**Summary Compensation Table**

Name and Principal Position	Year	Salary(\$)	Bonus(\$)	Stock Awards(\$)(1)	Option Awards(#)(1)(2)	All Other Compensation(\$)	Total
Karen Zaderej	2012	291,200	11,646	—	—	7,893	310,739
CEO(3)(4)	2011	252,403	23,254	—	516,697	7,537	799,891
Gregory G. Freitag(5)	2012	204,069	8,161	—	—	5,594	217,824
Former CEO and CFO and General Counsel	2011	154,808	100,000	—	172,859	—	427,667
John P. Engels	2012	174,888	8,689	—	—	5,600	189,177
Vice President(6)	2011	171,138	16,833	—	121,998	5,453	315,422
Jill Schiaparelli	2012	173,654	6,202	—	208,672	5,377	393,905
Senior Vice President Business Strategy and Marketing(7)	2011	—	—	—	—	—	—

- (1) The amounts in this column are calculated based on the aggregate grant date fair value computed in accordance with Accounting Standards Codification ("ASC") Topic 718 as of December 31 of the year indicated.
- (2) The amounts shown for option awards relate to option awards granted under the AxoGen Corporation 2002 Stock Incentive Plan, as amended. These amounts are equal to the aggregate grant date fair value of the options computed in accordance with FASB ASC Topic 718 using the assumptions set forth in Note 10 to AxoGen's audited consolidated financial statements included elsewhere in this Form 10-K.
- (3) Ms. Zaderej voluntarily accepted reduced salaries for a portion of 2011.
- (4) Ms. Zaderej has been CEO of the Company since September 30, 2011 as a result of the Merger, CEO of AC since May 2010 and was Chief Operating Officer of AC from 2007 through May 2010. The amounts include life insurance premiums paid by AxoGen on behalf of Zaderej in 2011 of \$365 and \$393 in 2012 and also includes amounts contributed by the Company to the SIMPLE IRA plan on her behalf for 2011 of \$7,172 and 2012 of \$7,500.
- (5) Mr. Gregory G. Freitag is our current CFO and General Counsel and has been serving in such capacity since June 1, 2010. Mr. Freitag stepped down as CEO on September 30, 2011 in conjunction with the Merger. On September 30, 2011, Mr. Freitag received a one-time bonus as a result of completing the Merger. The amounts include life insurance premiums paid by AxoGen on behalf of Mr. Freitag in 2012 of \$411 and also includes amounts contributed by the Company to the SIMPLE IRA plan on his behalf for 2012 of \$5,183.
- (6) The amounts include life insurance premiums paid by AxoGen on behalf of Mr. Engels in 2011 of \$319 and \$353 in 2012 and also includes amounts contributed by the Company to the SIMPLE IRA plan on his behalf for 2011 of \$5,134 and 2012 of \$5,247.
- (7) The amounts include life insurance premiums paid by AxoGen on behalf of Ms. Schiaparelli in 2012 of \$167 and also includes amounts contributed by the Company to the SIMPLE IRA plan on her behalf for 2012 of \$5,210.



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**Outstanding Equity Awards at Fiscal Year End**

The following table summarizes the equity awards granted to our named executive officers that remain outstanding as of December 31, 2012.

Option Awards					
Name	Option Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Karen Zaderej	11/18/2008	126	— (1)	\$ 0.27	11/18/2018
	6/9/2010	36,111	54,167(1)	\$ 0.27	6/9/2020
	12/26/2011	68,750	206,250(2)	\$ 2.74	12/26/2018
	12/26/2011	—	— (3)	\$ 2.74	12/26/2018
Gregory G. Freitag	6/1/2010	125,000(4)	—	\$ 3.50	6/1/2020
	12/26/2011	23,000	69,000(5)	\$ 2.74	12/26/2018
John P. Engels	6/7/2006	3,727(6)		\$ 0.27	6/7/2016
	12/6/2007	719(6)		\$ 0.27	12/6/2017
	11/18/2008	406(6)		\$ 0.27	11/18/2018
	6/9/2010	28,554(6)	17,131(6)	\$ 0.27	6/9/2020
	12/16/2011	16,250	48,750(7)	\$ 2.74	12/16/2018
Jill Schiaparelli	2/27/2012	—	90,913(8)	\$ 3.02	2/27/2019

- (1) Ms. Zaderej received these options to purchase shares of AC common stock, which options pursuant to the Merger have been adjusted and provide for the right to purchase Company Common Stock. The options vest semi-annually and become fully vested and exercisable four years from the grant date. The options were granted under plans previously approved by AxoGen's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the AxoGen's common stock on the date of grant.
- (2) Ms. Zaderej received this option to purchase 275,000 shares of the Company's common stock. All shares pursuant to the option will be fully vested on December 26, 2015 (4 years from the option grant date) based upon a vesting schedule whereby 25% of the aggregate shares vest on December 26, 2012 (12 months from the option grant date) and an additional 12.5% of aggregate shares each 6 months thereafter and will expire December 26, 2018. The option was granted under plans previously approved by the Company's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the Company's common stock on the date of grant.
- (3) Ms. Zaderej received this option to purchase 100,000 shares of the Company's common stock. The shares under the Option are subject to a performance vesting provision (the "Performance Shares") whereby all, none or a portion of the Performance Shares, to the extent to which the performance standards established by the Board of Directors are met, will vest as to 25% of the Performance Shares on March 31, 2013, and an additional 12.5% of the Performance Shares each six months thereafter, with all Performance Shares being fully vested on December 26, 2015 (4 years from the Option grant date) and will expire December 26, 2018. The option was granted under plans previously approved by the Company's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the Company's common stock on the date of grant. These options were forfeited on December 31, 2012 due to not achieving the performance standard.
- (4) Mr. Freitag received this option which became fully vested and exercisable on August 29, 2011 pursuant to the vesting terms of the option. The option was granted outside of plans previously approved by the Company's shareholders and the exercise price for the option was issued at a price equal to the fair market value of the Company's common stock on the date of grant.
- (5) Mr. Freitag received this option to purchase 92,000 shares of the Company's common stock. All shares pursuant to the option will be fully vested on December 26, 2015 (4 years from the option grant date) based upon a vesting schedule whereby 25% of the aggregate shares vest on December 26, 2012 (12 months from

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the option grant date) and an additional 12.5% of aggregate shares each 6 months thereafter and will expire December 26, 2018. The option was granted under plans previously approved by the Company's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the Company's common stock on the date of grant.

- (6) Mr. Engels received these options to purchase shares of AC common stock, which options pursuant to the Merger have been adjusted and provide for the right to purchase Company Common Stock. The options vest semi-annually and become fully vested and exercisable four years from the grant date. The options were granted under plans previously approved by AxoGen's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the AxoGen's common stock on the date of grant.
- (7) Mr. Engels received this option to purchase 65,000 shares of the Company's common stock. All shares pursuant to the option will be fully vested on December 16, 2015 (4 years from the option grant date) based upon a vesting schedule whereby 25% of the aggregate shares vest on December 26, 2012 (12 months from the option grant date) and an additional 12.5% of aggregate shares each 6 months thereafter and will expire December 16, 2018. The option was granted under plans previously approved by the Company's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the Company's common stock on the date of grant.
- (8) Ms. Schiaparelli received this option to purchase 90,913 shares of the Company's common stock. All shares pursuant to the option will be fully vested on February 2, 2016 (4 years from the option grant date) based upon a vesting schedule whereby 25% of the aggregate shares vest on February 2, 2013 (12 months from the option grant date) and an additional 12.5% of aggregate shares each 6 months thereafter and will expire February 27, 2019. The option was granted under plans previously approved by the Company's shareholders and the exercise price for the options were issued at a price equal to the fair market value of the Company's common stock on the date of grant.

### ***Employment Agreements***

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

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

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

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

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

- any person who holds less than 20% of the combined voting power of the securities of AC or AxoGen, Inc., becomes the beneficial owner, directly or indirectly, of securities of AC or AxoGen, Inc., representing 50% or more of the combined voting power of the securities of AC or AxoGen, Inc. then outstanding;
- during any period of 24 consecutive months, individuals who at the beginning of such period constitute all members of the AxoGen, Inc.'s Board of Directors cease, for any reason, to constitute at least a majority of the board of directors, unless the election of each director who was not a director at the beginning of the period was either nominated for election by, or was approved by a vote of, at least two-thirds of the directors then still in office who were directors at the beginning of the period;
- AC or AxoGen, Inc. consolidates or merges with another company and AC or AxoGen, Inc. is not the continuing or surviving corporation, provided, however, that any consolidation or merger whereby AxoGen, Inc. continues as the majority holder of AC securities or a merger or consolidation of AC and AxoGen, Inc. will not constitute a change in control;
- shares of AC's or AxoGen, Inc.'s common stock are converted into cash, securities, or other property (other than by a merger set forth in (iii) above) in which the holders of the AC's or AxoGen, Inc.'s common stock immediately prior to the merger have the same proportionate ownership of common stock of the surviving corporation as immediately after the merger;
- AC or AxoGen, Inc. sells, leases, exchanges, or otherwise transfers all or substantially all of its assets (in one transaction or in a series of related transactions); or
- the holders of AxoGen's stock approve a plan or proposal for the liquidation or dissolution of AC or AxoGen, Inc.

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

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

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

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

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

### ***Pension Benefits***

AxoGen adopted the AxoGen SIMPLE IRA plan in 2007. The AxoGen named executive officers participate in the SIMPLE IRA plan. Eligibility is immediate upon employment, and enrollment is available any time during employment. Participating employees may make annual pretax contributions to their accounts up to a maximum amount as limited by law. The SIMPLE IRA plan requires AxoGen to make matching contributions of between 1% and 3% of the employee's annual salary as long as the employee participates in the SIMPLE IRA plan. Additionally, the matching contribution has to be at least 3% for three of the first five years of the SIMPLE IRA. Both employee contributions and AxoGen contributions are fully vested at all times. In 2012 and 2011, AxoGen's matching contribution was 3% of the AxoGen named executive officers' annual base salary. AxoGen contributed approximately \$23,000 and \$12,000 in matching funds for the AxoGen named executive officers during 2012 and 2011, respectively.

### ***Director Compensation***

Each non-employee director receives a quarterly cash retainer payment of \$3,000 for services to AxoGen starting in the first quarter after election, which cash payment is paid in advance each quarter. Non-employee directors are also paid \$1,500 per in-person Board of Directors meeting if they attend in person and \$750 for such in-person meeting if they participate by telephone. No additional compensation is provided for telephonic Board meetings or actions taken pursuant to written minutes of action of the Board. Non-employee directors are paid \$1,000 per committee meeting attended in-person if they attend in person and \$500 for such in-person committee meeting if they participate by telephone. The total board and committee member fees cannot exceed \$2,500 per day.

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

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The following table shows the compensation earned by all persons serving as members of our Board of Directors during 2012.

### Director Compensation Table

Name	Fees Earned or Paid in Cash (\$)	Stock Awards(\$)	Option Awards\$(3)	Total (\$)
Robert J. Rudelius	11,750	—	—	11,750
Gregory G. Freitag	—	—	—	—
Karen Zaderej(1)	—	—	—	—
Jamie M. Grooms(1)	9,000	—	—	9,000
Mark Gold, M.D.(1)	11,000	—	—	11,000
John Harper(1)	11,750	—	—	11,750
Joe Mandato(1)	—	—	—	—
John McLaughlin(2)	\$ 1,500	—	—	\$ 1,500

- (1) Service as a member of our Board of Directors began on September 30, 2011 when their election at the Company's 2010 Annual Meeting of Shareholders took effect as a result of the closing of the Merger.
- (2) Service as a member of our Board of Directors began on October 4, 2012 when Mr. McLaughlin was appointed to the Board pursuant to the PDL Royalty contract. Mr. McLaughlin's director fees were paid to PDL.
- (3) The amounts in this column are calculated based on the aggregate grant date fair value computed in accordance with Accounting Standards Codification (ASC) Topic 718 as of December 31, 2012.

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

### *Securities Authorized for Issuance Under Equity Compensation Plans*

The following table summarizes, with respect to the Company's equity compensation plans, the number of shares of the Company's common stock to be issued upon exercise of outstanding options, warrants and other rights to acquire shares, the weighted-average exercise price of these outstanding options, warrants and rights and the number of shares remaining available for future issuance under the Company's equity compensation plans as of December 31, 2012.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (\$)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column)
Equity compensation plans approved by security holders	1,889,671	2.53	806,571
Equity compensation plans not approved by security holders	—	—	—
Total	1,889,671	2.53	806,571

### *AxoGen, Inc. 2010 Stock Incentive Plan*

In September 2010 AxoGen's shareholders approved, the AxoGen, Inc. 2010 Stock Incentive Plan, which was Amended and Restated in September 2011 by shareholder approval (the "Stock Incentive Plan"). The purpose of the Stock Incentive Plan is to promote the interests of AxoGen's and its shareholders by aiding AxoGen in attracting and retaining employees, officers, consultants, advisors and non-employee directors who the Company expects will contribute to its success and to enable these individuals to participate in the

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Company's long-term success and growth by giving them a proprietary interest in LecTec. The aggregate number of shares of AxoGen common stock that may be issued under all stock-based awards made under the Stock Incentive Plan is 2,750,000.

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

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

The Stock Incentive Plan permits grants of:

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

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

If an award entitles the holder to receive or purchase shares of Company common stock, the shares covered by such award or to which the award relates will be counted against the aggregate number of shares available for awards under the Stock Incentive Plan. For SARs settled in shares upon exercise, the aggregate number of shares

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with respect to which the SAR is exercised, rather than the number of shares actually issued upon exercise, will be counted against the number of shares available for awards under the Stock Incentive Plan. Awards that do not entitle the holder to receive or purchase shares and awards that are settled in cash will not be counted against the aggregate number of shares available for awards under the Stock Incentive Plan.

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

Unless terminated by the Board of Directors, the Stock Incentive Plan will expire on September 27, 2021. No awards may be made after that date. However, unless otherwise expressly provided in an applicable award agreement, any award granted under the Stock Incentive Plan prior to expiration may extend beyond the expiration of the Stock Incentive Plan through the award's normal expiration date. The Board of Directors may amend, alter, suspend, discontinue or terminate the Stock Incentive Plan at any time, although shareholder approval must be obtained for any amendment to the Stock Incentive Plan that would: (1) increase the number of shares of our common stock available under the Stock Incentive Plan, (2) increase the award limits under the Stock Incentive Plan, (3) permit awards of options or SARs at a price less than fair market value, (4) permit repricing of options or SARs or (5) cause Section 162(m) of the Internal Revenue Code to become unavailable with respect to the Stock Incentive Plan. Shareholder approval is also required for any action that requires shareholder approval under the rules and regulations of the Securities and Exchange Commission or any other securities exchange that are applicable to us.

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

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

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 12, 2013, by each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock, each of our directors, each of our executive officers named in the Summary Compensation Table above and all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock under options held by that person that are currently exercisable or exercisable within 60 days of, March 12, 2012 are considered outstanding. Each shareholder named in the table has sole voting and investment power for the shares shown as beneficially owned by them, and such shares are not subject to any pledge. Percentage of ownership is based on 11,127,869 shares of common stock outstanding on March 8, 2012.

<u>Name of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned</u>	<u>Number of Shares Underlying Options Beneficially Owned</u>	<u>Percent of Shares Outstanding (%)</u>
DeNovo Ventures II, LP(1) 2180 Sand Hill Rd. Suite 200 Menlo Park, CA 94025	1,426,392		12.8%
JAM Mark 3:1, LP 16 Boardwalk Plaza Saint Simons Island, GA 31522	1,114,613		10.0%
CHP II, L.P. 230 Nassau St. Princeton, NJ 08542 Attn: John Park	886,556		8.0%
AMV Partners I, L.P. 2750 Premier Parkway Suite 200 Duluth, GA 30097	1,017,904		9.2%
Karen Zaderej	120,790	104,987	2.0%
Jamie M. Grooms(2)	351,417	107,992	4.1%
John P. Engels	90,698	49,656	1.3%
Mark Gold, M.D.(3)	252,697	25,000	2.4%
John Harper	147,428	35,540	1.6%
Joe Mandato(1)	—	25,000	0.2%
Robert Rudelius	23,273	45,000	0.6%
Greg Freitag	24,318	148,000	1.5%
All directors and executive officers as a group (12 persons)(1)(2)(3)(4)	1,022,036	586,991	13.7%

- (1) Mr. Mandato is a Managing Partner of this venture capital fund. Mr. Mandato disclaims beneficial ownership of the shares owned by the fund.
- (2) These shares include 218,534 shares of record held by Mr. Grooms, and 132,883 shares held by the Jamie Grooms Trust, of which Mr. Grooms is the trustee.
- (3) These shares include 107,690 shares held by Dr. Gold's wife and 125,523 shares held by MJSK, Ltd., an investment trust held by Dr. Gold's family.
- (4) Includes 5,665 shares held by Mark Friedman and 5,750 held by Jill Schiaparelli. Also includes a number of shares underlying options equal to 22,728, 4,207 and 18,881, for Jill Schiaparelli, Mark Friedman and Dave Hansen, respectively.



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

We are not a listed issuer and so are not subject to the director independence requirements of any exchange or inter-dealer quotation system. Nevertheless, in determining whether our directors and director nominees are independent, we use the definition of independence provided in Rule 5605 (a)(2) of The NASDAQ Stock Market's Marketplace Rules. Under this definition of independence, directors Robert Rudelius, John Harper, and Dr. Mark Gould would be considered independent directors. Members of our Board Gregory Freitag and Karen Zaderej would not be considered independent because they serve as Executive Officers, Joe Mandato would not be considered independent because he is the Managing Partner of DeNovo Ventures II, L.P. which is a greater than 5% shareholder of the Company's Common Stock, Jamie Grooms would not be considered independent because he was employed by the Company in the last three fiscal years and John McLaughlin would not be considered independent because he is an executive officer of PDL and PDL's payments to the Company under the Interim Revenue Interest Purchase Agreement exceeded the limit set forth in independence standards under the NASDAQ rules.

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

***Audit Fees***

Fees billed or expected to be billed to us for audit services by our independent registered public accounting firm, Lurie Besikof Lapidus & Company, LLP ("Lurie Besikof") for the audit of our annual financial statements and for reviews of our financial statements included in our quarterly reports on Form 10-Q for the fiscal years ended December 31, 2012 and 2011 were \$91,000 and \$155,817, respectively.

***Audit-Related Fees***

No fees were billed or are expected to be billed to us by Lurie Besikof for audit-related services provided during the fiscal years ended December 31, 2012 and 2011.

***Tax Fees***

Fees billed or expected to be billed to us by Lurie Besikof for tax compliance, tax advice, and tax planning for the fiscal years ended December 31, 2012 or 2011 were \$15,000 and \$7,500, respectively.

***All Other Fees***

No fees were billed or are expected to be billed to us by Lurie Besikof for other services not included above during the fiscal years ended December 31, 2012 or 2011.

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

Because of our size, complexity, financial condition, and prospects, the Audit Committee is apprised of and pre-approves all fees for services provided by our independent registered public accounting firm. All fees paid to our independent registered public accounting firm for 2012 and 2011 were approved by our Audit Committee. The Audit Committee has considered whether non-audit services provided by our independent registered public accounting firm during 2012 and 2011 were compatible with maintaining the accounting firm's independence.

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

***(a) Documents filed as part of this Report***

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

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

(3) Exhibits

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of May 31, 2011, among LecTec Corporation, Nerve Merger Sub Corp. and AxoGen Corporation (incorporated by reference to Exhibit 2.1 to LecTec Corporation's Current Report on Form 8-K filed on June 2, 2011)
2.2	Amendment No. 1 to Agreement and Plan of Merger, dated as of June 30, 2011, among LecTec Corporation, Nerve Merger Sub Corp. and AxoGen Corporation (incorporated by reference to Appendix A2 to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
2.3	Amendment No. 2 to Agreement and Plan of Merger, dated as of August 9, 2011, among LecTec Corporation, Nerve Merger Sub Corp. and AxoGen Corporation (incorporated by reference to Appendix A3 to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
3.1	Amended and Restated Articles of Incorporation of AxoGen, Inc. (incorporated by reference to Appendix B to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
3.2	AxoGen, Inc. Amended and Restated Bylaws. (incorporated by reference to Appendix C to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
**10.1	Patent License Agreement, dated as of August 3, 2005, by and between AxoGen Corporation and the Board of Regents of the University of Texas System (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
**10.2	Amended and Restated Standard Exclusive License Agreement with Sublicensing Terms, dated as of February 21, 2006, by and between AxoGen Corporation and the University of Florida Research Foundation, Inc. (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
**10.3	Sid Martin Biotechnology Development Institute Incubator License Agreement, dated as of September 26, 2006, by and between AxoGen, Inc. and the University of Florida Research Foundation, Inc. (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
**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)
- \*\*10.5.1 Distribution Agreement, dated as of August 27, 2008, by and between AxoGen, Inc. and Cook Biotech Incorporated (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
- 10.5.2 Amendment dated March 14, 2012 to Distribution Agreement, dated as of August 27, 2008, by and between AxoGen, Inc. and Cook Biotech Incorporated (Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2011)
- \*+10.6.1 Revenue Interests Purchase Agreement, dated as of October 5, 2012, by and among AxoGen, Inc. and PDL BioPharma, Inc.
- \*+10.6.2 Guarantee and Collateral Agreement, dated as of October 5, 2012, by and among AxoGen, Inc. and AxoGen Corporation and PDL BioPharma, Inc.
- 10.6.3 Interim Revenue Interests Purchase Agreement dated August 14, 2012, by and between AxoGen, Inc. and PDL BioPharma, Inc. (Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012)
- 10.7 LecTec Corporation 2010 Stock Incentive Plan, Amended and Restated on September 27, 2011 (incorporated by reference to Appendix E to the Proxy Statement/Prospectus included as part of LecTec Corporation's Amendment No. 2 to Registration Statement on Form S-4 filed on August 29, 2011)
- \*\*\*10.8.1 Executive Employment Agreement, effective as of October 15, 2007, by and between AxoGen Corporation and Karen Zaderej (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
- \*\*\*10.8.2 Amendment to Executive Employment Agreement, effective as of September 29, 2011, by and between AxoGen Corporation and Karen Zaderej (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
- \*\*\*10.9.1 Executive Employment Agreement, effective as of May 6, 2003, by and between AxoGen Corporation and John P. Engels (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
- \*\*\*10.9.2 Amendment to Executive Employment Agreement, effective as of September 29, 2011, by and between AxoGen Corporation and John P. Engels (incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
- 10.10 Lease dated as of February 6, 2007, by and between AxoGen Corporation and WIGSHAW, LLC, its successors and assigns (incorporated by reference to the Company's Quarterly Report on Form 10-Q filed on November 14, 2011)
- \*\*\*10.15 Form of Employee Incentive Stock Option Agreement (Incorporated by reference to the Company's Current Report on Form 8-K filed on September 26, 2007)
- 10.16 Settlement Agreement and Mutual Release, dated May 29, 2009, by and between LecTec Corporation and The Mentholatum Company (Incorporated by reference to the Company's Current Report on Form 8-K filed on June 6, 2009)
- \*10.17 Supply and License Agreement, entered into as of January 1, 2004, by and between Novartis Consumer Health, Inc. and LecTec Corporation (Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009)
- 10.18 Term Sheet between Endo Pharmaceuticals Inc. and LecTec Corporation (Incorporated by reference to the Company's Current Report on Form 8-K filed on November 12, 2009)

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10.19	Settlement and License Agreement, dated November 11, 2009, by and between LecTec Corporation and Endo Pharmaceuticals Inc. (Incorporated by reference to the Company's Current Report on Form 8-K filed on November 12, 2009)
*10.20	Settlement Agreement and Mutual Release, dated December 18, 2009, by and between LecTec Corporation and Johnson & Johnson Consumer Companies, Inc. (Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2010)
***10.21	Executive Employment Agreement, effective as of October 1, 2011, by and between AxoGen, Inc. and Gregory G. Freitag (Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2011)
***10.22	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)
+10.23	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
10.24.1	Loan and Security Agreement, dated as of September 30, 2011, by and among AxoGen, Inc. and AxoGen Corporation, as borrower, Midcap Financial SBIC, LP, as administrative agent, and the Lenders listed on Schedule 1 thereto (Incorporated by reference to the Company's Current Report on Form 8-K filed on October 6, 2011)
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+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	Certification pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
+99.1	AxoGen, Inc. press release, dated March 12, 2013
+101	Interactive Data File

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

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

\*\*\* Management contract or compensatory plan or arrangement.

+ Filed herewith.

++ Included on signature page.

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**SIGNATURES**

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

AXOGEN, INC

/s/ KAREN ZADEREJ

Karen Zaderej  
Chief Executive Officer

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

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

<u>/s/ KAREN ZADEREJ</u> Karen Zaderej Chief Executive Officer and Director (Principal Executive Officer)	March 12, 2013
<u>/s/ GREGORY FREITAG</u> Gregory Freitag Chief Financial Officer, General Counsel and Director (Principal Financial Officer) (Principal Accounting Officer)	March 12, 2013
<u>/s/ JAMIE GROOMS</u> Jamie Grooms Director	March 12, 2013
<u>/s/ ROBERT RUDELIUS</u> Robert Rudelius Director	March 12, 2013
<u>/s/ MARK GOLD, MD</u> Mark Gold, M.D. Director	March 12, 2013
<u>/s/ JOHN HARPER</u> John Harper Director	March 12, 2013
<u>/s/ JOE MANDATO</u> Joe Mandato Director	March 12, 2013
<u>/s/ JOHN MCLAUGHLIN</u> John McLaughlin Director	March 12, 2013

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**EXHIBIT INDEX**

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+31.1	Certification of Principal Executive Officer
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\*\* Confidential treatment has been granted for portions of this Exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934 as amended. The confidential portions have been deleted and filed separately with the United States Securities and Exchange Commission.

\*\*\* Management contract or compensatory plan or arrangement.

+ Filed herewith.

++ Included on signature page.



Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “\* \* \*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

REVENUE INTERESTS PURCHASE AGREEMENT

Dated as of October 5, 2012

between

AxoGen, Inc.

and

PDL BioPharma, Inc.

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## EXHIBITS

- Exhibit A – Form of Guarantee and Collateral Agreement
- Exhibit B – Form of Assignment of Interests
- Exhibit C – Form of Deposit Agreement
- Exhibit D – Form of Legal Opinion

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## REVENUE INTERESTS PURCHASE AGREEMENT

This **REVENUE INTERESTS PURCHASE AGREEMENT** (as amended, supplemented or otherwise modified from time to time, this "Agreement") is made and entered into as of October 5, 2012, by and between AxoGen, Inc., a Minnesota corporation (the "Company"), and PDL BioPharma, Inc., a Delaware corporation ("Purchaser").

**WHEREAS**, the Company wishes to obtain financing in respect of the commercialization of the Product (as hereinafter defined) and to sell, assign, convey and transfer to Purchaser in consideration for its payment of the Purchase Price (as hereinafter defined), and Purchaser wishes to purchase from the Company, the Assigned Interests (as hereinafter defined), all upon and subject to the terms and conditions hereinafter set forth;

**WHEREAS**, the Company and Purchaser entered into that certain Interim Royalty Purchase Agreement, dated August 14, 2012 ("Interim Royalty Purchase Agreement"), pursuant to which, Purchaser paid \$1,750,000.00 (the "Interim Payment") for the acquisition of certain of the Company's revenue rights; and

**WHEREAS**, the parties desire for this Agreement to amend, restate and replace the Interim Royalty Purchase Agreement in its entirety.

**NOW, THEREFORE**, in consideration of the mutual covenants, agreements representations and warranties set forth herein, the parties hereto agree as follows:

### ARTICLE I

#### DEFINITIONS

##### **Section 1.01 Definitions.**

The following terms, as used herein, shall have the following meanings:

"2013 Annual Meeting" shall have the meaning set forth in Section 5.15.

"Accounts" shall mean, collectively, the Deposit Account, the Joint Concentration Account, the Company Concentration Account and the Purchaser Concentration Account, each established and maintained pursuant to the Deposit Agreement.

"Affiliate" shall mean any Person that controls, is controlled by, or is under common control with another Person. For purposes of this definition, "control" shall mean (i) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities.

"Aggregate Deposit Funds" shall mean any and all financial assets, funds, monies, checks or other items deposited into the Deposit Account.

"Agreement" shall have the meaning set forth in the first paragraph hereof.

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“Applicable Percentage” shall mean \* \* \*.

“Assigned Interests” shall mean the following amounts of the Company’s Net Revenues:

(a) from the Closing Date until September 30, 2014, an amount equal to the product of the Applicable Percentage multiplied by the Company’s Net Revenues;

(b) for each of the following twenty-four (24) Fiscal Quarters, the greater of (i) an amount equal to the Applicable Percentage of the Company’s Net Revenues for such Fiscal Quarter or (ii) the following amounts:

- (i) for the quarter ending December 31, 2014, \* \* \*;
- (ii) for the quarter ending March 31, 2015\* \* \*;
- (iii) for the quarter ending June 30, 2015, \* \* \*;
- (iv) for the quarter ending September 30, 2015, \* \* \*;
- (v) for the quarter ending December 31, 2015, \* \* \*;
- (vi) for the quarter ending March 31, 2016, \* \* \*;
- (vii) for the quarter ending June 30, 2016, \* \* \*;
- (viii) for the quarter ending September 30, 2016, \* \* \*;
- (ix) for the quarter ending December 31, 2016, \* \* \*;
- (x) for the quarter ending March 31, 2017, \* \* \*;
- (xi) for the quarter ending June 30, 2017, \* \* \*;
- (xii) for the quarter ending September 30, 2017, \* \* \*;
- (xiii) for the quarter ending December 31, 2017, \* \* \*;
- (xiv) for the quarter ending March 31, 2018, \* \* \*;
- (xv) for the quarter ending June 30, 2018, \* \* \*;
- (xvi) for the quarter ending September 30, 2018, \* \* \*;
- (xvii) for the quarter ending December 31, 2018, \* \* \*;
- (xviii) for the quarter ending March 31, 2019, \* \* \*;
- (xix) for the quarter ending June 30, 2019, \* \* \*;
- (xx) for the quarter ending September 30, 2019, \* \* \*;

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(xxi) for the quarter ending December 31, 2019, \* \* \*;

(xxii) for the quarter ending March 31, 2020, \* \* \*;

(xxiii) for the quarter ending June 30, 2020, \* \* \*; and

(xxiv) for the quarter ending September 30, 2020, \* \* \*.

“Assigned Interests Collateral” shall mean the property included in the definition of “Collateral” in the Guarantee and Collateral Agreement.

“Assignment of Interests” shall mean the Assignment of Interests pursuant to which the Company shall assign to Purchaser all of its rights and interests in and to the Assigned Interests purchased hereunder, which Assignment of Interests shall be substantially in the form of Exhibit B.

“Audit Costs” shall mean, with respect to any audit of the books and records of the Company with respect to amounts payable or paid under this Agreement, the reasonable out-of-pocket cost of such audit, including all fees, costs and expenses incurred in connection therewith.

“Bankruptcy Event” shall mean the occurrence of any of the following:

(a) the Company shall commence any case, proceeding or other action (i) under any existing or future law of any jurisdiction, domestic or foreign, relating to bankruptcy, insolvency, reorganization, relief of debtors or the like, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts, or (ii) seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or any portion of its assets, or the Company shall make a general assignment for the benefit of its creditors;

(b) there shall be commenced against the Company any case, proceeding or other action of a nature referred to in clause (a) above which remains undismissed, undischarged or unbonded for a period of sixty (60) days;

(c) there shall be commenced against the Company any case, proceeding or other action seeking issuance of a warrant of attachment, execution, distraint or similar process against (i) all or any substantial portion of its assets and/or (ii) the Product or any substantial portion of the Intellectual Property related to the Product, which results in the entry of an order for any such relief which shall not have been vacated, discharged, stayed, satisfied or bonded pending appeal within sixty (60) days from the entry thereof;

(d) the failure of the Company to take action to object to any of the acts set forth in clause (b) or (c) above within ten (10) days of the Company receiving written notice of such act; or

(e) the Company shall generally not, or shall be unable to, or shall admit in writing its inability to, pay its respective debts as they become due.



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“BLA” shall mean a biologics license application and all amendments and supplements thereto, submitted to the FDA with respect to Avance® Nerve Graft.

“Board” shall mean the Board of Directors of the Company.

“Business Day” shall mean any day other than a Saturday, a Sunday, any day which is a legal holiday under the laws of the State of New York, or any day on which banking institutions located in the State of New York are required by law or other governmental action to close.

“Call Closing Date” shall have the meaning set forth in Section 5.07(c).

“Call Option” shall have the meaning set forth in Section 5.07(c).

“Change of Control” shall mean:

(a) the acquisition by any Person or group (within the meaning of Sections 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended) of beneficial ownership of any capital stock of the Company, if after such acquisition, such Person or group would be the “beneficial owner” (as defined in Rule 13d-3 under the Securities Exchange Act of 1934, as amended), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company’s then outstanding securities entitled to vote generally in the election of directors;

(b) a merger or consolidation of the Company, with any other Person, other than a merger or consolidation which would result in the Company’s voting securities outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the combined voting power of the Company’s voting securities or such surviving entity’s voting securities outstanding immediately after such merger or consolidation;

(c) during any period of two (2) consecutive years, measured from the first Business Day after the Purchaser Designee appointed pursuant to Section 5.15 hereof takes office, individuals who at the beginning of such period constitute the board of directors of the Company (together with any new directors (other than a director designated by a Person who has entered into an agreement with the Company to effect a transaction described in clause (a) or (b) of this definition of “Change of Control”), whose election by such board of directors or nomination for election by the Company’s stockholders, as applicable, was approved by a vote of a majority of the directors then still in office who either were directors at the beginning of such period or whose election or nomination for election was previously so approved) cease for any reason to constitute at least a majority of the board of directors of the Company then in office, provided that for purposes of determining a Change of Control pursuant to this clause (c), the directorship held by the Purchaser Designee shall be disregarded.

(d) the bona fide sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Company or any of its Subsidiaries of all or substantially all the assets of the Company and its Subsidiaries, taken as a whole, or the sale or disposition (whether by merger or otherwise) of one or more Subsidiaries of the Company if substantially all of the assets of the Company and its Subsidiaries, taken as a whole, are held

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by such Subsidiary or Subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned (direct or indirect) Subsidiary of the Company.

“Change of Control Payment” shall mean the sum of (i) an amount that, when paid to Purchaser, would generate an IRR to Purchaser of \* \* \* on all payments made by Purchaser pursuant to the Interim Royalty Purchase Agreement and Section 2.03 of this Agreement as of the date of the Change of Control Payment, taking into account the amount and timing of all payments made by the Company to Purchaser (and retained by Purchaser) pursuant to Sections 2.02 and 5.08 of this Agreement and, if applicable, the Interim Royalty Purchase Agreement, prior to and as of the date of payment of the Change of Control Payment, plus (ii) any Delinquent Assigned Interests Payment owed (it being understood and agreed that in calculating the Change of Control Payment, in no event shall Purchaser be required to repay any amounts previously paid to Purchaser pursuant to Sections 2.02 and 5.08 of this Agreement if such payments exceed the IRR required pursuant to this definition).

“Closing” shall have the meaning set forth in Section 2.03(a).

“Closing Date” shall have the meaning set forth in Section 2.03(a).

“Company” shall have the meaning set forth in the first paragraph hereof.

“Company Concentration Account” shall mean a segregated account established and maintained at the Deposit Bank pursuant to the terms of the Deposit Agreement and this Agreement. The Company Concentration Account shall be the account into which the funds remaining in the Joint Concentration Account after payment therefrom of the amounts payable to Purchaser pursuant to this Agreement are swept in accordance with the terms of this Agreement and the Deposit Agreement.

“Company Indemnified Party” shall have the meaning set forth in Section 7.05(b).

“Confidential Information” shall mean, as it relates to the Company and its Affiliates and the Product, the Intellectual Property, confidential business information, financial data and other like information (including ideas, research and development, know-how, formulas, schematics, compositions, technical data, specifications, customer and supplier lists, pricing and cost information, and business and marketing plans and proposals), inventory, ideas, algorithms, processes, computer software programs or applications (in both source code and object code form), client lists and tangible or intangible proprietary information or material, or such other information that either party identifies to the other as confidential or the nature of which or the circumstances of the disclosure of which would reasonably indicate that such information is confidential. Notwithstanding the foregoing definition, Confidential Information shall not include information that (a) is already in the public domain at the time the information is disclosed, (b) thereafter becomes lawfully obtainable from other sources who, to the knowledge of the recipient, have no obligation of confidentiality, (c) can be shown to have been independently developed by the recipient or its representatives without reference to any Confidential Information of the other party, or (d) is required to be disclosed under securities laws, rules and regulations applicable to the Company or its Affiliates or the Purchaser or its Affiliates, as the case may be, or pursuant to the rules and regulations of any securities exchange

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or trading system or pursuant to any other laws, rules or regulations of any Governmental Authority having jurisdiction over the Company and its Affiliates or Purchaser and its Affiliates.

“Controlled” or “Control” shall mean, with respect to Intellectual Property, the right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to grant a license, sublicense or other right to or under such Intellectual Property without violating the terms of any agreement with a third party related to such Intellectual Property.

“Daily Amount” shall have the meaning set forth in Section 2.02(b).

“Default” shall mean the occurrence of any event or circumstance that would, with the giving of notice, lapse of time, or both, be an Event of Default.

“Delinquent Assigned Interests Payment” shall mean, with respect to any Assigned Interests Payment and, if owed by the Company to Purchaser, any payment due under Section 5.08(g)(iii) that is not paid when due shall, in each case, be an amount equal to the product of the amount so owed multiplied by the lower of (i) the highest rate permitted by applicable law, and (ii) one and one-half percent (1.5%) per month, compounded monthly.

“Deposit Account” shall mean collectively, any deposit and segregated deposit account established and maintained at the Deposit Bank pursuant to a Deposit Agreement and this Agreement. The Deposit Account shall be the account into which all payments made to the Company in respect of the sale of the Product are to be remitted.

“Deposit Agreement” shall mean the agreement entered into by a Deposit Bank, the Company and Purchaser, substantially in the form of Exhibit C attached hereto, pursuant to which, among other things, the Deposit Account, the Joint Concentration Account, the Purchaser Concentration Account and the Company Concentration Account shall be established and maintained.

“Deposit Bank” shall mean Silicon Valley Bank or such other bank or financial institution approved by each of Purchaser and the Company and a party to any Deposit Agreement (it being understood that the parties intend to engage a new bank within 120 days of the date hereof).

“Dispute” shall have the meaning set forth in Section 3.12(e).

“Event of Default” shall mean the occurrence of any Put Option Event (other than pursuant to clause of (a) of said definition) and any material breach by the Company of the Transaction Documents, whether or not constituting a Put Option Event.

“Excluded Liabilities and Obligations” shall have the meaning set forth in Section 2.04.

“Existing Agent” shall mean Midcap Financial SBIC LP, in its capacity as agent for the lenders under the Existing Credit Agreement.

“Existing Credit Agreement” shall mean that certain Loan and Security Agreement, dated as of September 30, 2011 among the Company, its Subsidiary, the Existing Agent and the

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lenders party thereto, as amended, restated, supplemented or otherwise modified from time to time.

“FDA” shall mean the United States Food and Drug Administration or any successor federal agency thereto.

“Financial Statements” shall mean (a) the audited consolidated balance sheets of the Company and its Subsidiary as of December 31, 2012 and 2011, and the related audited consolidated statements of operations, cash flows and shareholders’ equity for the Fiscal Years then ended and (b) the unaudited consolidated balance sheet of the Company and its Subsidiary as of June 30, 2012, and the related unaudited consolidated statements of operations, cash flows and shareholders’ equity for the three (3) and six (6) month period then ended.

“Fiscal Quarter” shall mean each three (3) month period commencing January 1, April 1, July 1 or October 1, provided however that (a) the first Fiscal Quarter of the Term shall extend from the Closing Date to the end of the first full Fiscal Quarter thereafter, and (b) the last Fiscal Quarter of the Term shall end upon the expiration of this Agreement.

“Fiscal Year” shall mean the calendar year.

“GAAP” shall mean generally accepted accounting principles in the United States in effect from time to time.

“Governmental Authority” shall mean any government, court, regulatory or administrative agency or commission, or other governmental authority, agency or instrumentality, whether foreign, federal, state or local (domestic or foreign), including the United States Patent and Trademark Office, the FDA, or the United States National Institutes of Health.

“Gross Product Revenues” means, for any period of determination, the sum of the following for such period: (a) the amounts invoiced and recognized as revenue in accordance with GAAP by the Company, its Subsidiaries or any of their Affiliates with respect to the sale of Product to a Third Party by the Company, its Subsidiaries or any of their Affiliates, (b) the amounts invoiced and recognized as revenue in accordance with GAAP by the Company, its Subsidiaries or any of their Affiliates from a Third Party with respect to the sale, distribution or other use of the Product by such Third Party in connection with any marketing, royalty, manufacturing, co-promotion, co-development, equity investment, cost sharing or other strategic arrangements, and (c) any collections in respect of write-offs or allowances for bad debts in respect of items described in the preceding clauses (a) and (b). For purposes of prevention of duplication, “Gross Product Revenue” shall not include amounts invoiced by distributors, wholesalers or other Persons acting in similar capacities.

“Guarantee and Collateral Agreement” shall mean the Guarantee and Collateral Agreement between the Company and Purchaser providing for, among other things, the grant by the Company in favor of Purchaser of a valid continuing, perfected lien on and security interest in, the Assigned Interests and the other Assigned Interests Collateral described therein, which Guarantee and Collateral Agreement shall be substantially in the form of Exhibit A.

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“Intellectual Property” shall mean all proprietary information; technical data; laboratory notebooks; clinical data; priority rights; trade secrets; know-how; confidential information; inventions (whether patentable or unpatentable and whether or not reduced to practice or claimed in a pending patent application) and improvements thereto; Patents; registered or unregistered trademarks, trade names, service marks, including all goodwill associated therewith; registered and unregistered copyrights and all applications thereof; in each case that are owned, Controlled by, generated by, issued to, licensed to, licensed by or hereafter acquired by or licensed by the Company, in each case relating to, or otherwise relevant or desirable, now or in the future, for the manufacture and sale of the Product.

“Interim Payment” shall have the meaning set forth in the Recitals.

“Interim Royalty Purchase Agreement” shall have the meaning set forth in the Recitals.

“IRR” shall mean the internal rate of return utilizing the same methodology utilized by the XIRR function in Microsoft Excel.

“Joint Concentration Account” shall mean a segregated account, subject to a control agreement in favor of Purchaser, established for the benefit of the Company and Purchaser and maintained at the Deposit Bank pursuant to the terms of the Deposit Agreement and this Agreement. The Joint Concentration Account shall be the account into which the Deposit Bank sweeps the funds held in the Deposit Account.

“Knowledge” shall mean the actual knowledge, or that which would or should have been known after reasonable inquiry, of any officer, director or employee of the Company or its Subsidiaries relating to a particular matter.

“License Agreement” shall mean any existing or future license, commercialization, co-promotion, collaboration, distribution, marketing or partnering agreement entered into before or during the Revenue Interest Period by the Company or any of its Affiliates relating to the Product and/or under the Intellectual Property.

“Licensees” shall mean, collectively, the licensees, sublicensees or distributors under the License Agreements; each a “Licensee”.

“Liens” shall mean any lien, hypothecation, charge, instrument, license, preference, priority, security agreement, security interest, interest, mortgage, deed of trust, option, privilege, pledge, liability, covenant, order, tax, right of recovery, trust or deemed trust (whether contractual, statutory or otherwise arising) or any encumbrance, right or claim of any other person of any kind whatsoever whether choate or inchoate, filed or unfiled, noticed or unnoticed, recorded or unrecorded, contingent or non-contingent, material or non-material, known or unknown, including, without limitation, any conditional sale or other title retention agreement, any lease having the same financial effect as any of the foregoing, and the filing of, or agreement to give, any financing statement under the UCC.

“Losses” shall mean collectively, any and all claims, damages, losses, judgments, awards, penalties, liabilities, costs and expenses (including reasonable expenses of investigation and reasonable attorneys’ fees and expenses incurred in connection with investigating, preparing for or defending any action, suit or proceeding).

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“Major Countries” shall mean the United States.

“Material Adverse Change” shall mean, with respect to the Company and its Subsidiaries, any event, change, circumstance, occurrence, effect or state of facts that has caused or is reasonably likely to cause a material adverse change on the business, operations, assets, condition (financial or otherwise), results of operations or prospects of the Company and its Subsidiaries, taken as a whole.

“Material Adverse Effect” shall mean (a) the effect of a Material Adverse Change, (b) a material adverse effect on the validity or enforceability of any of the Transaction Documents, (c) material adverse effect on the ability of the Company to perform any of its obligations under the Transaction Documents, (d) the inability or failure of Company to make payment of the Assigned Interests or any other amounts in violation of this Agreement, and (e) any material adverse effect on the Product or the ability of the Company to distribute, market and/or sell the Product.

“Material Contract” shall mean: (a) any marketing agreement, co-promotion agreement or partnering agreement related to the manufacture, sale or distribution of the Product in any of the Major Countries; or (b) any agreement relating to any Material Patent, including any license, assignment, or agreement related to Control of such Material Patent.

“Net Revenues” shall mean, for any period of determination, the difference of

(a) Gross Product Revenues for such period, less

(b) the sum, with respect to the items described in clauses (i) and (ii) of the definition of Gross Product Revenues, of

(i) cash, trade discounts and rebates actually granted or paid Third Parties in accordance with customary industry standards,

(ii) allowances and adjustments actually credited to customers for Product that is spoiled, damaged, outdated, obsolete, returned or otherwise recalled, but only if and to the extent the same are in accordance with sound business practices and not in excess of customary industry standards,

(iii) charges for freight, postage, shipping, delivery, service and insurance charges, to the extent invoiced,

(iv) taxes, duties or other governmental charges to the extent invoiced,

(v) write-offs or allowances for bad debts,

(vi) rebates and chargebacks and other price reduction programs granted to managed care entities, Governmental Authorities, group purchasing organizations or pharmaceutical benefit management companies, and

(vii) other payments required by law to be made under Medicaid, Medicare or other government special medical assistance programs.

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Net Revenues shall be determined in accordance with GAAP as applied by the Company and its Subsidiary on the date of this Agreement.

“New Securities” shall mean, collectively, equity securities of the Company, whether or not currently authorized, as well as rights, options, or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such equity securities.

“Obligations” shall mean any and all obligations of the Company under the Transaction Documents.

“Offer Notice” shall have the meaning set forth in Section 5.16(a).

“Patents” shall mean all patents, patent rights, patent applications, patent disclosures and invention disclosures issued or filed, together with all reissues, divisions, continuations, continuations-in-part, revisions, term extensions, substitutes, supplementary protection certificates and reexaminations, including the inventions claimed in any of the foregoing and any priority rights arising therefrom, covering or related to the manufacture, use and sale of the Product that are issued or filed as of the date hereof or during the Revenue Interest Period, including, without limitation, those identified in Schedule 3.12 in each case, which are owned, Controlled by, issued to, licensed to or licensed by the Company, its Subsidiary or any of its Affiliates.

“Person” shall mean an individual, corporation, partnership, limited liability company, association, trust or other entity or organization, but not including a government or political subdivision or any agency or instrumentality of such government or political subdivision.

“Product” shall mean Avance® Nerve Graft, AXOGUARD® Nerve Protector and AXOGUARD® Nerve Connector, regardless of the purpose for which such products are marketed or sold, and any and all future iterations of such products developed or licensed by the Company as a solution to repair or protect nerves as marketed in any jurisdiction.

“Purchase Price” shall mean \$20,800,000 less the Interim Payment and any additional amounts due and payable under the Interim Royalty Purchase Agreement as of the Closing Date.

“Purchaser” shall have the meaning set forth in the first paragraph hereof.

“Purchaser Concentration Account” shall mean a segregated account established for the benefit of Purchaser and maintained at a bank specified in writing by Purchaser pursuant to the terms of the Deposit Agreement and this Agreement. The Purchaser Concentration Account shall be the account into which the funds held in the Joint Concentration Account which are payable to Purchaser pursuant to this Agreement are swept by the Deposit Bank in accordance with the terms of this Agreement and the Deposit Agreement.

“Purchaser Designee” shall have the meaning set forth in Section 5.15(a).

“Purchaser Indemnified Party” shall have the meaning set forth in Section 7.05(a).

“Put Option” shall have the meaning set forth in Section 5.07(b).

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“Put Option Closing Date” shall have the meaning set forth in Section 5.07(b).

“Put Option Event” shall mean any one of the following events:

- (a) the anniversary of four (4) years from the Closing Date;
- (b) any Bankruptcy Event;
- (c) occurrence of a Material Adverse Effect;

(d) any Transfer by the Company of its interests in the Revenue Interests or substantially all of its interest in the Product; or

(e) any material breach of any representation or warranty made by the Company in this Agreement or any material breach of or default under any covenant or agreement by the Company pursuant to a Transaction Document, which breach is not cured within thirty (30) days after the earlier of (1) written notice thereof being delivered by Purchaser to the Company and (2) the date the Company becomes aware of such material breach.

“Put Price” shall mean the sum of (i) an amount that, when paid to Purchaser, would generate an IRR to Purchaser of \* \* \* on all payments made by Purchaser pursuant to the Interim Royalty Purchase Agreement and Section 2.03 of this Agreement as of the date of payment of the Put Price, taking into account the amount and timing of all payments made by the Company to Purchaser (and retained by Purchaser) pursuant to Sections 2.02 and 5.08 of this Agreement and, if applicable, the Interim Royalty Purchase Agreement, prior to and as of the date of payment of the Put Price, plus (ii) any Delinquent Assigned Interests Payment owed (it being understood and agreed that in calculating the Put Price, in no event shall Purchaser be required to repay any amounts previously paid to Purchaser pursuant to Sections 2.02 and 5.08 of this Agreement if such payments exceed the IRR required pursuant to this definition).

“Quarterly Report” shall mean, with respect to the relevant Fiscal Quarter of the Company, (a) a report showing Gross Profit Revenues for such quarter and the adjustments and other reconciliations used to arrive at Net Revenues for such quarter, reconciled, in each case, to the most applicable line item in the Company’s consolidated statements of operations as most recently filed or to be filed with the Securities and Exchange Commission or furnished to Purchaser pursuant to Section 5.02(h) and (b) a reconciliation of all payments made by the Company to Purchaser pursuant to this Agreement during such quarter, including all amounts deposited into the Purchaser Concentration Account during such quarter.

“Regulatory Agency” shall mean a Governmental Authority with responsibility for the approval of the marketing and sale of pharmaceuticals in the United States or other regulation of pharmaceuticals.

“Regulatory Approval” shall mean all approvals (including, without limitation, where applicable, pricing and reimbursement approval and schedule classifications), product and/or establishment licenses, registrations or authorizations of any Governmental Authority necessary for the manufacture, use, storage, import, export, transport, offer for sale, or sale of the Product in a regulatory jurisdiction.



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“Revenue Interest Period” shall mean the period from and including the Closing Date through the earliest of:

- (a) expiration of eight (8) complete years following the Closing Date;
- (b) payment of the Put Price; or
- (c) payment of the Change of Control Payment.

“Revenue Interests” shall mean all of the Company’s interest in the Gross Product Revenues.

“Secretary’s Certificate” shall mean the duly executed Secretary’s and Officer’s Certificate, dated as of the Closing Date, in form and substance reasonably satisfactory to Purchaser, (W) attaching certified copies of the Company’s organizational documents (together with any and all amendments thereto); (X) attaching certified copies of the resolutions adopted by the board of directors of the Company authorizing and approving the execution, delivery and performance by the Company of the Agreement and the Assignment of Interests and the transactions contemplated herein and therein; (Y) setting forth the incumbency of the officer or officers of the Company who have executed and delivered the Agreement and the Assignment of Interests; and (Z) attaching copies, certified by such officer as true and complete, of a certificate of the appropriate Governmental Authority of the Company’s jurisdiction of formation, stating that the Company is in good standing under the laws of the State of Minnesota.

“Subsidiary” shall mean, with respect to any Person, any other Person controlled by such first Person, directly or indirectly, through one or more intermediaries.

“Tax” or “Taxes” shall mean any federal, state, local or foreign tax, levy, impost, duty, assessment, fee, deduction or withholding or other charge, including all excise, sales, use, value added, transfer, stamp, documentary, filing, recordation and other fees imposed by any taxing authority (and interest, fines, penalties and additions related thereto).

“Tax Return” shall mean any report, return, form (including elections, declarations, statements, amendments, claims for refund, schedules, information returns or attachments thereto) or other information supplied or required to be supplied to a Governmental Authority with respect to Taxes.

“Term” shall have the meaning set forth in Section 6.01.

“Term Sheet” shall mean the Term Sheet between the Company and Purchaser, dated July 26, 2012.

“Third Party” shall mean any Person other than the Company.

“Transaction Documents” shall mean, collectively, this Agreement, the Assignment of Interests, the Guarantee and Collateral Agreement, the UCC Financing Statements, the Deposit Agreement, the Secretary’s Certificate and any related ancillary documents or agreements.

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“Transfer” shall mean any sale, conveyance, assignment, disposition, pledge, hypothecation or transfer.

“True-Up Amount” shall have the meaning set forth in Section 5.08(g)(i).

“True-Up Statement” shall have the meaning set forth in Section 5.08(g)(i).

“UCC” shall mean the Uniform Commercial Code (or any similar or equivalent legislation) as in effect in any applicable jurisdiction.

“UCC Financing Statements” shall mean the UCC-1 financing statements, in form and substance reasonably satisfactory to Purchaser, that shall be filed at or promptly following the Closing, as well as any additional UCC-1 financing statements or amendments thereto as reasonably requested from time to time, to perfect Purchaser’s security interest in the Assigned Interests Collateral.

“United States” shall mean the United States of America.

“Year-to-Date Assigned Interests” shall have the meaning set forth in Section 5.08(g)(i).

“Year-to-Date Net Revenues” shall have the meaning set forth in Section 5.08(g)(i).

## ARTICLE II PURCHASE OF INTERESTS

### **Section 2.01 Purchase.**

(a) Upon the terms and subject to the conditions set forth in this Agreement, the Company agrees to sell, assign, transfer and convey to Purchaser, and Purchaser agrees to purchase from the Company, free and clear of all Liens (except those Liens created in favor of Purchaser pursuant to the Guarantee and Collateral Agreement, the Assignment of Interests and any other Transaction Document), all of the Company’s rights and interests in and to the Assigned Interests on the Closing Date. Purchaser’s ownership interest in each of the Assigned Interests so acquired shall vest immediately upon the Company’s receipt of payment for such Assigned Interests pursuant to Section 2.03(a).

(b) The Company and Purchaser intend and agree that the sale, assignment and transfer of the Assigned Interests under this Agreement is a true sale by the Company to Purchaser that provides Purchaser with the full benefits of ownership of the Assigned Interests. The Company waives any right to contest or otherwise assert that this Agreement is other than a true sale by the Company to Purchaser in any bankruptcy or insolvency proceeding relating to the Company.

(c) The Company hereby consents to Purchaser recording and filing, at Purchaser’s sole cost and expense, the UCC Financing Statements and other financing statements in the appropriate filing offices under the UCC (and continuation statements with respect to such financing statements when applicable) meeting the requirements of applicable law in such manner and in such jurisdictions as are necessary or appropriate to perfect the purchase by Purchaser of the Assigned Interests.

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**Section 2.02 Payments by the Company.**

(a) Payments in Respect of the Assigned Interests. In connection with the assignment of the Assigned Interest, Purchaser shall be entitled to receive (i) the Assigned Interests in respect of Net Revenues earned during the Revenue Interest Period and (ii) any Delinquent Assigned Interests Payment, as and when due.

(b) Interim Payments into Deposit Accounts. Subject to Section 5.08(a), within 120 days of the date hereof, the Applicable Percentage of the Aggregate Deposit Funds in each Fiscal Year shall be swept from the Deposit Account into the Purchaser Concentration Account on a daily basis (the "Daily Amount") pursuant to Section 5.08. Prior to the establishment of Purchaser Concentration Account as contemplated by Section 5.08(a), the Company shall promptly pay to Purchaser upon demand the aggregate Daily Amount.

(c) Payment Procedure. Other than payments made pursuant to the Deposit Agreement, any payments to be made by the Company to Purchaser hereunder or under any other Transaction Document shall be made by wire transfer of immediately available funds.

**Section 2.03 Closing; Payment Purchase Price; Closing Deliveries.**

(a) Closing. The closing of the purchase of the Assigned Interests pursuant to this Agreement (the "Closing") will take place concurrently with the execution of this Agreement on the date hereof (the "Closing Date") and will be held at the offices of PDL.

(b) Payment of Purchase Price. At the Closing, Purchaser shall pay to the Company the Purchase Price by wire transfer of immediately available funds to the account designated by the Company prior to the date hereof.

(c) Closing Deliveries.

(i) At the Closing, the Company will deliver to Purchaser:

A. its duly executed counterpart to each of the Transaction Documents to which the Company is a party;

B. a duly executed Secretary's Certificate, dated as of the Closing Date;

C. a payoff letter in form and substance reasonably satisfactory to Purchaser and duly executed and delivered by the Company and the Existing Agent which provides for the payment in full of the obligations owing under the Existing Credit Agreement and release of the liens thereunder;

D. copies of the UCC Financing Statements in respect of the Assigned Interests Collateral in form for filing in each appropriate jurisdiction; and

E. a legal opinion reasonably satisfactory to Purchaser from Morgan, Lewis & Bockius LLP addressing such matters with respect to the Transaction Documents as set forth on Exhibit D hereto.

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- (ii) At the Closing, the Purchaser will deliver to the Company:
- A. payment of the Purchase Price consistent with Section 2.03(b); and
  - B. its duly executed counterpart to each of the Transaction Documents to which Purchaser is a party.

**Section 2.04 No Assumed Obligations.**

Notwithstanding any provision in this Agreement or any other writing to the contrary, Purchaser is acquiring only the Assigned Interests and is not assuming any liability or obligation of the Company or any of its Affiliates of whatever nature, whether presently in existence or arising or asserted hereafter, whether under any Transaction Document or otherwise. All such liabilities and obligations shall be retained by and remain obligations and liabilities of the Company or its Affiliates (the "Excluded Liabilities and Obligations").

**ARTICLE III  
REPRESENTATIONS AND WARRANTIES OF COMPANY**

For purposes of all the representations and warranties contained in Article III, the term "Product" shall mean Avance® Nerve Graft, AXOGUARD® Nerve Protector and AXOGUARD® Nerve Connector as such products currently exist and are marketed in any jurisdiction, and no broader definition shall be implied. The Company hereby represents and warrants to Purchaser, as of the Closing Date, the following:

**Section 3.01 Organization.**

Each of the Company and its Subsidiary is a corporation duly incorporated, validly existing and in good standing under the laws of the States of Minnesota and Delaware, respectively, and has all corporate powers and all licenses, authorizations, consents and approvals required to carry on its respective business as now conducted and as proposed to be conducted in connection with the transactions contemplated by the Transaction Documents. Each of the Company and its Subsidiary is duly qualified to do business as a foreign corporation and is in good standing in every jurisdiction in which the failure to do so would have a Material Adverse Effect. The Company has no direct or indirect Subsidiaries, other than AxoGen Corporation, a Delaware corporation.

**Section 3.02 Authorization.**

The Company has all necessary power and authority to enter into, execute and deliver the Transaction Documents and to perform all of the obligations to be performed by it hereunder and thereunder and to consummate the transactions contemplated hereunder and thereunder. The Transaction Documents have been duly authorized, executed and delivered by the Company and each Transaction Document constitutes the valid and binding obligation of the Company, enforceable against the Company in accordance with their respective terms, subject, as to enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or general equitable principles.

**Section 3.03 Governmental Authorization.**

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The execution and delivery by the Company of the Transaction Documents, and the performance by the Company of its obligations hereunder and thereunder, does not require any notice to, action or consent by, or in respect of, or filing with, any Governmental Authority, except for the filing of the UCC Financing Statements.

**Section 3.04 Ownership.**

(a) The Company owns, Controls, or holds a valid license under, all of the Intellectual Property and the Regulatory Approvals which it currently purports to own related to the Product free and clear of all Liens, and no license or covenant not to sue under any Intellectual Property has been granted to or exists in any Third Party. Neither the Company nor its Subsidiary has granted, nor does there exist, any Lien on the Revenue Interests, the Assigned Interests or any other Collateral (except those Liens created in favor of Purchaser pursuant to the Guarantee and Collateral Agreement, the Assignment of Interests and any other Transaction Document).

(b) The Company, immediately prior to the purchase of the Assigned Interests, owns, and is the sole holder of, all the Revenue Interests; and the Company owns, and is the sole holder of, and/or has and holds a valid, enforceable and subsisting license to, all of those other assets that are required to produce or receive any payments from any Licensee or payor under and pursuant to, and subject to the terms of any License Agreement, in each case free and clear of any and all Liens, except those Liens created in favor of Purchaser pursuant to the Guarantee and Collateral Agreement, the Assignment of Interests and any other Transaction Document. The Company has not transferred, sold, or otherwise disposed of, or agreed to transfer, sell, or otherwise dispose of any portion of the Revenue Interests other than under the Interim Royalty Purchase Agreement or as contemplated by this Agreement. No Person other than the Company has any right to receive the payments payable under any License Agreement, other than Purchaser's rights with respect to the Assigned Interests, from and after the Closing Date. The Company has the full right to sell, transfer, convey and assign to Purchaser all of the Company's rights and interests in and to the Assigned Interests being sold, transferred, conveyed and assigned to Purchaser pursuant to this Agreement without any requirement to obtain the consent of any Person. By the delivery to Purchaser of the executed Assignment of Interests, the Company shall transfer, convey and assign to Purchaser all of the Company's rights and interests in and to the Assigned Interests being sold, transferred, conveyed and assigned to Purchaser pursuant to this Agreement, free and clear of any Liens, except those Liens created in favor of Purchaser pursuant to the Guarantee and Collateral Agreement, the Assignment of Interests and any other Transaction Document. At the Closing, and upon the delivery of the Assignment of Interests to Purchaser by the Company, Purchaser shall have acquired good and valid rights and interests of the Company in and to the Assigned Interests being sold, transferred, conveyed and assigned to Purchaser pursuant to this Agreement, free and clear of any and all Liens, except those Liens created in favor of Purchaser pursuant to the Guarantee and Collateral Agreement, the Assignment of Interests and any other Transaction Document.

(c) As of the Closing Date and upon the Company's execution and delivery of the Guarantee and Collateral Agreement, Purchaser shall have valid, continuing, first perfected lien on and security interest in the Revenue Interests, the Assigned Interests and the other Assigned Interests Collateral described in the Guarantee and Collateral Agreement.

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**Section 3.05 Financial Statements.**

The Financial Statements are complete and accurate in all material respects, were prepared in conformity with GAAP and present fairly in all material respects the financial position and the financial results of the Company and its Subsidiary as of the dates and for the periods covered thereby.

**Section 3.06 No Undisclosed Liabilities.**

Except for those liabilities (a) specifically identified on the face of the Financial Statements, (b) incurred by the Company in the ordinary course of business since June 30, 2012, or (c) in connection with the Obligations under the Transaction Documents, there are no material liabilities of the Company or its Subsidiary of any kind whatsoever, whether accrued, contingent, absolute, determined or determinable.

**Section 3.07 Solvency.**

The Company and its Subsidiary, taken as a whole, are not insolvent as defined in any statute of the United States Bankruptcy Code or in the fraudulent conveyance or fraudulent transfer statutes of the States of Delaware, Florida, Minnesota or New York. Assuming consummation of the transactions contemplated by the Transaction Documents, (a) the present fair saleable value of the Company's and its Subsidiary's assets and the fair value of the Company's and its Subsidiary's assets are each greater than the total amount of liabilities (including contingent and unliquidated liabilities) of the Company and its Subsidiary as such liabilities mature, (b) neither the Company nor its Subsidiary has unreasonably small capital with which to engage in its respective business, and (c) neither the Company nor its Subsidiary has incurred, nor does either have present plans to or intend to incur, debts or liabilities beyond their respective ability to pay such debts or liabilities as they become absolute and matured.

**Section 3.08 Litigation.**

There is no (a) action, suit, arbitration proceeding, claim, investigation or other proceeding pending or, to the Knowledge of the Company, threatened against the Company or its Subsidiary or (b) any governmental inquiry pending or, to the Knowledge of the Company, threatened against the Company or its Subsidiary, in each case with respect to clauses (a) and (b) above, which, if adversely determined, would question the validity of, or could adversely affect the transactions contemplated by any of the Transaction Documents or could reasonably be expected to have a Material Adverse Effect. There is no action, suit, arbitration proceeding, claim, investigation or other proceeding pending or, to the Knowledge of the Company, threatened against the Company, its Subsidiary or any other Person relating to the Product, the Intellectual Property, the Regulatory Approvals, the Revenue Interests or the Assigned Interests.

**Section 3.09 Compliance with Laws.**

Neither the Company nor its Subsidiary (a) is in violation of, has violated, or to the Knowledge of the Company, is under investigation with respect to, and, (b) has been threatened to be charged with or been given notice of any violation of any law, rule, ordinance or regulation of, or any judgment, order, writ, decree, permit or license entered by any Governmental

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Authority applicable to the Company, the Assigned Interests or the Revenue Interests which would reasonably be expected to have a Material Adverse Effect.

**Section 3.10 Conflicts.**

Neither the execution and delivery of any of this Agreement or the other Transaction Documents to which the Company is a party nor the performance or consummation of the transactions contemplated hereby or thereby will: (a) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, in any material respects any provisions of: (i) any law, rule, ordinance or regulation of any Governmental Authority, or any judgment, order, writ, decree, permit or license of any Governmental Authority, to which the Company or its Subsidiary or any of their respective assets or properties may be subject or bound; or (ii) any contract, agreement, commitment or instrument to which the Company or its Subsidiary is a party or by which the Company or its Subsidiary or any of their respective assets or properties is bound or committed; (b) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, any provisions of the articles or certificate of incorporation or bylaws (or other organizational or constitutional documents) of the Company or its Subsidiary; (c) except for the filing of the UCC Financing Statements required hereunder and filings with the United States Patent and Trademark Office, require any notification to, filing with, or consent of, any Person or Governmental Authority; (d) give rise to any right of termination, cancellation or acceleration of any right or obligation of the Company, its Subsidiary or any other Person or to a loss of any benefit relating to the Revenue Interests or the Assigned Interests; or (e) other than pursuant to the Guarantee and Collateral Agreement, the Assignment of Interests, or any other Transaction Document, result in the creation or imposition of any Lien on (i) the assets or properties of the Company or its Subsidiary or (ii) the Assigned Interests, the Revenue Interests, or any other Assigned Interests Collateral, except, in the case of the foregoing clauses (a), (c), (d) or (e), for any such breaches, defaults or other occurrences that would not, individually or in the aggregate, have a Material Adverse Effect.

**Section 3.11 Subordination.**

The claims and rights of Purchaser created by any Transaction Document in and to the Assigned Interests, the Revenue Interests and any other Assigned Interests Collateral are not and shall not be subordinated to any creditor of the Company or any other Person.

**Section 3.12 Intellectual Property.**

(a) Schedule 3.12(a) sets forth an accurate, true and complete list of all (i) Patents and utility models, (ii) trade names, registered trademarks, registered service marks, and applications for trademark registration or service mark registration, (iii) registered copyrights and (iv) domain name registrations and websites, in each case with respect to clauses (i), (ii), (iii) and (iv) above in this subsection (a) that the Company owns or licenses and which are necessary to make, have made, use, sell, have sold, offer for sale, import, develop, promote, market, distribute, manufacture, commercialize or otherwise exploit the Product in the jurisdictions where the Product marketed and sold. For each item of Intellectual Property listed on Schedule 3.12(a), the Company has identified (x) the owner, (y) the countries in which such listed item is patented or registered or in which an application for Patent or registration is pending and (z) the application

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number, the Patent number or registration number. To the Company's Knowledge, except as disclosed therein, each Patent and trademark listed on Schedule 3.12(a) is valid, enforceable and subsisting and none has lapsed, expired, been cancelled or become abandoned. The Patent applications listed in Schedule 3.12(a) have been prosecuted by competent patent counsel in a diligent manner. After due inquiry, the Company has determined that there are no published patents, patent applications, articles, prior art references, public uses, undisclosed information (including best mode) or other grounds, factors or circumstances that could adversely affect the validity or enforceability of any of the Patents listed in Schedule 3.12(a). After due inquiry, the Company has determined that all Persons relevant to the prosecution of any of the Material Patents or applications related thereto have complied with the duty to disclose information and/or the duty of candor, including obligations to the United States Patent and Trademark Office specified under Rule 56. To the Company's Knowledge, each of the Material Patents and Material Patent applications correctly identifies each and every inventor of the claims thereof as determined in accordance with the laws of the jurisdiction in which such Material Patent is issued or such Material Patent application is pending. To the Company's Knowledge, each Person who has or has had any rights in or to the Intellectual Property listed on Schedule 3.12(a) that are owned by, or licensed to, the Company, including, each inventor named on the Patents and Patent applications listed in Schedule 3.12(a), has executed an agreement assigning his, her or its entire right, title and interest in and to such Intellectual Property, and the inventions embodied, described and/or claimed therein, to the purported owner and no such Person has any contractual or other obligation that would preclude or conflict with any such assignment or otherwise conflict with the obligations of such Person to the applicable owner of each listed Intellectual Property. To the Company's Knowledge, all Persons having a claim to inventorship to any pending or issued claim of the Patents are currently listed as inventors with respect to such Patents, and that the Company has performed an appropriate inquiry with respect to such inventorship.

(b) Except for Intellectual Property licensed to and owned by the Company and set forth on Schedule 3.12(a), no other Intellectual Property is necessary to make, have made, offer to sell, sell, have sold, use, import, distribute, commercialize or market the Product in the Major Countries. The use, manufacture, import, export, offer for sale, distribution, marketing and sale of the Product does not infringe any patents that are owned by a Third Party in the Major Countries.

(c) The Company has the full right, power and authority to grant all of the rights and interests granted to Purchaser in this Agreement.

(d) To the Company's Knowledge, there are no unpaid maintenance, annuity or renewal fees currently overdue for any of the Patents that cover the manufacture, use or sale of the Product or which cover compositions of matter and/or processes which relate to the Product or alternatives thereto ("Material Patents").

(e) There is, and has been, no pending, decided or settled opposition, interference proceeding, reexamination proceeding, cancellation proceeding, injunction, claim, lawsuit, declaratory judgment, administrative post-grant review proceeding, other administrative or judicial proceeding, hearing, investigation, complaint, arbitration, mediation, International Trade Commission investigation, decree, or any other filed claim (collectively referred to hereinafter as "Disputes") related to any of the Material Patents, nor, to the Knowledge of the Company, has



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any such Dispute been threatened challenging the legality, validity, enforceability or ownership of any Material Patents or which would give rise to a credit against the revenues or royalties due to the Company for the manufacture, sale, offer for sale, use, importation or exportation of the Product and the Company has no notice of any facts that would form the basis for such a Dispute. There are no Disputes by any Person or Third Party against the Company, its Licensees or its licensor, and the Company has not received any written notice or claim of any such Dispute as pertaining to the Product. Neither the Company nor its licensor has sent any notice of any such Dispute to a Third Party. The Company is not subject to any outstanding injunction, judgment, order, decree, ruling, charge, settlement or other disposition of Dispute which relates to the Product or the Patents.

(f) There is no pending or threatened action, suit, or proceeding, or any investigation or claim by any Governmental Authority to which the Company is a party (i) that would be the subject of a claim for indemnification by any Person or Third Party under any agreement, or (ii) that the marketing, sale or distribution of the Product worldwide by the Company or its Licensees pursuant to the related License Agreement, as applicable, does or will infringe on any patent of any other Person, and there is no basis for any such action, suit, proceeding, investigation or claim of the type described in clause (i) or (ii) above. To the Company's Knowledge, there are no pending published or unpublished United States, international or foreign patent applications owned by any other Person, which, if issued, would limit or prohibit, in any material respect, the use of the Product or the licensed Intellectual Property relating to the Product.

(g) The Company has taken all commercially reasonable measures and precautions necessary to protect and maintain (i) the confidentiality of all Intellectual Property that it owns and (ii) the value of all Intellectual Property related to the Product, except where such failure to take action would not have a Material Adverse Effect.

(h) No material trade secret of the Company has been published or disclosed to any Person except pursuant to a written agreement requiring such Person to keep such trade secret confidential, except where such disclosure would not have a Material Adverse Effect.

(i) Each Product, or its manufacture or use, is covered by one or more claims of an issued Patent in the United States.

### **Section 3.13 Regulatory Approval**

(a) The Company and its Subsidiary have made available to Purchaser any written reports or other written communications received from a Governmental Authority that would indicate that any Regulatory Agency (A) is not likely to approve the BLA, (B) is likely to revise or revoke any current Regulatory Approval granted by any Regulatory Agency with respect to the Product, or (C) is likely to pursue any material compliance actions against the Company.

(b) The Company and its Subsidiary possess all Regulatory Approvals issued or required by the appropriate Regulatory Agencies, which Regulatory Approvals are necessary to conduct the current clinical trials relating to the Product, and neither the Company nor its Subsidiary has received any notice of proceedings relating to the revocation, suspension, termination or modification of any such Regulatory Approvals.

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(c) The Company and its Subsidiary are in material compliance with, and has materially complied with, all applicable federal, state, local and foreign laws, rules, regulations, standards, orders and decrees governing its business, including all regulations promulgated by each Regulatory Agency, the failure of compliance with which could reasonably be expected to result in a Material Adverse Effect; the Company and its Subsidiary have not received any notice citing action or inaction by any of them that would constitute any material non-compliance with any applicable federal, state, local and foreign laws, rules, regulations, or standards, which could reasonably be expected to result in a Material Adverse Effect; and to the Company's Knowledge, no prospective change in any applicable federal, state, local or foreign laws, rules, regulations or standards has been adopted which, when made effective, could reasonably be expected to result in a Material Adverse Effect.

(d) Preclinical and clinical trials conducted on behalf of the Company or its Subsidiary relating to the Product were conducted in compliance with applicable laws and, in all material respects, in accordance with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards; the descriptions of the results of such trials provided to Purchaser are accurate in all material respects. Neither the Company nor its Subsidiary has received any notices or correspondence from any Regulatory Agency or comparable authority requiring the termination, suspension, or material modification or clinical hold of any clinical trials conducted by or on behalf of the Company or its Subsidiary with respect to the Product, which termination, suspension, material modification or clinical hold could reasonably be expected to result in a Material Adverse Effect.

#### **Section 3.14 Material Contracts.**

Neither the Company nor its Subsidiary is in breach of or in default under any Material Contract which default, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect. To the Knowledge of the Company, nothing has occurred and no condition exists that would permit any other party thereto to terminate any Material Contract. Neither the Company nor its Subsidiary has received any notice or, to the Knowledge of the Company, any threat of termination of any such Material Contract. To the Knowledge of the Company, no other party to a Material Contract is in breach of or in default under such Material Contract. All Material Contracts are valid and binding on the Company or its Subsidiary and, to the Knowledge of the Company, on each other party thereto, and are in full force and effect. The Company is in compliance with all obligations of the Amended and Restated Standard Exclusive License Agreement with Sublicensing Terms between AxoGen Corporation and the University of Florida Research Foundation dated February 21, 2006, and the Patent License Agreement between AxoGen Corporation and the Board of Regents of The University of Texas System dated July 19, 2005.

#### **Section 3.15 Place of Business.**

The Company's principal place of business and chief executive office are set forth on Schedule 3.15.

#### **Section 3.16 Broker's Fees.**

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The Company and its Subsidiary have not taken any action that would entitle any Person to any commission or broker's fee in connection with this Agreement except fees, commissions and expenses to be paid to JMP Securities LLC, all of which will be paid by the Company.

**Section 3.17 Other Information.**

No written statement, information, report or materials prepared by or on behalf of the Company or its Subsidiary and furnished to Purchaser by or on behalf of the Company or its Subsidiary in connection with any Transaction Document or any transaction contemplated hereby or thereby, no written representation, warranty or statement made by the Company or its Subsidiary in any Transaction Document, and no Schedule or Exhibit hereto or thereto, in each case taken in the aggregate, contains any untrue statement of a material fact or omits any statement of material fact necessary in order to make the statements made therein in light of the circumstances under which they were made not misleading.

**Section 3.18 Insurance.**

There are in full force and effect insurance policies maintained by the Company with an insurance company rated not less than "A-" by A.M. Best Company, Inc., with coverages and in amounts customary for companies of comparable size and condition similarly situated in the same industry as the Company, including product liability insurance, directors and officers insurance and insurance against litigation liability, subject only to such exclusions and deductible items as are usual and customary in insurance policies of such type. All material insurable risks in respect of the business and assets of the Company and its Subsidiary are covered by such insurance policies. The Company has named Purchaser as an additional insured party with respect to its general liability and product liability insurance policies. A schedule of the Company's insurance policy or insurance policies is attached hereto as Schedule 3.18.

**Section 3.19 Taxes.**

The Company has timely filed (taking into account all extensions of due dates) all Tax returns required to be filed by, or on behalf of, it and has timely paid all Taxes required to be paid with such returns. All Tax Returns filed by the Company (or on its behalf) have been true, correct and complete in all material respects. Except as set forth on Schedule 3.19, there is no outstanding or, to the Company's Knowledge, threatened action, claim or other examination or proceeding with respect to Taxes of the Company or its assets (including with respect to the Assigned Interests and the Revenue Interests). Except as set forth on Schedule 3.19, there are no Taxes of the Company that form or could form, individually or in the aggregate, the basis for a material encumbrance (other than encumbrances for current taxes not yet past due) on any of its assets (including the Assigned Interests and the Revenue Interests).

**ARTICLE IV  
REPRESENTATIONS AND WARRANTIES OF PURCHASER**

Purchaser represents and warrants to the Company the following:

**Section 4.01 Organization.**

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Purchaser is a corporation duly incorporated and validly existing under the laws of the State of Delaware.

**Section 4.02 Authorization.**

Purchaser has all necessary power and authority to enter into, execute and deliver the Transaction Documents and to perform all of the obligations to be performed by it hereunder and thereunder and to consummate the transactions contemplated hereunder and thereunder. The Transaction Documents have been duly authorized, executed and delivered by Purchaser and each Transaction Document constitutes the valid and binding obligation of Purchaser, enforceable against Purchaser in accordance with their respective terms, subject, as to enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or general equitable principles.

**Section 4.03 Broker's Fees.**

Purchaser has not taken any action that would entitle any Person to any commission or broker's fee in connection with the transactions contemplated by the Transaction Documents.

**Section 4.04 Conflicts.**

Neither the execution and delivery of this Agreement or any other Transaction Document to which Purchaser is a party nor the performance or consummation of the transactions contemplated hereby or thereby will: (a) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, in any material respects any provisions of: (i) any law, rule or regulation of any Governmental Authority, or any judgment, order, writ, decree, permit or license of any Governmental Authority, to which Purchaser or any of its assets or properties may be subject or bound; or (ii) any contract, agreement, commitment or instrument to which Purchaser is a party or by which Purchaser or any of its assets or properties is bound or committed; (b) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, any provisions of the organizational or constitutional documents of Purchaser; or (c) require any notification to, filing with, or consent of, any Person or Governmental Authority, except, in the case of the foregoing clauses (a) or (c), for any such breaches, defaults or other occurrences that would not, individually or in the aggregate, have a material adverse effect on the ability of Purchaser to perform any of its obligations under the Transaction Documents.

**ARTICLE V  
COVENANTS**

From the date hereof through and including the end of the Revenue Interest Period, the following covenants shall apply:

**Section 5.01 Consents and Waivers.**

The Company shall use its commercially reasonable efforts to obtain and maintain any required consents, acknowledgements, certificates or waivers so that the transactions contemplated by this Agreement or any other Transaction Document may be consummated and shall not result in any default or breach or termination of any of the Material Contracts.

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## **Section 5.02 Access; Information.**

(a) **License Notices.** Subject to any applicable confidentiality restrictions, the Company shall promptly provide Purchaser with copies of any material written notices received or given by the Company under any Material Contract, and to the extent the Company is barred from providing Purchaser with copies of such notices due to any applicable confidentiality restrictions, the Company shall (i) inform Purchaser of the existence of such notice accompanied by a written description of the substance contained in such notice and (ii) promptly seek the removal or waiver of any such confidentiality restrictions so as to permit a free exchange of information with the Purchaser regarding the substance of such notice. The Company shall promptly notify Purchaser of any breaches or alleged breaches under any Material Contracts and of any other events with respect to any Material Contract or the subject matter thereof which could reasonably be expected to have a Material Adverse Effect.

(b) **Litigation or Investigations.** The Company shall promptly notify Purchaser of (i) any action, demand, suit, claim, cause of action, proceeding or investigation pending or, to the best knowledge of the Company, threatened by or against the Company, or (ii) proceeding or inquiry of any Governmental Authority pending or, to the best knowledge of the Company, threatened against the Company, related to any Material Contract, the Product, the Patents or any Transaction Document.

(c) **Maintenance of Books and Records.** The Company shall keep and maintain, or cause to be kept and maintained, at all times accurate and complete books and records. During the Term, the Company shall keep and maintain, or cause to be kept and maintained, at all times full and accurate books of account and records adequate to correctly reflect all payments paid and/or payable with respect to the Revenue Interests and Assigned Interests and all deposits made into the applicable deposit accounts.

(d) **Inspection Rights.** Purchaser and any of Purchaser's representatives shall have the right, once a year (and at any other time a Default or Event of Default shall have occurred or be continuing), to visit the Company and its Subsidiaries' offices and properties where the Company and its Subsidiaries keep and maintain their books and records relating or pertaining to the Revenue Interests, the Assigned Interests and the other Assigned Interests Collateral for purposes of conducting an audit of such books and records, and to inspect, copy and audit such books and records, during normal business hours, and, upon five (5) Business Days' written notice given by Purchaser to the Company (provided one (1) Business Day's notice shall be required if a Default or Event of Default shall have occurred and be continuing), the Company will provide Purchaser and any of Purchaser's representatives reasonable access to such books and records, and shall permit Purchaser and any of Purchaser's representatives to discuss the business, operations, properties and financial and other condition of the Company or any of its Affiliates including, but not limited to, matters relating or pertaining to the Revenue Interests, the Assigned Interests and any the other Assigned Interests Collateral with officers of such parties, and with their independent certified public accountants.

(e) **Audit Costs.** In the event any audit of the books and records of the Company and its Subsidiaries relating to the Revenue Interests, Assigned Interests, and the other Assigned Interests Collateral by Purchaser and/or any of Purchaser's representatives reveals that the amounts paid to Purchaser hereunder for the period of such audit have been understated by more

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than five percent (5%) of the amounts determined to be due for the period subject to such audit, then the Audit Costs in respect of such audit shall be borne by the Company; and in all other cases, such Audit Costs shall be borne by Purchaser.

(f) Quarterly Reports. During the Term, the Company shall, promptly after the end of each Fiscal Quarter of the Company (but in no event later than forty-five (45) days following the end of such quarter), produce and deliver to Purchaser a Quarterly Report for such quarter, together with a certificate of the Company, certifying that to the best Knowledge of the Company (i) such Quarterly Report is a true and complete copy and (ii) any statements and any data and information therein prepared by the Company are true, correct and accurate in all material respects.

(g) GAAP Accounting. The Company shall maintain a system of accounting established and administered in accordance with sound business practices to permit preparation of financial statements in conformity with GAAP.

(h) Periodic Reports. In the event that the Company is not subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the Company shall deliver to Purchaser the following financial statements:

(i) Within forty-five (45) days after the end of each Fiscal Quarter, copies of the unaudited consolidated financial statements of the Company and its Subsidiaries for such Fiscal Quarter; and

(ii) Within forty-five (45) days after the end of each Fiscal Year, copies of the audited consolidated financial statements of the Company and its Subsidiaries for such Fiscal Year.

#### **Section 5.03 Material Contracts.**

The Company shall comply with all material terms and conditions of and fulfill all of its obligations under all the Material Contracts. The Company shall not amend, modify or supplement any Material Contract in a manner which would adversely affect Purchaser or issue any waivers, consents, or other approvals under any Material Contract in a manner which would adversely affect Purchaser without the prior written consent of Purchaser. Upon the occurrence of a material breach of any Material Contract by any Third Party thereto, which is not cured pursuant to the express terms as provided therein (disregarding any rights of waiver or extensions of time or other rights or consents that are excisable at the discretion of the Company), the Company shall, in its discretion but in accordance with its sound business judgment, use its commercially reasonable efforts to enforce its rights and remedies thereunder.

#### **Section 5.04 Confidentiality; Public Announcement.**

(a) All Confidential Information furnished by Purchaser to the Company or by the Company to Purchaser in connection with this Agreement and any other Transaction Document and the transactions contemplated hereby and thereby, as well as the terms, conditions and provisions of this Agreement and any other Transaction Document, shall be kept confidential by the Company and Purchaser. Notwithstanding the foregoing, the Company and Purchaser may disclose such Confidential Information to their partners, directors, employees, managers,

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officers, investors, bankers, advisors, trustees and representatives, provided that such Persons shall be informed of the confidential nature of such information and shall be obligated to keep such information confidential pursuant to the terms of this Section 5.04(a). The Company will consult with Purchaser, and Purchaser will consult with the Company, on the form, content and timing of any such disclosures of Confidential Information, including, without limitation, any disclosures made pursuant to applicable securities laws or made to investment or other analysts.

(b) Except as required by law or the rules and regulations of any securities exchange or trading system or the FDA or any Governmental Authority with similar regulatory authority, or except with the prior written consent of the other party (which consent shall not be unreasonably withheld), no party shall issue any press release or make any other public disclosure with respect to the transactions contemplated by this Agreement or any other Transaction Document; provided, however, that the Company and Purchaser may jointly prepare a press release for dissemination promptly following the Closing Date.

**Section 5.05 Guarantee and Collateral Agreement.**

During the Revenue Interest Period, the Company shall, at all times until the Obligations are paid and performed in full, grant in favor of Purchaser a valid, continuing, first perfected lien on and security interest in the Revenue Interests, the Assigned Interests and the other Assigned Interests Collateral described in the Guarantee and Collateral Agreement.

**Section 5.06 Efforts; Further Assurance.**

(a) Subject to the terms and conditions of this Agreement, each of Purchaser and the Company will use its commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary under applicable laws and regulations to consummate the transactions contemplated by this Agreement and any other Transaction Document. Purchaser and the Company agree to execute and deliver such other documents, certificates, agreements and other writings (including any financing statement filings requested by Purchaser) and to take such other actions as may be reasonably necessary in order to consummate or implement expeditiously the transactions contemplated by this Agreement and any other Transaction Document and to vest in Purchaser good, valid and marketable rights and interests in and to the Assigned Interests free and clear of all Liens, except those Liens created in favor of Purchaser pursuant to the Guarantee and Collateral Agreement, the Assignment of Interests and any other Transaction Document.

(b) Purchaser and the Company shall execute and deliver such additional documents, certificates and instruments, and perform such additional acts, as may be reasonably requested and necessary or appropriate to carry out and effectuate all of the provisions of this Agreement and any other Transaction Document and to consummate all of the transactions contemplated by this Agreement and any other Transaction Document.

(c) Purchaser and the Company shall cooperate and provide assistance as reasonably requested by the other party in connection with any Third Party litigation, arbitration or other Third Party proceeding (whether threatened, existing, initiated, or contemplated prior to, on or after the date hereof) to which any party hereto or any of its officers, directors, shareholders, agents or employees is or may become a party or is or may become otherwise directly or

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indirectly affected or as to which any such Persons have a direct or indirect interests, in each case relating to this Agreement, any other Transaction Document, the Assigned Interests or any other Assigned Interests Collateral, or the transactions described herein or therein.

**Section 5.07 Change of Control; Put Option.**

(a) Change of Control. In the event that a Change of Control shall occur during the Revenue Interest Period, the Company shall repurchase the Assigned Interests from Purchaser for a repurchase price equal to the Change of Control Payment on or prior to the third Business Day after the occurrence of a Change of Control. The Change of Control Payment shall be made by wire transfer of immediately available funds to the account designated by Purchaser.

(b) Put Option. In the event that a Put Option Event shall occur during the Term, Purchaser shall have the right, but not the obligation (the "Put Option") to require the Company to repurchase from Purchaser the Assigned Interests at the Put Price. In the event Purchaser elects to exercise its Put Option, Purchaser shall deliver written notice to the Company specifying the closing date which date shall be forty-five (45) days from such notice date (the "Put Option Closing Date"), which notice must be given within sixty (60) days of Purchaser's receipt of written notice from the Company of a Put Option Event. Failure to provide notice by such times will be deemed an irrevocable waiver of the right to exercise the Put Option. On the Put Option Closing Date, the Company shall repurchase from Purchaser the Assigned Interests at the Put Price in cash, the payment of which shall be made by wire transfer of immediately available funds to the account designated by Purchaser. Notwithstanding anything to the contrary contained herein, immediately upon the occurrence of a Bankruptcy Event, Purchaser shall be deemed to have automatically and simultaneously elected to have the Company repurchase from Purchaser the Assigned Interests for the Put Price in cash and the Put Price shall be immediately due and payable without any further action or notice by any party.

(c) Call Option. At any time after the fourth anniversary following the Closing Date, the Company shall have the right (the "Call Option"), exercisable upon ten (10) days' written notice to Purchaser, to repurchase the Assigned Interests from Purchaser at a repurchase price equal to the Change of Control Payment. In order to exercise the Call Option, the Company shall deliver written notice to Purchaser of its election to so repurchase the Assigned Interests not less than ten (10) days prior to the proposed closing date (the "Call Closing Date"). On the Call Closing Date, the Company shall repurchase from Purchaser the Assigned Interests at the Change of Control Payment, the payment of which shall be made by wire transfer of immediately available funds to the account designated by Purchaser.

(d) Obligations of Purchaser. In connection with the consummation of a repurchase of the Assigned Interests pursuant to the Change of Control Payment or the Put Option, Purchaser agrees that it will (i) promptly but no later than three (3) Business Days execute and deliver to the Company such UCC termination statements and other documents as may be necessary to release Purchaser's Lien on the Assigned Interests Collateral and otherwise give effect to such repurchase and (ii) take such other actions or provide such other assistance as may be necessary to give effect to such repurchase.



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### **Section 5.08 Remittance to Deposit Account.**

(a) On the Closing Date, the parties hereto shall enter into a Deposit Agreement in form and substance reasonably satisfactory to the parties hereto and the Deposit Bank, which Deposit Agreement will provide for, among other things, the establishment and maintenance of a Deposit Account and Joint Concentration Account in accordance with the terms herein and therein. Funds deposited into the Deposit Account shall be swept by the Deposit Bank on a daily basis into the Joint Concentration Account. The parties understand and agree that the current Deposit Bank cannot accommodate multiple Deposit Accounts; and accordingly, so long as the Company has not established a separate Company Concentration Account and Purchaser Concentration Account as required pursuant to Section 5.08(b), the Company shall be responsible for computing the Daily Amount and shall retain at all times (subject to any payments of the Daily Amount paid to Purchaser, which payments shall be made promptly upon Purchaser's request) an amount equal to the aggregate Daily Amount owed to Purchaser pursuant to this Agreement.

(b) Notwithstanding any provision herein or in any other Transaction Document to the contrary, the Company shall no later than one hundred twenty (120) days after the Closing Date to enter into a new Deposit Agreement (in form and substance reasonably satisfactory to Purchaser) with a bank or financial institution approved by Purchaser, which bank or financial institution shall thereafter serve as the Deposit Bank pursuant to the terms hereof. Upon engagement of the replacement Deposit Bank and the entering into the new Deposit Agreement in accordance with the immediately preceding sentence, such Deposit Agreement shall provide for, among other things, the establishment and maintenance of a Deposit Account, a Joint Concentration Account, a Company Concentration Account and a Purchaser Concentration Account in accordance with the terms herein and therein. Any Purchaser Concentration Account shall be held solely for the benefit of Purchaser, but shall be subject to the terms and conditions of this Agreement, the Guarantee and Collateral Agreement and the other Transaction Documents. Funds deposited into the Deposit Account shall be swept by the Deposit Bank on a daily basis into the Joint Concentration Account and subsequent thereto, the Daily Amount shall be swept into the Purchaser Concentration Account. Purchaser shall have immediate and full access to any funds held in the Purchaser Concentration Account and such funds shall not be subject to any conditions or restrictions whatsoever. After the Daily Amount is swept into the Purchaser Concentration Account, the amounts remaining in the Joint Concentration Account shall then be swept, at the direction of the Company, into the Company Concentration Account. The Company shall have immediate and full access to any funds held in the Company Concentration Account and such funds shall not be subject to any conditions or restrictions whatsoever other than those of the Deposit Bank; provided, however, that nothing herein shall (i) affect or reduce the Company's obligations to pay in full all amounts due to Purchaser under this Agreement, or (ii) in any manner limit the recourse of Purchaser to the Assigned Interests Collateral to satisfy the Company's Obligations.

(c) The Company shall pay all fees, expenses and charges of the Deposit Bank (including the replacement Deposit Bank contemplated by Section 5.08(b)).

(d) The Company shall use commercially reasonable efforts to amend each License Agreement, within thirty (30) Business Days after the engagement of the replacement Deposit Bank contemplated by Section 5.08(b), to contain a provision providing for all payments in

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respect of sales of the Product and in respect of royalties received from Licensees to be remitted directly by the applicable party into the Deposit Account and the Company shall cause such payments to be remitted directly by the applicable party into the Deposit Account. If the Company is unsuccessful in amending the License Agreements in accordance with the foregoing sentence and at all times prior to the engagement of the replacement Deposit Bank as contemplated by Section 5.08(b), the Company shall instruct each Licensee to such License Agreement to remit to the Deposit Account when due all applicable payments in respect of sales and licensing revenue in respect of the Product and in respect of royalties received from such Licensees. Without in any way limiting the foregoing, commencing on the Closing Date and thereafter, any and all payments in respect of sales of the Product received by the Company shall be deposited into the Deposit Account within two (2) Business Days of the Company's receipt thereof.

(e) With respect to any License Agreement (excluding License Agreement that do not call for direct payment to the Company) entered into by the Company from and after the engagement of the replacement Deposit Bank contemplated by Section 5.08(b), the Company shall (i) at the time of the execution and delivery of such agreement, instruct any party thereto under such agreement to remit to the Deposit Account when due all applicable payments in respect of sales and licensing revenue in respect of the Product and in respect of royalties received from Licensees that are due and payable to the Company in respect of or derived from such agreement during the Revenue Interest Period and (ii) deliver to Purchaser evidence of such instruction and of such applicable party's agreement thereto. Without in any way limiting the foregoing, commencing on the Closing Date and thereafter, any and all payments in respect of sales of the Product received by the Company shall be deposited into the Deposit Account within two (2) Business Days of the Company's receipt thereof.

(f) Prior to the termination of this Agreement, the Company shall not have any right to terminate the Deposit Bank without Purchaser's prior written consent. Any such consent, which Purchaser may grant or withhold in its sole and absolute discretion, shall be subject to the satisfaction of each of the following conditions to the satisfaction of Purchaser:

(i) the successor Deposit Bank shall be acceptable to Purchaser;

(ii) Purchaser, the Company and the successor Deposit Bank shall have entered into a deposit agreement substantially in the form of the Deposit Agreement initially entered into;

(iii) all funds and items in the accounts subject to the Deposit Agreement to be terminated shall be transferred to the new accounts held at the successor Deposit Bank prior to the termination of the then existing Deposit Bank; and

(iv) Purchaser shall have received evidence that all of the applicable parties making payments in respect of sales of the Product have been instructed to remit all future payments in respect of sales of the Product to the new accounts held at the successor Deposit Bank.

(g) True-Up.

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(i) Following the end of each Fiscal Quarter, as soon as the Company shall have determined the Net Revenues for such Fiscal Quarter and for each other Fiscal Quarter in the Fiscal Year in which the then most recently ended Fiscal Quarter occurred (the “Year-to-Date Net Revenues”) and in any event no later than forty-five (45) days after the end of such Fiscal Quarter (unless such Fiscal Quarter is the last Fiscal Quarter of a Fiscal Year in which case no later than ninety (90) days after the end of such Fiscal Quarter), the Company shall present Purchaser a certificate, in reasonable detail with supporting calculations and information, detailing the Year-to-Date Net Revenues (the “True-Up Statement”). The True-Up Statement shall include a calculation of (A) the year-to-date Assigned Interests as of the end of such quarterly period, which shall be the product of the Applicable Percentage multiplied by the Year-to-Date Net Revenues, with a separate calculation taking into account any mandatory minimum payments as provided in the definition of Assigned Interests (“Year-to-Date Assigned Interests”) and (B) the difference between (X) the amount Purchaser has received on or prior to the last day of the most recently ended Fiscal Quarter in payments from the Company under Section 2.02(a) or this Section 5.08 in respect of the Fiscal Year for which Year-to-Date Net Revenues is calculated less (Y) the Year-to-Date Assigned Interests (the “True-Up Amount”).

(ii) If the True-Up Amount calculated pursuant to clause (i) above is positive, Purchaser shall pay such amount to the Company within five (5) days of receipt by Purchaser of the True-Up Statement.

(iii) If the True-Up Amount calculated pursuant to clause (i) above is negative, the Company shall pay the absolute value of such amount to Purchaser within five (5) days of the receipt by Purchaser of the True-Up Statement.

#### **Section 5.09 Intellectual Property.**

(a) The Company shall, at its sole expense, either directly or by causing any Licensee to do so, take any and all actions (including taking legal action to specifically enforce the applicable terms of any License Agreement), and prepare, execute, deliver and file any and all agreements, documents or instruments which are necessary to diligently maintain the Material Patents. The Company shall ensure that all patent applications corresponding to the Material Patents are diligently prosecuted with the intent to protect the Product. In the exercise of its reasonable business discretion, the Company shall diligently defend or assert such Intellectual Property and such Patents against infringement or interference by any other Persons, and against any claims of invalidity or unenforceability, in any jurisdiction (including, without limitation, by bringing any legal action for infringement or defending any counterclaim of invalidity or action of a Third Party for declaratory judgment of non-infringement or non-interference). The Company shall not, and shall use its commercially reasonable efforts to cause any Licensee not to, disclaim or abandon, or fail to take any action necessary or desirable to prevent the disclaimer or abandonment of, the Material Patents.

(b) In the event that the Company becomes aware that any intellectual property licensed by it to a Licensee under any License Agreement infringes or violates any Third Party intellectual property, the Company shall, in the exercise of its reasonable business discretion, use commercially reasonable efforts to attempt to secure the right to use such intellectual property on behalf of itself and the affected Licensee and shall pay all costs and amounts associated with obtaining any such license, without any reduction in the Assigned Interests.

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(c) The Company shall directly, or through a Licensee, take any and all actions and prepare, execute, deliver and file any and all agreements, documents or instruments that are necessary or commercially reasonable or desirable to secure and maintain, all Regulatory Approvals in the United States.

(d) The Company shall notify PDL regarding any material developments with the Material Patents, including new filings, allowance and issuance, abandonment, or the initiation of any interference, reexamination, reissue, post-grant review proceeding and litigation, and shall provide PDL with an updated patent schedule upon request, but at least once per year.

**Section 5.10 Protective Covenants.**

(a) The Company shall not, without the prior written consent of Purchaser:

(i) Forgive, release or compromise any amount owed to the Company or its Subsidiary and relating to the Assigned Interests outside the ordinary course of business;

(ii) Waive, amend, cancel or terminate, exercise or fail to exercise, any of its material rights constituting or relating to the Revenue Interests (including any rights under any License Agreement) outside the ordinary course of business;

(iii) Amend, modify, restate, cancel, supplement, terminate or waive any material provision of any Material Contract, or grant any consent thereunder, or agree to do any of the foregoing, including, without limitation, entering into any agreement with any Person under the provisions of such Material Contract;

(iv) Enter into any agreement that would be reasonably expected to have a Material Adverse Effect;

(v) Create, incur, assume or suffer any interference with the direction of payments set for in Section 5.08; or

(vi) Create, incur, assume or suffer to exist any Lien, or exercise any right of rescission, offset, counterclaim or defense, upon or with respect to the Assigned Interests, the Revenue Interests or the other Assigned Interests Collateral, or agree to do or suffer to exist any of the foregoing, except for any Lien or agreements in favor of Purchaser granted under or pursuant to this Agreement and the other Transaction Documents.

(b) During the Term, the Company agrees that, within five (5) Business Days of any Person becoming a direct or indirect wholly owned Subsidiary of the Company, the Company shall cause such Subsidiary to deliver to Purchaser an Assumption Agreement (as defined in the Guarantee and Collateral Agreement) executed by such Subsidiary, pursuant to which such Subsidiary shall become a guarantor of the obligations hereunder and grant a security interest in the Assigned Interests Collateral.

**Section 5.11 Insurance.**

The Company shall (i) maintain the current insurance policies with its current insurance companies or with companies having at the least the same rating from A.M. Best Company, Inc.,

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including product liability insurance and directors and officers insurance and insurance against litigation, liability, subject only to such exclusions and deductible items as are usual and customary in insurance policies of such type, and (ii) maintain Purchaser as an additional insured party with respect to its general liability and product liability insurance policies. From time to time (with reasonable frequency) the Company will revise its insurance policy so as to maintain coverage in amounts customary for companies of comparable size and condition similarly situated in the same industry as the Company.

**Section 5.12 Notice.**

The Company shall provide Purchaser with written notice as promptly as practicable (and in any event within two (2) Business Days) after becoming aware of any of the following:

(a) any material breach or default by the Company of any covenant, agreement or other provision of this Agreement, or any other Transaction Document;

(b) any representation or warranty made or deemed made by the Company in any of the Transaction Documents or in any certificate delivered to Purchaser pursuant hereto shall prove to be untrue, inaccurate or incomplete in any material respect on the date as of which made or deemed made;

(c) the occurrence of a Change of Control; or

(d) the occurrence of a Put Option Event.

**Section 5.13 Use of Proceeds.**

The Company shall use proceeds received from Purchaser in support of the business plan for the Product, including sales operation and expansion and additional clinical studies. The Company shall take commercially reasonable measures to support the sales of the Product.

**Section 5.14 Taxes.**

(a) The Company shall timely file (taking into account all extensions of due dates) all Tax Returns required to be filed by it and will pay all Taxes required to be paid with such returns.

(b) Each payment made by the Company pursuant to the Transaction Documents shall be payable free of any Tax, withholding or other deduction except for any Tax, withholding or deduction imposed by applicable law. The Company and Purchaser agree that to each of their knowledge such payments are not subject to any deduction or withholding under current applicable law.

**Section 5.15 Board Designee.**

Effective immediately after the Closing, Purchaser shall have the right to designate, and the Company shall appoint an individual designated by the Purchaser (the "Purchaser Designee"), who shall serve on the Board until the 2013 Annual Meeting of Shareholders (the "2013 Annual Meeting"). For the 2013 Annual Meeting and each annual meeting thereafter

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during the Term, the Board shall nominate and recommend the Purchaser Designee as a director nominee to serve on the Board until the next annual meeting and shall include such nomination in the Company's proxy statement for the 2013 Annual Meeting and each annual meeting thereafter, provided that the election of the Purchaser Designee is subject to shareholders' approval. Should at any time there become a vacancy on the Board as a result of (1) the resignation, death or removal of the Purchaser Designee or (2) such Purchaser Designee failing to obtain the requisite approval of the Company's shareholders at any annual or special meeting of the Company's shareholders and where no other individual is elected to such vacancy, Purchaser shall have the right to designate an individual to fill such vacancy, and the Company shall take such actions necessary to appoint, such individual to the Board. The Company shall have taken all actions necessary at or prior to the Closing to ensure there is a vacancy on the Board as of the Closing to permit the appointment of the Purchaser Designee to the Board as of the Closing.

**Section 5.16 Rights to Future Stock Issuances.**

Subject to the terms and conditions of this Section 5.16 and applicable securities laws, if the Company proposes to offer or sell any New Securities, the Company shall first offer such New Securities to the Purchaser. The Purchaser shall be entitled to apportion the right of first offer hereby granted to it among itself and its Affiliates in such proportions as it deems appropriate.

(a) The Company shall give notice (the "Offer Notice") to the Purchaser, stating (i) its bona fide intention to offer such New Securities, (ii) the number of such New Securities to be offered, and (iii) the price and terms, if any, upon which it proposes to offer such New Securities.

(b) By notification to the Company within five (5) days after the Offer Notice is given, the Purchaser may elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to \* \* \* of such New Securities. The closing of any sale pursuant to this Section 5.16(b) shall occur within the later of one hundred and twenty (120) days of the date that the Offer Notice is given and the date of initial sale of New Securities pursuant to Section 5.16(c).

(c) If all New Securities referred to in the Offer Notice are not elected to be purchased or acquired as provided in Section 5.16(b), the Company may, during the ninety (90) day period following the expiration of the periods provided in Section 5.16(b), offer and sell such New Securities (including any portion of New Securities Purchaser declined to acquire pursuant to Section 5.16(b)) to any Person or Persons at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the sale of the New Securities within such period, or if such agreement is not consummated within thirty (30) days of the execution thereof, the right provided hereunder shall be deemed to be revived and such New Securities shall not be offered unless first reoffered to the Purchaser in accordance with this Section 5.16.

(d) The right of first offer in this Section 5.16 shall not be applicable to (i) issuance of options under the Company's equity compensation plans, where such plans have been approved by the Company's shareholders; and (ii) issuance of equity securities to one or more counterparties in connection with the consummation, by the Company, of a strategic partnership,

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joint venture, collaboration or acquisition or license of any business products or technology (it being understood and agreed that the primary purpose of any issuance pursuant to this clause (ii) shall not be to raise capital).

(e) The Purchaser shall agree to treat the Offer Notice as confidential, and it shall not trade any securities of the Company while the terms of the Offer Notice remain as material, non-public information.

**Section 5.17 Dividends.**

During the period from the Closing Date to sixty (60) days after the fourth anniversary of the Closing Date (or the payment of the Put Price in the event the Put Option is exercised on or prior to 60 days after the fourth anniversary of the Closing Date), the Company shall not, nor shall it permit any Subsidiary to, declare, pay or make any dividend or distribution on any shares of the common stock or preferred stock of such Person (other than dividends or distributions payable in its stock, or split-ups or reclassifications of its stock) or apply any of its funds, property or assets to the purchase, redemption or other retirement of any common or preferred stock, or of any options to purchase or acquire any such shares of common or preferred stock of any such Person (collectively, "Restricted Payments"), except that: (a) each Subsidiary may make direct or indirect Restricted Payments to the Company; and (b) the Company and each Subsidiary may purchase, redeem or otherwise acquire Equity Interests issued by it solely with the proceeds received from the substantially concurrent issue of new shares of its common stock or other common Equity Interests. For purposes of this Agreement, "Equity Interests" of any Person means any and all shares, rights to purchase, options, warrants, general, limited or limited liability partnership interests, member interests, participation or other equivalents of or interest in (regardless of how designated) equity of such Person, whether voting or nonvoting, including common stock, preferred stock, convertible securities or any other "equity security" (as such term is defined in Rule 3a11-1 of the General Rules and Regulations promulgated by the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended).

**ARTICLE VI  
TERMINATION**

**Section 6.01 Termination Date.**

This Agreement shall terminate upon the earlier of expiration or termination of the Revenue Interest Period, in each case after full satisfaction of any amounts due under this Agreement by Company to the Purchaser (the "Term").

**Section 6.02 Effect of Termination.**

In the event of the termination of this Agreement pursuant to Section 6.01, this Agreement shall forthwith become void and have no effect without any liability on the part of any party hereto or its Affiliates, directors, officers, stockholders, partners, managers or members other than the provisions of this Section 6.02 and Sections 5.04, and Article VII hereof, which shall survive any termination as set forth in Section 6.01. Nothing contained in this Section 6.02 shall relieve any party from liability for any breach of this Agreement.

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**ARTICLE VII  
MISCELLANEOUS**

**Section 7.01 Survival.**

(a) All representations and warranties made herein and in any other Transaction Document, any certificates or in any other writing delivered pursuant hereto or thereto shall survive the execution and delivery of this Agreement and shall continue to survive until the termination of this Agreement in accordance with Article VI.

(b) Any investigation or other examination that may have been made or may be made at any time by or on behalf of the party to whom representations and warranties are made shall not limit, diminish or in any way affect the representations and warranties in the Transaction Documents, and the parties may rely on the representations and warranties in the Transaction Documents irrespective of any information obtained by them by any investigation, examination or otherwise.

**Section 7.02 Specific Performance; Limitations on Damages.**

(a) Each of the parties hereto acknowledges that the other party will have no adequate remedy at law if it fails to perform any of its obligations under any of the Transaction Documents. In such event, each of the parties agrees that the other party shall have the right, in addition to any other rights it may have (whether at law or in equity), to specific performance of this Agreement.

(b) Notwithstanding anything to the contrary in this Agreement, in no event shall either party be liable for special, indirect, incidental, punitive or consequential damages of the other party, whether or not caused by or resulting from the actions of such party or the breach of its covenants, agreements, representations or warranties hereunder, even if such party has been advised of the possibility of such damages.

**Section 7.03 Notices.**

All notices, consents, waivers and communications hereunder given by any party to the other shall be in writing (including facsimile transmission) and delivered personally, by telegraph, telecopy, telex or facsimile, by a recognized overnight courier, or by dispatching the same by certified or registered mail, return receipt requested, with postage prepaid, in each case addressed:

If to Purchaser to:

PDL BioPharma, Inc.  
932 Southwood Blvd.  
Attention: General Counsel  
Facsimile No.: (775) 832-8501

with a copy to:



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Gibson, Dunn & Crutcher LLP  
333 South Grand Avenue  
Los Angeles, CA 90071-3197  
Attention: Dhiya El-Saden  
Facsimile No.: (213) 229-7520

If to the Company to:

AxoGen, Inc.  
AxoGen Corporation  
13859 Progress Blvd.  
Alachua, FL 32615  
Attention: Karen Zaderej  
Fax: (386) 462-6803

with a copy to:

Morgan, Lewis & Bockius LLP  
1701 Market Street  
Philadelphia, Pennsylvania 19103  
Attention: Fahd M.T. Riaz  
Fax: (215) 963-5001

or to such other address or addresses as Purchaser or the Company may from time to time designate by notice as provided herein, except that notices of changes of address shall be effective only upon receipt. All such notices, consents, waivers and communications shall: (a) when posted by certified or registered mail, postage prepaid, return receipt requested, be effective three (3) Business Days after dispatch, unless such communication is sent trans-Atlantic, in which case they shall be deemed effective five (5) Business Days after dispatch, (b) when telegraphed, telecopied, telexed or facsimiled, be effective upon receipt by the transmitting party of confirmation of complete transmission, or (c) when delivered by a recognized overnight courier or in person, be effective upon receipt when hand delivered.

**Section 7.04 Successors and Assigns.**

The provisions of this Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns. The Company shall not be entitled to assign any of its obligations and rights under the Transaction Documents without the prior written consent of Purchaser. Solely upon the consent of the Company (which consent may not be unreasonably withheld, delayed or conditioned), Purchaser may assign any of its obligations or rights under the Transaction Documents without restriction; provided, however, that Purchaser, notwithstanding such assignment, will remain liable under Section 5.08(g) (to the extent of any amount subject thereto during the Fiscal Quarter as of the date of such assignment) and Section 7.05.

**Section 7.05 Indemnification.**

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(a) The Company hereby indemnifies and holds Purchaser and its Affiliates and any of their respective partners, directors, managers, members, officers, employees and agents (each, a "Purchaser Indemnified Party") harmless from and against any and all Losses (including all Losses in connection with any product liability claims or claims of infringement or misappropriation of any Intellectual Property rights of any Third Parties) incurred or suffered by any Purchaser Indemnified Party arising out of any breach of any representation, warranty or certification made by the Company in any of the Transaction Documents or certificates given by the Company in writing pursuant hereto or thereto or any breach of or default under any covenant or agreement by the Company pursuant to any Transaction Document, including any failure by the Company to satisfy any of the Excluded Liabilities and Obligations.

(b) Purchaser hereby indemnifies and holds the Company, its Affiliates and any of their respective partners, directors, managers, officers, employees and agents (each, a "Company Indemnified Party") harmless from and against any and all Losses incurred or suffered by a Company Indemnified Party arising out of any breach of any representation, warranty or certification made by Purchaser in any of the Transaction Documents or certificates given by Purchaser in writing pursuant hereto or thereto or any breach of or default under any covenant or agreement by Purchaser pursuant to any Transaction Document.

(c) If any claim, demand, action or proceeding (including any investigation by any Governmental Authority) shall be brought or alleged against an indemnified party in respect of which indemnity is to be sought against an indemnifying party pursuant to the preceding paragraphs, the indemnified party shall, promptly after receipt of notice of the commencement of any such claim, demand, action or proceeding, notify the indemnifying party in writing of the commencement of such claim, demand, action or proceeding, enclosing a copy of all papers served, if any; provided, that the omission to so notify such indemnifying party will not relieve the indemnifying party from any liability that it may have to any indemnified party under the foregoing provisions of this Section 7.05 unless, and only to the extent that, such omission results in the forfeiture of, or has a material adverse effect on the exercise or prosecution of, substantive rights or defenses by the indemnifying party. In case any such action is brought against an indemnified party and it notifies the indemnifying party of the commencement thereof, the indemnifying party will be entitled to participate therein and, to the extent that it may wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party (who shall not, except with the consent of the indemnified party, be counsel to the indemnifying party), and after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, the indemnifying party will not be liable to such indemnified party under this Section 7.05 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof other than reasonable costs of investigation. In any such proceeding, an indemnified party shall have the right to retain its own counsel, but the reasonable fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the indemnifying party and the indemnified party shall have mutually agreed to the retention of such counsel, (ii) the indemnifying party has assumed the defense of such proceeding and has failed within a reasonable time to retain counsel reasonably satisfactory to such indemnified party or (iii) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential conflicts of interests between them based on the advice of such counsel. It is agreed that the indemnifying party shall not, in

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connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees and expenses of more than one separate law firm (in addition to local counsel where necessary) for all such indemnified parties. The indemnifying party shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any loss or liability by reason of such settlement or judgment. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement of any pending or threatened proceeding in respect of which any indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party, unless such settlement includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such proceeding.

(d) To the extent that any breach by the Company of this Agreement does not trigger a Put Option Event, Purchaser's sole remedy shall be to recover any monetary damages associated with such breach, subject to the other terms and provisions contained in this Agreement.

**Section 7.06 No Implied Representations and Warranties.**

Each party acknowledges and agrees that, other than the representations and warranties specifically contained in any of the Transaction Documents or certificates given in writing by a party hereto or thereto, there are no representations or warranties of either party or any other Person either expressed or implied with respect to the Assigned Interests or the transactions contemplated hereby. Without limiting the foregoing, Purchaser acknowledges and agrees that (a) Purchaser and its Affiliates, together with its and its Affiliates' representatives, have made their own investigation of the Product and the Intellectual Property and are not relying on any implied warranties or upon any representation or warranty whatsoever as to the future amount or potential amount of the Assigned Interests or as to the creditworthiness of Company and (b) except as expressly set forth in any representation or warranty in a Transaction Document, Purchaser shall have no claim or right to indemnification pursuant to Section 7.05 (or otherwise) with respect to any information, documents or materials furnished to Purchaser, any of its Affiliates, or any of its or its Affiliates' representatives, including any information, documents or material made available to Purchaser and its Affiliates and its Affiliates' representatives in any data room, presentation, interview or any other form relating to the transactions contemplated hereby.

**Section 7.07 Independent Nature of Relationship.**

(a) The relationship between the Company and its Subsidiary, on the one hand, and Purchaser, on the other, is solely that of seller and purchaser, and neither Purchaser, on the one hand, nor the Company and its Subsidiary, on the other, has any fiduciary or other special relationship with the other or any of their respective Affiliates. Nothing contained herein or in any other Transaction Document shall be deemed to constitute the Company and its Subsidiary and Purchaser as a partnership, an association, a joint venture or other kind of entity or legal form.

(b) No officer or employee of Purchaser will be located at the premises of the Company or any of its Affiliates, except in connection with an audit performed pursuant to

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Section 5.02. No officer, manager or employee of Purchaser shall engage in any commercial activity with the Company or any of its Affiliates other than as contemplated herein and in the other Transaction Documents.

(c) The Company and/or any of its Affiliates shall not at any time obligate Purchaser, or impose on Purchaser any obligation, in any manner or respect to any Person not a party hereto.

**Section 7.08 Federal Tax.**

Notwithstanding the accounting treatment thereof, for United States federal, state and local tax purposes, the Company and Purchaser shall treat the transactions contemplated by the Transaction Documents as debt for United States tax purposes. The parties hereto agree not to take any position that is inconsistent with the provision of this Section 7.08 on any tax return or in any audit or other administrative or judicial proceeding unless (a) the other party to this Agreement has consented to such actions, which consent shall not be unreasonably withheld, or (b) the party that contemplates taking such an inconsistent position has been advised by its tax advisor in writing that it is more likely than not (i) that there is no "reasonable basis" (within the meaning of Treasury Regulation Section 1.6662-3(b)(3)) for the position specified in this Section 7.08 or (ii) that taking such a position would otherwise subject the party to penalties under the Internal Revenue Code of 1986, as amended.

**Section 7.09 Entire Agreement.**

This Agreement, together with the Exhibits and Schedules hereto (which are incorporated herein by reference), and the other Transaction Documents constitute the entire agreement between the parties with respect to the subject matter hereof and supersede all prior agreements (including the Term Sheet and the Interim Revenue Interest Purchase Agreement), understandings and negotiations, both written and oral, between the parties with respect to the subject matter of this Agreement. No representation, inducement, promise, understanding, condition or warranty not set forth herein (or in the Exhibits, Schedules or other Transaction Documents) has been made or relied upon by either party hereto. None of this Agreement, nor any provision hereof, is intended to confer upon any Person other than the parties hereto any rights or remedies hereunder.

**Section 7.10 Amendments; No Waivers.**

(a) This Agreement or any term or provision hereof may not be amended, changed or modified except with the written consent of the parties hereto. No waiver of any right hereunder shall be effective unless such waiver is signed in writing by the party against whom such waiver is sought to be enforced.

(b) No failure or delay by either party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by law.

**Section 7.11 Interpretation.**

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When a reference is made in this Agreement to Articles, Sections, Schedules or Exhibits, such reference shall be to an Article, Section, Schedule or Exhibit to this Agreement unless otherwise indicated. The words “include”, “includes” and “including” when used herein shall be deemed in each case to be followed by the words “without limitation”. Neither party hereto shall be or be deemed to be the drafter of this Agreement for the purposes of construing this Agreement against one party or the other.

**Section 7.12 Headings and Captions.**

The headings and captions in this Agreement are for convenience and reference purposes only and shall not be considered a part of or affect the construction or interpretation of any provision of this Agreement.

**Section 7.13 Counterparts; Effectiveness.**

This Agreement may be executed in two or more counterparts, each of which shall be an original, but all of which together shall constitute one and the same instrument. This Agreement shall become effective when each party hereto shall have received a counterpart hereof signed by the other parties hereto. Any counterpart may be executed by facsimile or pdf signature and such facsimile or pdf signature shall be deemed an original.

**Section 7.14 Severability.**

If any provision of this Agreement is held to be invalid or unenforceable, the remaining provisions shall nevertheless be given full force and effect.

**Section 7.15 Expenses.**

The Company will pay all of its own fees and expenses in connection with entering into and consummating the transactions contemplated by this Agreement. The Company shall, promptly (and, in any event, within five (5) Business Days) upon demand, reimburse Purchaser up to \* \* \* for its reasonable legal fees and expenses incurred in connection with the transactions contemplated by the Transaction Documents, less any amounts reimbursed in connection with the Interim Royalty Purchase Agreement, not to exceed \* \* \* in the aggregate.

**Section 7.16 Governing Law; Jurisdiction.**

(a) This Agreement shall be governed by, and construed, interpreted and enforced in accordance with, the laws of the state of New York, without giving effect to the principles of conflicts of law thereof.

(b) Any legal action or proceeding with respect to this Agreement or any other Transaction Document may be brought in any state or federal court of competent jurisdiction in the State of Nevada, Washoe County and city of Reno. By execution and delivery of this Agreement, each party hereto hereby irrevocably consents to and accepts, for itself and in respect of its property, generally and unconditionally the non-exclusive jurisdiction of such courts. Each party hereto hereby further irrevocably waives any objection, including any objection to the laying of venue or based on the grounds of forum non conveniens, which it may now or hereafter

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have to the bringing of any action or proceeding in such jurisdiction in respect of any Transaction Document.

(c) Each party hereto hereby irrevocably consents to the service of process out of any of the courts referred to in subsection (b) of this Section 7.16 in any such suit, action or proceeding by the mailing of copies thereof by registered or certified mail, postage prepaid, to it at its address set forth in this Agreement. Each party hereto hereby irrevocably waives any objection to such service of process and further irrevocably waives and agrees not to plead or claim in any suit, action or proceeding commenced hereunder or under any other Transaction Document that service of process was in any way invalid or ineffective. Nothing herein shall affect the right of a party to serve process on the other party in any other manner permitted by law.

**Section 7.17 Waiver of Jury Trial**

Each party hereto hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any action, proceeding, claim or counterclaim arising out of or relating to any Transaction Document or the transactions contemplated under any Transaction Document. This waiver shall apply to any subsequent amendments, renewals, supplements or modifications to any Transaction Document.

[SIGNATURE PAGE FOLLOWS]

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**IN WITNESS WHEREOF**, the parties hereto have caused this Agreement to be duly executed by their respective authorized officers as of the date first above written.

COMPANY:

**AXOGEN, INC.**

By: /s/ Karen Zaderej

Name: Karen Zaderej

Title: Chief Executive Officer

PURCHASER:

**PDL BIOPHARMA, INC.**

By: /s/ John P. McLaughlin

Name: John P. McLaughlin

Title: President and Chief Executive Officer

[Signature Page to Revenue Purchase Agreement]

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**Exhibit A**

**Form of Guarantee and Collateral Agreement**

[See attached.]



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**Exhibit B**

**Form of Assignment of Interests**

[See attached.]

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**Exhibit C**

**Form of Deposit Agreement**

[See attached.]

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**Exhibit D**

**Form of Legal Opinion**

In form and substance agreed to by the parties.

Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “\* \* \*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

Execution Version

**GUARANTEE AND COLLATERAL AGREEMENT**

DATED AS OF OCTOBER 5, 2012

BY

AXOGEN, INC.,

AND

AXOGEN CORPORATION,

AS GRANTORS

IN FAVOR OF

PDL BIOPHARMA, INC.,

AS PURCHASER

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GUARANTEE AND COLLATERAL AGREEMENT, dated as of October 5, 2012 by AXOGEN, INC., a Minnesota corporation ( the “Seller”; and together with any other entity on the signature pages hereto or that may become a party hereto as a grantor as provided herein, each a “Grantor” and collectively, jointly and severally, the “Grantors”), in favor of PDL BIOPHARMA, INC., a Delaware corporation, as Purchaser (in such capacity, the “Purchaser”) under the Revenue Interests Purchase Agreement, dated as of October 5, 2012 (as amended, supplemented or otherwise modified from time to time, the “Purchase Agreement”) between the Seller and the Purchaser.

W I T N E S S E T H:

WHEREAS, pursuant to the Purchase Agreement, the Purchaser has agreed to purchase the Assigned Interests (as defined in the Purchase Agreement) upon the terms and conditions set forth therein; and

WHEREAS, it is a condition precedent to the purchase by Purchaser of the Assigned Interests that the Grantors shall have executed and delivered this Agreement to the Purchaser;

NOW, THEREFORE, in consideration of the premises and for other good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

Section 1. DEFINITIONS.

1.01. Definition of Terms Used Herein Generally. Except as otherwise provided herein, all capitalized terms used herein (including in the preamble hereto) but not defined herein shall have the meanings set forth in the Purchase Agreement. Except as specifically provided herein, all terms used herein and defined in the NYUCC shall have the same definitions herein as specified therein as of the date hereof; provided, however, that if a term is defined in Article 9 of the NYUCC differently than in another Article of the NYUCC, the term has the meaning specified in Article 9 of the NYUCC as of the date hereof.

1.02. Definition of Certain Terms Used Herein. As used herein, the following terms shall have the following meanings:

“Agreement”: this Guarantee and Collateral Agreement, as the same may be amended, supplemented, replaced or otherwise modified from time to time.

“Collateral”: as defined in Section 3.

“Event of Default”: the occurrence of any Put Option Event under the Purchase Agreement.

“Fully Satisfied”: with respect to the Secured Obligations, at any time that (a) all amounts constituting Secured Obligations shall have been paid in full in cash; and (b) all fees, expenses and other amounts (including contingent obligations, including those in respect of indemnification provisions contained in the Transaction Documents, but excluding obligations in respect of such indemnification provisions for which no claim has been made and for which no notice of claim has been given) unpaid as of such time which constitute Secured Obligations shall have been paid in full in cash.

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“Grantor”: as defined in the preamble.

“Guarantors”: the collective reference to each Grantor, other than Borrower.

“NYUCC”: the Uniform Commercial Code as in effect in the State of New York from time to time.

“Person”: any natural person, corporation, limited liability company, trust, joint venture, association, company, partnership, Governmental Authority or other entity.

“Pledged Stock”: the shares of capital stock or other equity interests owned at any time by any Person, together with any other shares, stock certificates, options, rights or security entitlements of any nature whatsoever in respect of the capital stock or other equity interests of any Person that may be issued or granted to, or held by, any Person.

“Proceeds”: all “proceeds” as such term is defined in Section 9-102(64) of the NYUCC.

“Purchase Agreement”: as defined in the preamble.

“Purchaser”: as defined in the preamble.

“Secured Obligations”: means the “Obligations” of the Seller to the Purchaser, as defined in the Purchase Agreement, and any obligations owed by a Grantor other than the Seller to the Purchaser pursuant to the terms of the Transaction Documents.

“Security Interest”: the security interest granted pursuant to Section 3, as well as all other security interests created or assigned as additional security for the Secured Obligations pursuant to the provisions of this Agreement.

“Seller”: as defined in the preamble. Any references herein to “each,” “either” or “such” Seller or to the “applicable” Seller, or to the “the Seller” shall mean and refer to Seller.

“UCC”: the Uniform Commercial Code as in effect in any jurisdiction (except as otherwise contemplated in Section 7.18). References to particular sections of Article 9 of the UCC shall be, unless otherwise indicated, references to revised Article 9 of the UCC adopted and effective in certain jurisdictions on or after July 1, 2001.

1.03. Rules of Interpretation. The rules of interpretation specified in Section 7.10 of Purchase Agreement shall be applicable to this Agreement. References to “Sections,” “Exhibits” and “Schedules” shall be to Sections, Exhibits and Schedules, respectively, of this Agreement unless otherwise specifically provided. Any of the terms defined in this Section 1 may, unless the context otherwise requires, be used in the singular or the plural depending on the reference. All references to statutes and related regulations shall include (unless otherwise specifically provided herein) any amendments of same and any successor statutes and regulations.

## Section 2. GUARANTEE

2.01. Guarantee. (a) Each of the Guarantors hereby, jointly and severally, unconditionally and irrevocably, guarantees to the Purchaser and its successors, indorsees, transferees and assigns, the prompt and complete payment and performance by Seller when due of the Secured Obligations.

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(b) Anything herein or in any other Transaction Document to the contrary notwithstanding, the maximum liability of each Guarantor hereunder and under the other Transaction Documents shall in no event exceed the amount which can be guaranteed by such Guarantor under applicable federal, state and other laws relating to the insolvency of debtors (after giving effect to the right of contribution established in Section 2.02).

(c) Each Guarantor agrees that the Secured Obligations may at any time and from time to time exceed the amount of the liability of such Guarantor hereunder without impairing the guarantee contained in this Section 2 or affecting the rights and remedies of the Purchaser hereunder.

(d) The guarantee contained in this Section 2 shall remain in full force and effect until all the Secured Obligations shall have been Fully Satisfied notwithstanding that from time to time during the term of the Purchase Agreement Seller may be free from any Secured Obligations.

(e) No payment made by the Seller, any of the Guarantors, any other guarantor or any other Person or received or collected by the Purchaser from the Seller, any of the Guarantors, any other guarantor or any other Person by virtue of any action or proceeding or any set-off or appropriation or application at any time or from time to time in reduction of or in payment of the Secured Obligations shall be deemed to modify, reduce, release or otherwise affect the liability of any Guarantor hereunder which shall, notwithstanding any such payment, remain liable for the Secured Obligations up to the maximum liability of such Guarantor hereunder until the Secured Obligations are Fully Satisfied.

2.02. Right of Contribution. Each Guarantor hereby agrees that to the extent that a Guarantor shall have paid more than its proportionate share of any payment made hereunder, such Guarantor shall be entitled to seek and receive contribution from and against any other Guarantor hereunder which has not paid at least its proportionate share of such payment. Each Guarantor's right of contribution shall be subject to the terms and conditions of Section 2.03. The provisions of this Section 2.02 shall in no respect limit the obligations and liabilities of any Guarantor to the Purchaser and each Guarantor shall remain liable to the Purchaser for the full amount guaranteed by such Guarantor hereunder.

2.03. Subrogation. Notwithstanding any payment made by any Guarantor hereunder or any set-off or application of funds of any Guarantor by the Purchaser, (i) no Guarantor shall be entitled to be subrogated to any of the rights of the Purchaser against the Seller or any other Guarantor or Grantor or any collateral security or guarantee or right of offset held by the Purchaser for the payment of the Secured Obligations, (ii) no Guarantor shall seek or be entitled to seek any contribution or reimbursement from the Seller or any other Guarantor or Grantor in respect of payments made by such Guarantor hereunder, and (iii) each Guarantor hereby expressly and irrevocably waives any and all rights at law or in equity to subrogation, reimbursement, exoneration, contribution, indemnification or set off and any and all defenses available to a surety, guarantor or accommodation co-obligor, in each case, until all Secured Obligations are Fully Satisfied. If any amount shall be paid to any Guarantor on account of such subrogation rights at any time when all of the Secured Obligations shall not have been Fully Satisfied, such amount shall be held by such Guarantor in trust for the Purchaser, and shall, forthwith upon receipt by such Guarantor, be turned over to the Purchaser in the exact form received by such Guarantor (duly endorsed by such Guarantor to the Purchaser, if required), to be applied against the Secured Obligations, whether matured or unmatured, in such order as the

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Purchaser may determine. Each Guarantor acknowledges and agrees that this waiver is intended to benefit the Purchaser and shall not limit or otherwise affect such Guarantor's liability hereunder or the enforceability of this Section 2.03, and that the Purchaser and its successors and assigns are intended third-party beneficiaries of the waivers and agreements set forth in this Section 2.03, and its rights under this Section 2.03, shall survive payment in full of the Obligations.

2.04. Amendments, etc. with respect to the Secured Obligations. Each Guarantor shall remain obligated hereunder notwithstanding that, without any reservation of rights against any Guarantor and without notice to or further assent by any Guarantor, any demand for payment of any of the Secured Obligations made by the Purchaser may be rescinded by the Purchaser and any of the Secured Obligations continued, and the Secured Obligations, or the liability of any other Person upon or for any part thereof, or any collateral security or guarantee therefor or right of offset with respect thereto, may, from time to time, in whole or in part, be renewed, extended, amended, modified, accelerated, compromised, waived, surrendered or released by the Purchaser, and the Purchase Agreement and the other Transaction Documents and any other documents executed and delivered in connection therewith may be amended, modified, supplemented or terminated, in whole or in part, as the Purchaser may deem advisable from time to time, and any collateral security, guarantee or right of offset at any time held by the Purchaser for the payment of the Secured Obligations may be sold, exchanged, waived, surrendered or released. The Purchaser shall not have any obligation to protect, secure, perfect or insure any Lien at any time held by it as security for the Secured Obligations or for the guarantee contained in this Section 2 or any property subject thereto.

2.05. Guarantee Absolute and Unconditional. Each Guarantor waives any and all notice of the creation, renewal, extension or accrual of any of the Secured Obligations and notice of or proof of reliance by the Purchaser upon the guarantee contained in this Section 2 or acceptance of the guarantee contained in this Section 2; the Secured Obligations, and any of them, shall conclusively be deemed to have been created, contracted or incurred, or renewed, extended, amended or waived, in reliance upon the guarantee contained in this Section 2; and all dealings between the Seller and any of the Guarantors, on the one hand, and the Purchaser, on the other hand, likewise shall be conclusively presumed to have been had or consummated in reliance upon the guarantee contained in this Section 2. Each Guarantor waives diligence, presentment, protest, demand for payment and notice of default or nonpayment to or upon Seller or any of the Guarantors with respect to the Secured Obligations, except as required pursuant to the Purchase Agreement. Each Guarantor understands and agrees that the guarantee contained in this Section 2 shall be construed as a continuing, absolute and unconditional guarantee of payment and performance (and not of collection) without regard to (a) the validity or enforceability of the Purchase Agreement or any other Transaction Document (other than this Agreement), any of the Secured Obligations or any other collateral security therefor or guarantee or right of offset with respect thereto at any time or from time to time held by the Purchaser; (b) any defense, set-off or counterclaim (other than a defense of complete payment and performance hereunder) which may at any time be available to or be asserted by the Seller or any other Person against the Purchaser; or (c) any other circumstance whatsoever (with or without notice to or knowledge of Seller or such Guarantor) which constitutes, or might be construed to constitute, an equitable or legal discharge of Seller for the Secured Obligations, or of such Guarantor under the guarantee contained in this Section 2, in bankruptcy or in any other instance. When making any demand hereunder or otherwise pursuing its rights and remedies hereunder against any Guarantor, the Purchaser may, but shall be under no obligation to, make a similar demand on or otherwise pursue such rights and remedies as it may have against Seller, any other Guarantor or any other

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Person or against any collateral security or guarantee for the Secured Obligations or any right of offset with respect thereto, and any failure by any Secured Creditor to make any such demand, to pursue such other rights or remedies or to collect any payments from Seller, any other Guarantor or any other Person or to realize upon any such collateral security or guarantee or to exercise any such right of offset, or any release of Seller, any other Guarantor or any other Person or any such collateral security, guarantee or right of offset, shall not relieve any Guarantor of any obligation or liability hereunder, and shall not impair or affect the rights and remedies, whether express, implied or available as a matter of law, of the Purchaser against any Guarantor. For the purposes hereof, "demand" shall include the commencement and continuance of any legal proceedings.

2.06. Reinstatement. The guarantee contained in this Section 2 shall continue to be effective, or be reinstated, as the case may be, if at any time payment, or any part thereof, of any of the Secured Obligations is rescinded or must otherwise be restored or returned by the Purchaser upon the insolvency, bankruptcy, dissolution, liquidation or reorganization of the Seller or any Guarantor, or upon or as a result of the appointment of a receiver, intervenor or conservator of, or trustee or similar officer for, the Seller or any Guarantor or any substantial part of its property, or otherwise, all as though such payments had not been made.

2.07. Payments. Each Guarantor hereby guarantees that payments hereunder will be paid to the Purchaser without set-off or counterclaim in Dollars in immediately available funds to the account of Purchaser and that all such payments will be subject to the provisions of the Transaction Agreement.

2.08. Waiver of Subrogation. Notwithstanding anything to the contrary in this Agreement or in any other Transaction Document, and except as set forth in Section 2.11, each Guarantor hereby expressly and irrevocably waives until all Secured Obligations have been paid in full any and all rights at law or in equity to subrogation, reimbursement, exoneration, contribution, indemnification or set off and any and all defenses available to a surety, guarantor or accommodation co-obligor. Each Guarantor acknowledges and agrees that this waiver is intended to benefit the Purchaser and shall not limit or otherwise affect such Guarantor's liability hereunder or the enforceability of this Section 2.08, and that the Purchaser and its successors and assigns are intended third-party beneficiaries of the waivers and agreements set forth in this Section 2.08, and its rights under this Section 2.08, shall survive payment in full of the Obligations. The foregoing waiver shall not be deemed to limit or prohibit the payment of indebtedness or other obligations of any Guarantor to any other Guarantor or other Person which is otherwise permitted under this Agreement or any other Transaction Document.

2.09. Election of Remedies. If the Purchaser may, under applicable law, proceed to realize its benefits under any of the Transaction Documents giving the Purchaser a Lien upon any Collateral, whether owned by any Guarantor or by any other Person, either by judicial foreclosure or by nonjudicial sale or enforcement, the Purchaser may, at its sole option, determine which of its remedies or rights it may pursue without affecting any of its rights and remedies under this Section 2. If, in the exercise of any of its rights and remedies, the Purchaser shall forfeit any of its rights or remedies, including its right to enter a deficiency judgment against any Guarantor or any other Person, whether because of any applicable laws pertaining to "election of remedies" or the like, each Guarantor hereby consents to such action by the Purchaser and waives, to the extent permitted by applicable law, any claim based upon such action, even if such action by Purchaser shall result in a full or partial loss of any rights of subrogation that each Guarantor might otherwise have had but for such action by the Purchaser. Any election of remedies that results in the denial or impairment of the right of the Purchaser to

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seek a deficiency judgment against any Guarantor shall not impair any other Guarantor's obligation to pay the full amount of the Secured Obligations. In the event the Purchaser shall bid at any foreclosure or trustee's sale or at any private sale permitted by law or the Transaction Documents, the Purchaser may bid all or less than the amount of the Secured Obligations and the amount of such bid need not be paid by the Purchaser but shall be credited against the Secured Obligations. The amount of the successful bid at any such public sale, whether the Purchaser or any other party is the successful bidder, shall be conclusively deemed to be the fair market value of the Collateral and the difference between such bid amount and the remaining balance of the Secured Obligations shall be conclusively deemed to be the amount of the Secured Obligations guaranteed under this Section 2, notwithstanding that any present or future law or court decision or ruling may have the effect of reducing the amount of any deficiency claim to which the Purchaser might otherwise be entitled but for such bidding at any such sale.

2.10. Limitation. Notwithstanding any provision herein contained to the contrary, each Guarantor's liability under this Section 2 (which liability is in any event in addition to amounts for which such Guarantor is primarily liable under Section 2 of the Purchase Agreement) shall be limited to an amount not to exceed as of any date of determination the amount that could be claimed by the Purchaser from such Guarantor under this Section 2.10 without rendering such claim voidable or avoidable under Section 548 of Chapter 11 of the Bankruptcy Code or under any applicable state Uniform Fraudulent Transfer Act, Uniform Fraudulent Conveyance Act or similar statute or common law after taking into account, among other things, such Guarantor's right of contribution and indemnification from each other Guarantor under Section 2.11.

2.11. Contribution with Respect to Guaranty Obligations.

(a) To the extent that any Guarantor shall make a payment under this Section 2.11 of all or any of the Secured Obligations which it has agreed to guarantee pursuant hereto (a "Guarantor Payment") that, taking into account all other Guarantor Payments then previously or concurrently made by any other Guarantor, exceeds the amount that such Guarantor would otherwise have paid if each Guarantor had paid the aggregate Secured Obligations satisfied by such Guarantor Payment in the same proportion that such Guarantor's Allocable Amount (as defined below) (as determined immediately prior to such Guarantor Payment) bore to the aggregate Allocable Amounts of each of the Guarantors as determined immediately prior to the making of such Guarantor Payment, then, following indefeasible payment in full in cash of the Secured Obligations, such Guarantor shall be entitled to receive contribution and indemnification payments from, and be reimbursed by, each other Guarantor for the amount of such excess, pro rata based upon their respective Allocable Amounts in effect immediately prior to such Guarantor Payment.

(b) As of any date of determination, the "Allocable Amount" of any Guarantor shall be equal to the maximum amount of the claim that could then be recovered from such Guarantor under this Section 2 without rendering such claim voidable or avoidable under Section 548 of Chapter 11 of the Bankruptcy Code or under any applicable state Uniform Fraudulent Transfer Act, Uniform Fraudulent Conveyance Act or similar statute or common law.

(c) This Section 2.11 is intended only to define the relative rights of Guarantors and nothing set forth in this Section 2.11 is intended to or shall impair the obligations of Guarantors, jointly and severally, to pay any amounts as and when the same shall become due and payable in accordance with the terms of this Agreement, including Section 2.01. Nothing contained in this

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Section 2.11 shall limit the liability of Seller to pay the payments owing from it to the Purchaser for which Seller shall be primarily liable.

(d) The parties hereto acknowledge that the rights of contribution and indemnification hereunder shall constitute assets of the Guarantor to which such contribution and indemnification is owing.

(e) The rights of the indemnifying Guarantors against other Grantors under this Section 2.11 shall be exercisable upon the full and indefeasible payment of the Secured Obligations.

### Section 3. GRANT OF SECURITY INTEREST.

Each Grantor hereby grants to the Purchaser a security interest in, and mortgage on, all of the following property now owned or at any time hereafter acquired by such Grantor or in which such Grantor now has, or at any time in the future may acquire, any right, title or interest (collectively, the "Collateral"), as collateral security for the prompt and complete payment and performance when due (whether at the stated maturity, by acceleration or otherwise) of the Secured Obligations:

- a. all accounts, including health-care receivables, all instruments, chattel paper, and promissory notes evidencing such accounts and all Pledged Stock delivered to a Grantor in respect of settlement of any account;
- b. all deposit accounts, all claims now or hereafter arising therefrom, all funds now or hereafter held therein, all amounts now or hereafter credited thereto and all certificates and instruments, if any, from time to time representing or evidencing such bank accounts; and
- c. all cash, provided that such shall exclude any deposits given for security of any lease.

Section 4. AUTHORIZATION TO FILE FINANCING STATEMENTS. Each Grantor hereby irrevocably authorizes the Purchaser at any time and from time to time to file in any jurisdiction in which the UCC has been adopted any initial financing statements and amendments thereto that (a) indicate the Collateral (i) as "all accounts receivable, including health care receivables, and all instruments, chattel paper, and promissory notes evidencing such accounts and all Pledged Stock delivered to a Grantor in respect of settlement of any account; all deposit accounts, all claims now or hereafter arising therefrom, all funds now or hereafter held therein, all amounts now or hereafter credited thereto and all certificates and instruments, if any, from time to time representing or evidencing such bank accounts; and all cash of such Grantor or words of similar effect, regardless of whether any particular asset comprised in the Collateral falls within the scope of Article 9 of the NYUCC or such jurisdiction, or (ii) as being of an equal or lesser scope or with greater detail, and (b) contain any other information required by part 5 of Article 9 of the UCC for the sufficiency or filing office acceptance of any initial financing statement or amendment, including whether such Grantor is an organization, the type of organization and any organization identification number issued to such Grantor. Each Grantor agrees to furnish any such information to the Purchaser promptly upon request. Each Grantor also ratifies its authorization for the Purchaser to have filed in any UCC jurisdiction any like initial financing statements or amendments thereto if filed prior to the date hereof.

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Section 5. [RESERVED].

Section 6. Representations and Warranties. To induce the Purchaser to enter into the Purchase Agreement and to induce the Purchaser to purchase the Secured Obligations from the Seller thereunder, each Grantor hereby represents and warrants to the Purchaser that:

6.01. Grantors' Legal Status. (a) Such Grantor is an organization as set forth in Schedule 6.01; (b) such organization is of the type, and is organized in the jurisdiction, set forth in Schedule 6.01; and (c) Schedule 6.01 sets forth such Grantor's correct legal name, prior organizational names within the previous five years, chief executive office, organizational identification number or states that such Grantor has none.

6.02. Grantors' Legal Names. Such Grantor's exact legal name is that set forth on the signature page hereof (or, in the case of any Grantor that becomes a party hereto after the date hereof, on the signature page to the applicable Assignment and Assumption Agreement).

6.03. Grantors' Locations. Schedule 6.01 sets forth such Grantor's place of business or (if it has more than one place of business) its chief executive office, as well as its mailing address if different. Such Grantor's place of business or (if it has more than one place of business) its chief executive office (if such Grantor is an organization) is located in a jurisdiction that has adopted the UCC or whose laws generally require that information concerning the existence of nonpossessory security interests be made generally available in a filing, recording or registration system as a condition or result of the security interest obtaining priority over the rights of a lien creditor with respect to the Collateral.

6.04. Representations in the Purchase Agreement. The representations and warranties set forth in Section 5 of the Purchase Agreement as they relate to such Grantor to the Transaction Documents to which such Grantor is a party, each of which is hereby incorporated herein by reference, are true and correct in all material respects, and the Purchaser shall be entitled to rely on each of them as if they were fully set forth herein; provided that each reference in each such representation and warranty to the applicable Seller's knowledge shall, for the purposes of this Section 6.04, be deemed to be a reference to such Grantor's knowledge.

6.05. Title to Collateral. The Collateral of such Grantor is owned by such Grantor free and clear of any Lien, except for Liens expressly permitted pursuant to the Purchase Agreement. Such Grantor has not filed or consented to the filing of (a) any financing statement or analogous document under the UCC or any other applicable laws covering any of its Collateral or (b) any assignment in which such Grantor assigns any Collateral or any security agreement or similar instrument covering any Collateral with any foreign governmental, municipal or other office, which financing statement or analogous document, assignment, security agreement or similar instrument is still in effect, except, in each case, with respect to Liens expressly permitted pursuant to the Purchase Agreement.

6.06. Nature of Collateral. None of the Collateral of such Grantor constitutes, or is the proceeds of, farm products and none of the Collateral has been purchased or will be used by such Grantor primarily for personal, family or household purposes, and as of the Closing Date, except as set forth on Schedule 6.06:



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(a) none of the account debtors or other persons obligated on any of the Collateral of such Grantor is a Governmental Authority subject to the Federal Assignment of Claims Act or like federal, state or local statute or rule in respect of such Collateral;

(b) such Grantor has no deposit accounts or other bank accounts; and

(c) such Grantor has no securities accounts or securities entitlements.

6.07. Compliance with Laws. Such Grantor has at all times operated its business in compliance with all laws, except as could not reasonably be expected to have a Material Adverse Effect.

6.08. Validity of Security Interest. (a) The Security Interest granted by each Grantor constitutes, to the extent possible under applicable law, a legal and valid security interest in all of the Collateral of such Grantor securing the payment and performance of the Secured Obligations and (b) upon the giving of value, the filing of financing statements describing the Collateral in the offices listed on the Schedule 6.01, and the taking of all applicable actions in respect of perfection contemplated by Sections 7.06 and 7.07 in respect of Collateral (in which a security interest cannot be perfected by the filing of a financing statement), the Security Interest will be valid, enforceable and perfected in all Collateral of such Grantor. The Security Interest is and shall be prior to any other Lien on the Collateral, other than Liens expressly permitted to be prior to the Security Interest under the Purchase Agreement.

6.09. Reserved.

6.10. Investment Property in lieu of Payment. No account exceeding \$50,000 has been settled with the Grantor's receipt of Pledged Stock that has not been delivered to the Purchaser.

6.11. Account Receivables. No amount exceeding \$50,000 and payable to such Grantor under or in connection with any account is evidenced by any instrument, promissory note, chattel paper, and no account exceeding \$50,000 has been settled by the account debtor granting to such Grantor Pledged Stock which has not been delivered to the Purchaser.

6.12. Accounts. (i) Each account of such Grantor is genuine and in all material respects what they purport to be, (ii) each account arises out of (A) a bona fide sale of goods sold and delivered by such Grantor (or is in the process of being delivered) or (B) services theretofore actually rendered or to be rendered by such Grantor to the account debtor named therein, (iii) no material account of such Grantor is evidenced by any instrument, promissory note or chattel paper other than any such instrument, promissory note or chattel paper that has been theretofore endorsed over, assigned and delivered to, or submitted to the control of, the Purchaser (accompanied by such instruments of transfer and assignment duly executed in blank as the Purchaser may from time to time specify), and (iv) no surety bond was required or given in connection with any account of such Grantor or the contracts or purchase orders out of which they arose and the right to receive payment under each account is assignable.

6.13. Reserved.

Section 7. COVENANTS. Each Grantor covenants and agrees with the Purchaser, in each case at such Grantor's own cost and expense, as follows.

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7.01. Grantors' Legal Status. Such Grantor shall not change its type of organization, jurisdiction of organization or other legal structure except upon not less than twenty (20) days' prior written notice to the Purchaser.

7.02. Grantors' Names. Such Grantor shall not change its name except upon not less than twenty (20) days' prior written notice to the Purchaser.

7.03. Grantors' Organizational Numbers. Without providing at least twenty (20) days' prior written notice to the Purchaser, such Grantor shall not change its organizational identification number if it has one. If such Grantor does not have an organizational identification number and later obtains one, such Grantor shall forthwith notify the Purchaser of such organizational identification number promptly upon obtaining such identification number.

7.04. Reserved.

7.05. Covenants in Purchase Agreement. Each Grantor shall take, or shall refrain from taking, as the case may be, each action that is necessary to be taken or not taken, as the case may be, so that no Default or Event of Default is caused by the failure to take such action or to refrain from taking such action by such Grantor or any of its subsidiaries.

7.06. Promissory Notes and Tangible Chattel Paper. If such Grantor, together with the other Grantors, shall at any time hold or acquire any instruments, promissory notes or tangible chattel paper in an aggregate principal amount of more than \$50,000 payable to such Grantor under or in connection with any account, such Grantor shall forthwith endorse, assign and deliver the same to the Purchaser, accompanied by such instruments of transfer or assignment duly executed in blank as the Purchaser may from time to time specify to be held by the Purchaser as Collateral pursuant to this Agreement.

7.07. Deposit Accounts. For each deposit account that such Grantor at any time opens or maintains, such Grantor shall, at the Purchaser's request and option, either (a) cause the depository bank to enter into a written agreement or other authenticated record with the Purchaser, in form and substance reasonably satisfactory to the Purchaser, pursuant to which such depository bank shall agree, among other things, to comply at any time with instructions from the Purchaser to such depository bank directing the disposition of funds from time to time credited to such deposit account, without further consent of the Grantor, or (b) arrange for the Purchaser to become the customer of the depository bank with respect to the deposit account; provided, however, that notwithstanding the foregoing, the requirements of this Section 7.07 shall not apply to any zero balance payroll or similar disbursement account maintained by any Grantor (and each Grantor agrees not to deposit in any payroll account or similar disbursement account maintained by it any funds, except funds needed at the time of deposit (or within three days thereafter) to meet payroll needs of such Grantor).

7.08. Pledged Stock. If such Grantor, together with the other Grantors, shall at any time hold or acquire any Pledged Stock granted to such Grantor by an account debtor to settle an account in an aggregate principal amount of more than \$50,000, such Grantor shall forthwith deliver the same to the Purchaser, accompanied by an executed blank stock power and such other instruments of transfer or assignment duly executed in blank as the Purchaser may from time to time specify to be held by the Purchaser as Collateral pursuant to this Agreement.

7.09. Reserved.

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7.10. Reserved.

7.11. Reserved.

7.12. Reserved.

7.13. Reserved.

7.14. Maintenance of Collateral; Compliance with Laws. (a) Such Grantor shall not use the Collateral in violation of any law to the extent that such violation could reasonably be expected to have a Material Adverse Effect.

7.15. Reserved.

7.16. Reserved.

7.17. Periodic Certification. From time to time on demand (which demand, absent an Event of Default, shall be no more frequent than once every four months) from the Purchaser such Grantor shall deliver to the Purchaser either (a) new Schedules setting forth the information required pursuant to Sections 6.01, 6.03 and 6.06, and a certificate from an executive officer of the Seller certifying as to the accuracy of the information set forth therein or (b) a certificate from an executive officer of the Seller confirming that there has been no change in the information set forth on the Schedules delivered as of the date hereof or since the date of the most recent certificate delivered pursuant to Section 7.17(a), as applicable.

7.18. Other Actions as to any and all Collateral. Such Grantor further agrees to take any other action reasonably requested by the Purchaser to insure the attachment, perfection and, first priority of, and the ability of the Purchaser to enforce, the Security Interest in any and all of the Collateral provided by such Grantor including, without limitation, (a) executing, delivering and, where appropriate, filing financing statements and amendments relating thereto under the UCC, to the extent, if any, that such Grantor's signature thereon is required therefor; (b) causing the Purchaser's name to be noted as secured party on any certificate of title for a titled good if such notation is a condition to attachment, perfection or priority of, or ability of the Purchaser to enforce, the Security Interest in such Collateral; (c) complying with any provision of any statute, regulation or treaty of the United States of America as to any Collateral if compliance with such provision is a condition to the attachment, perfection or priority of, or the ability of the Purchaser to enforce, the Security Interest in such Collateral; (d) obtaining governmental and other third-party consents and approvals, including without limitation any consent of any licensor, lessor or other person obligated on such Collateral; (e) providing to the Purchaser "control" over such Collateral, to the extent that perfection can only be achieved under the UCC by control or where obtaining perfection by control provides more protection to the Purchaser than perfection by filing a financing statement; and (f) taking all actions required by the UCC or by other law, as applicable in any relevant UCC jurisdiction, or by other law as applicable in any foreign jurisdiction; provided, however, that nothing contained in clause (d) or (e) shall require such Grantor to pay any consideration (other than any governmental application, processing, filing or recording fees) in order to obtain any consent or waiver referred to in such clauses.

7.19. Treatment of Accounts. Subject to Section 5.10 of the Purchaser Agreement, no Grantor shall grant or extend the time for payment of any material account, or

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compromise or settle any account for less than the full amount thereof, or release any person or property, in whole or in part, from payment thereof, or allow any credit or discount thereon, other than as normal and customary in the ordinary course of a Grantor's business.

Section 8. [RESERVED].

Section 9. COLLATERAL PROTECTION EXPENSES; PRESERVATION OF COLLATERAL.

9.01. Expenses Incurred by the Purchaser. In its discretion, the Purchaser may, if the relevant Grantor fails to do so, discharge taxes and other encumbrances at any time levied or placed on any material portion of the Collateral and pay any necessary filing fees. Each Grantor agrees to reimburse the Purchaser on demand for any and all expenditures so made, and all sums disbursed by the Purchaser in connection with this Section 9.01, including reasonable attorneys' fees, court costs, expenses and other charges relating thereto, shall be payable, upon demand, by such Grantor to the Purchaser shall bear interest at the per annum rate specified in Section 17 and shall constitute additional Secured Obligations. The Purchaser shall have no obligation to any Grantor to make any such expenditures, nor shall the making thereof relieve any Grantor of any default.

9.02. Purchaser's Obligations and Duties.

(a) Anything herein to the contrary notwithstanding, each Grantor shall remain liable under each contract or agreement comprised in the Collateral provided by it to be observed or performed by such Grantor thereunder. The Purchaser shall not have any obligation or liability under any such contract or agreement by reason of or arising out of this Agreement or the receipt by the Purchaser of any payment relating to any of the Collateral, nor shall the Purchaser be obligated in any manner to perform any of the obligations of any Grantor under or pursuant to any such contract or agreement, to make inquiry as to the nature or sufficiency of any payment received by the Purchaser in respect of the Collateral or as to the sufficiency of any performance by any party under any such contract or agreement, to present or file any claim, to take any action to enforce any performance or to collect the payment of any amounts which may have been assigned to the or to which the Purchaser may be entitled at any time or times.

(b) The Purchaser's sole duty with respect to the custody, safekeeping and physical preservation of the Collateral in its possession, under Section 9-207 of the NYUCC or otherwise, shall be to deal with such Collateral in the same manner as the Purchaser deals with similar property for its own account.

(c) Neither the Purchaser nor any of its respective officers, directors, partners, employees, agents, attorneys and other advisors, attorneys-in-fact or affiliates shall be liable for failure to demand, collect or realize upon any of the Collateral or for any delay in doing so or shall be under any obligation to sell or otherwise dispose of any Collateral upon the request of any Grantor or any other Person or to take any other action whatsoever with regard to the Collateral or any part thereof. The powers conferred on the Purchaser hereunder are solely to protect the Purchaser's interests in the Collateral and shall not impose any duty upon Purchaser to exercise any such powers. The Purchaser shall be accountable only for amounts that it actually receives as a result of the exercise of such powers, and neither it nor any of its officers, directors, partners, employees, agents, attorneys and other advisors, attorneys-in-fact or affiliates shall be responsible to any Grantor for any act or failure to act hereunder, except to the extent that any

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such act or failure to act is found by a final and non-appealable decision of a court of competent jurisdiction to have resulted from their respective gross negligence or willful misconduct.

(d) Each Grantor acknowledges that the rights and responsibilities of the Purchaser under this Agreement with respect to any action taken by the Purchaser or the exercise or non-exercise by the Purchaser of any option, voting right, request, judgment or other right or remedy provided for herein or resulting or arising out of this Agreement shall, be governed by the Purchase Agreement and by such other agreements with respect thereto as may exist from time to time among them.

9.03. Reserved.

Section 10. DEPOSITS. The Purchaser may after the occurrence and during the continuance of an Event of Default demand, sue for, collect, or make any settlement or compromise which it deems desirable with respect to the Collateral. Regardless of the adequacy of Collateral or any other security for the Secured Obligations, any deposits or other sums at any time credited by or due from the Purchaser to any Grantor may at any time be applied to or set off against any of the Secured Obligations whether or not due and owing.

Section 11. NOTIFICATION TO ACCOUNT DEBTORS AND OTHER PERSONS OBLIGATED ON COLLATERAL. If an Event of Default shall have occurred and be continuing, each Grantor shall, at the request of the Purchaser, notify account debtors and other persons obligated on any of the Collateral of such Grantor of the Security Interest in any account or chattel paper, promissory notes or instruments payable to such Grantor under or in connection with any account, or Pledged Stock delivered to such Grantor to settle an account, or other claims constituting Collateral that payment thereof is to be made directly to the Purchaser or to any financial institution designated by the Purchaser as the Purchaser's agent therefor, and the Purchaser may itself, if an Event of Default shall have occurred and be continuing, without notice to or demand upon any Grantor, so notify account debtors and other persons obligated on Collateral. After the making of such a request or the giving of any such notification, each Grantor shall hold any proceeds of collection of accounts and other claims constituting Collateral received by the Grantor as trustee for the Purchaser without commingling the same with other funds of the Grantor and shall turn the same over to the Purchaser in the identical form received, together with any necessary endorsements or assignments. The Purchaser shall have no liability or responsibility to any Grantor for acceptance of a check, draft or other order for payment of money bearing the legend "payment in full" or words of similar import or any other restrictive legend or endorsement or be responsible for determining the correctness of any remittance. Without limitation of the foregoing, during the continuation of an Event of Default (1) the Purchaser shall have the right, but not the obligation, to make test verifications of the accounts in any manner and through any medium that it reasonably considers advisable, and the Grantors shall furnish all such assistance and information as the Purchaser may require in connection with such test verifications, and (2) the Purchaser in its own name or in the name of others may communicate with account debtors on the accounts to verify with them to the Purchaser's satisfaction the existence, amount and terms of any accounts. The Purchaser may apply the proceeds of collection of accounts and other claims constituting Collateral received by the Purchaser to the Secured Obligations or hold such proceeds as additional Collateral, at the option of the Purchaser. The provisions of Section 9-209 of the NYUCC shall not apply to any account as to which notification of assignment has been sent to the account debtor or other person obligation on the Collateral, whether under this Section 11, Section 12 or Section 13.

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Section 12. POWER OF ATTORNEY.

12.01. Appointment and Powers of Purchaser. Upon the occurrence and during the continuance of an Event of Default, each Grantor hereby irrevocably constitutes and appoints the Purchaser and any officer or Purchaser thereof, with full power of substitution, as its true and lawful attorney-in-fact with full irrevocable power and authority in the place and stead of such Grantor and in the name of such Grantor or in its own name, for the purpose of carrying out the terms of this Agreement, to take any and all appropriate action and to execute any and all documents and instruments which may be necessary or desirable to accomplish the purposes of this Agreement, and, without limiting the generality of the foregoing, each Grantor hereby gives the Purchaser the power and right, on behalf of such Grantor, without notice to or assent by such Grantor, to do any or all of the following:

(a) in the name of such Grantor or its own name, or otherwise, take possession of and endorse and collect any checks, drafts, notes, acceptances or other instruments for the payment of moneys due under any account or with respect to any other Collateral and file any claim or take any other action or proceeding in any court of law or equity or otherwise deemed appropriate by the Purchaser for the purpose of collecting any and all such moneys due under any account or with respect to any other Collateral whenever payable;

(b) pay or discharge taxes and Liens levied or placed on or threatened against the Collateral, effect any repairs or provide any insurance and pay all or any part of the premiums therefor and the costs thereof;

(c) execute, in connection with any sale provided for in Section 13, any endorsements, assignments or other instruments of conveyance or transfer with respect to the Collateral;

(d) exercise all rights of such Grantor as owner of the Pledged Stock or as party to any partnership, limited liability company or similar agreement, including, without limitation, the right to sign any and all amendments, instruments, certificates, proxies, and other writings and exercise all voting and consent rights with respect to the Pledged Stock;

(e) (1) direct any party liable for any payment under any of the Collateral to make payment of any and all moneys due or to become due thereunder directly to the Purchaser or as the Purchaser shall direct; (2) ask or demand for, collect, and receive payment of and receipt for, any and all moneys, claims and other amounts due or to become due at any time in respect of or arising out of any Collateral; (3) commence and prosecute any suits, actions or proceedings at law or in equity in any court of competent jurisdiction to collect the Collateral or any portion thereof and to enforce any other right in respect of any Collateral; (4) defend any suit, action or proceeding brought against such Grantor with respect to any Collateral; (5) settle, compromise or adjust any such suit, action or proceeding and, in connection therewith, give such discharges or releases as the Purchaser may deem appropriate; and (6) generally, sell, transfer, pledge and make any agreement with respect to or otherwise deal with any of the Collateral as fully and completely as though the Purchaser were the absolute owner thereof for all purposes, and do, at the Purchaser's option and such Grantor's expense, at any time, or from time to time, all acts and things which the Purchaser deems necessary to protect, preserve or realize upon the Collateral and the Security Interest therein and to effect the intent of this Agreement, all as fully and effectively as such Grantor might do; and

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(f) to the extent that such Grantor's authorization given in Section 4 is not sufficient, to file such financing statements or similar documents under the laws of any jurisdiction with respect hereto, with or without such Grantor's signature, or a photocopy of this Agreement in substitution for a financing statement or such other document, as the Purchaser may deem appropriate and to execute in such Grantor's name such financing statements, other such documents and amendments thereto and continuation statements which may require such Grantor's signature.

Anything in this Section 12.01 to the contrary notwithstanding, the Purchaser agrees that it will not exercise any rights under the power of attorney provided for in this Section 12.01 (other than under paragraph (e) of this Section 12.01) unless an Event of Default shall have occurred and be continuing.

12.02. Failure of Grantor to Perform. If any Grantor fails to perform or comply with any of its agreements contained herein, the Purchaser, at its option, but without any obligation so to do, may perform or comply, or otherwise cause performance or compliance, with such agreement.

12.03. Expenses of Attorney-in-Fact. The expenses of the Purchaser incurred in connection with actions undertaken as provided in this Section 12, together with interest thereon at a rate equal to the lower of (i) the highest rate permitted by applicable law, and (ii) one and one-half percent (1.5%) per month, compounded monthly, shall be payable by such Grantor to the Purchaser on demand.

12.04. Ratification by Grantor. To the extent permitted by law, each Grantor hereby ratifies all that said attorneys shall lawfully do or cause to be done by virtue of this Section 12. This power of attorney is a power coupled with an interest and is irrevocable.

12.05. No Duty on Purchaser. The powers conferred on the Purchaser, its directors, officers and agents pursuant to this Section 12 are solely to protect the Purchaser's interests in the Collateral and shall not impose any duty upon any of them to exercise any such powers. The Purchaser shall be accountable only for the amounts that it actually receives as a result of the exercise of such powers, and neither it nor any of its officers, directors, employees or Purchasers shall be responsible to any Grantor for any act or failure to act, except for the Purchaser's own gross negligence or willful misconduct as determined in a final and non-appealable judgment by a court of competent jurisdiction.

### Section 13. REMEDIES.

13.01. Default. Grantors shall be in default under this Agreement (a) whenever any Event of Default has occurred and is continuing (and each of the Grantors shall thereupon be in default hereunder without regard to whether or to what degree any Grantor individually may have caused, participated in, or had any knowledge of the occurrence of such Event of Default) and (b) at all times after any Secured Obligation has become due and payable and remains unpaid beyond any applicable grace period.

13.02. Remedies Upon Default. At any time when any Grantor is in default under this Agreement as set forth in Section 13.01, the Purchaser may exercise and enforce, in any order, (i) each and all of the rights and remedies available to a secured party upon default under the NYUCC or any other applicable UCC or other applicable law, (ii) each and all of the

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rights and remedies available to it under the Purchase Agreement or any other Transaction Document, and (iii) each and all of the following rights and remedies:

(a) Collection Rights. Without notice to any Grantor or any other Loan Party, the Purchaser may notify any or all account debtors and obligors on any accounts, chattel paper or instruments evidencing an account, or other claims constituting Collateral of the Purchaser's Security Interests therein or the issuers of Pledged Stock delivered to settle an account and may direct, demand and enforce payment thereof directly to the Purchaser. The provisions of Section 9-209 of the NYUCC shall not apply to any account or chattel paper, promissory note or payment intangible as to which notification of assignment has been sent to the account debtor.

(b) Foreclosure. The Purchaser may sell, lease, license or otherwise dispose of or transfer any or all of the Collateral or any part thereof in one or more parcels at public sale or in private sale or transaction, on any exchange or market or at the Purchaser's offices or on any Grantor's premises or at any other location, for cash, on credit or for future delivery, and may enter into all contracts necessary or appropriate in connection therewith, without any notice whatsoever unless required by law. Where permitted by law, the Purchaser may be the purchaser at any such sale and in such event, the Purchaser may bid part or all of the Secured Obligations owing to it without necessity of any cash payment on account of the purchase price, even though any other purchaser at such sale is required to bid a purchase price payable in cash. Each Grantor agrees that at least ten (10) calendar days' written notice to such Grantor of the time and place of any public sale of Collateral owned by it (or, to the extent such Grantor is entitled by law to notice thereof, the public sale of any other Collateral), or the time after which any private sale of Collateral owned by it (or, to the extent such Grantor is entitled by law to notice thereof, the private sale of any other Collateral) is to be made, shall be commercially reasonable. For purposes of such notice, to the fullest extent permitted by law (i) each Grantor waives notice of any sale of Collateral owned by any other Grantor and (ii) each Grantor agrees that notice given to the Seller shall constitute notice given to such Grantor. The giving of notice of any such sale or other disposition shall not obligate the Purchaser to proceed with the sale or disposition, and any such sale or disposition may be postponed or adjourned from time to time, without further notice.

(c) Voting Rights. The Purchaser may exercise any and all rights of any Grantor as the owner of any Pledged Stock delivered to a Grantor to settle an account, including, without limitation, voting rights, rights to give or withhold consent under any agreement under which such Pledged Stock is issued.

(d) Appointment of Receiver. Without limiting any other right or remedy of the Purchaser in this Agreement, upon the occurrence and during the continuance of any Event of Default, the Purchaser may by instrument in writing appoint any person as a receiver of all or any part of the Collateral of each applicable Grantor. The Purchaser may from time to time remove or replace a receiver, or make application to any court of competent jurisdiction for the appointment of a receiver. Any receiver appointed by the Purchaser shall (for purposes relating to responsibility for the receiver's acts or omissions) be considered to be the Purchaser of each applicable Grantor. The Purchaser may from time to time fix the receiver's remuneration and the Grantors shall pay the amount of such remuneration to the Purchaser. The Purchaser shall not be liable to any Grantor or any other person in connection with appointing or not appointing a receiver or in connection with the receiver's actions or omissions.



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13.03. Reserved.

13.04. Waivers by Grantors. Each Grantor hereby irrevocably waives (a) all rights of redemption from any foreclosure sale; (b) the benefit of all valuation, appraisal, exemption and moratorium laws; (c) to the fullest extent permitted by law, all rights to notice or a hearing prior to the exercise by the Purchaser of its right to take possession of any Collateral, whether by self-help or by legal process and any right to object to the Purchaser taking possession of any Collateral by self-help; and (d) if the Purchaser seeks to obtain possession of any Collateral by replevin, claim and delivery, attachment, levy or other legal process, (i) any notice or demand for possession prior to the commencement of legal proceedings, (ii) the posting of any bond or security in any such proceedings, and (iii) any requirement that the Purchaser retain possession and not dispose of any Collateral until after a trial or final judgment in such proceedings.

13.05. Application of Proceeds. Except as expressly provided elsewhere in this Agreement, all proceeds received by the Purchaser in respect of any sale of, collection from, or other realization upon all or any part of the Collateral may, in the discretion of the Purchaser, be held by the Purchaser as Collateral for, or then, or at any other time thereafter, applied in full or in part by the Purchaser against, the Secured Obligations in the following order of priority:

FIRST: to the payment of all reasonable costs and expenses of such sale, collection or other realization, including reasonable compensation to the Purchaser and its agents and counsel, and all other reasonable expenses, liabilities and advances made or incurred by the Purchaser in connection therewith, and all amounts for which the Purchaser is entitled to indemnification hereunder and all reasonable advances made by the Purchaser hereunder for the account of any Grantor, and to the payment of all reasonable costs and expenses paid or incurred by the Purchaser in connection with the exercise of any right or remedy hereunder, all in accordance with Section 19.09;

SECOND: to the payment of all other Secured Obligations then due and payable in the manner and order provided in the Purchase Agreement;

THIRD: to any payments required by Section 9-608(a)(1)(C) or 9-615(a)(3) of the NYUCC or other applicable law; and

FOURTH, to the payment to or upon the order of the Grantor entitled thereto, or to whomsoever may be lawfully entitled to receive the same or as a court of competent jurisdiction may direct, of any surplus then remaining from such proceeds.

13.06. Surplus; Deficiency. Any surplus proceeds of any sale or other disposition by the Purchaser of any Collateral remaining after discharge of the Purchase Agreement and after all Secured Obligations are paid in full and in cash and any payments required by Section 9-608(a)(1)(C) or 9-615(a)(3) of the NYUCC are paid in full shall be paid over to the Grantor entitled thereto, or to whomever may be lawfully entitled to receive such surplus or as a court of competent jurisdiction may direct, but prior to termination and discharge of the Purchase Agreement, such surplus proceeds may be retained by the Purchaser and held as Collateral until termination and discharge of the Purchase Agreement. The Seller and each Guarantor shall be and remain liable for any deficiency.

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13.07. Information Related to the Collateral. If, during the continuance of an Event of Default, the Purchaser determines to sell or otherwise transfer any Collateral, each Grantor shall, and shall cause any Person controlled by it to, furnish to the Purchaser all information the Purchaser may request that pertains or could pertain to the value or condition of the Collateral or that would or might facilitate such sale or transfer. The Purchaser shall have the right, notwithstanding any confidentiality obligation or agreement otherwise binding upon it, freely (but not in violation of any law, including federal securities laws) to disclose such information, and any and all other information (including confidential information) pertaining in any manner to the Collateral or the assets, liabilities, results of operations, business or prospects of the Purchaser, freely to any Person that the Purchaser in good faith believes to be a potential or prospective purchaser in such sale or transfer, without liability for any disclosure, dissemination or use that may be made as to such information by any such Person.

13.08. Reserved.

13.09. Rights and Remedies Cumulative. The rights provided for in this Agreement and the other Transaction Documents are cumulative and are not exclusive of any other rights, powers or privileges or remedies provided by law or in equity, or under any other instrument, document or agreement. The Purchaser may exercise and enforce each right and remedy available to it either before or concurrently with or after, and independently of, any exercise or enforcement of any other right or remedy of the Purchaser against any Person or property. All such rights and remedies shall be cumulative, and no one of them shall exclude or preclude any other.

13.10. Reserved.

#### Section 14. STANDARDS FOR EXERCISING REMEDIES.

14.01. Commercially Reasonable Manner. To the extent that applicable law imposes duties on the Purchaser to exercise remedies in a commercially reasonable manner, each Grantor acknowledges and agrees that it is not commercially unreasonable for the Purchaser (a) to fail to obtain third-party consents for access to Collateral to be disposed of, or to obtain or, if not required by other law, to fail to obtain governmental or third-party consents for the collection or disposition of Collateral to be collected or disposed of; (b) to fail to exercise collection remedies against account debtors or other persons obligated on Collateral or to remove any Lien on or any adverse claims against Collateral; (c) to exercise collection remedies against account debtors and other persons obligated on Collateral directly or through the use of collection agencies and other collection specialists; (d) to advertise dispositions of Collateral through publications or media of general circulation, whether or not the Collateral is of a specialized nature; (e) to contact other persons, whether or not in the same business as such Grantor, for expressions of interest in acquiring all or any portion of the Collateral; (f) to hire one or more professional auctioneers to assist in the disposition of Collateral, whether or not the collateral is of a specialized nature; (g) to dispose of Collateral by utilizing Internet sites that provide for the auction of assets of the types included in the Collateral or that have the reasonable capability of doing so, or that match buyers and sellers of assets; (h) to dispose of assets in wholesale rather than retail markets; (i) to disclaim disposition warranties; (j) to purchase insurance or credit enhancements to insure the Purchaser against risks of loss, collection or disposition of Collateral or to provide to the Purchaser a guaranteed return from the collection or disposition of Collateral; or (k) to the extent deemed appropriate by the Purchaser, to obtain the services of other brokers, investment bankers, consultants and other professionals to assist the Purchaser in the collection or disposition of any

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of the Collateral. Each Grantor acknowledges that the purpose of this Section 14 is to provide non-exhaustive indications of what actions or omissions by the Purchaser would not be commercially unreasonable in the Purchaser's exercise of remedies against the Collateral and that other actions or omissions by the Purchaser shall not be deemed commercially unreasonable solely on account of not being indicated in this Section 14. Without limiting the foregoing, nothing contained in this Section 14 shall be construed to grant any rights to any Grantor or to impose any duties on the Purchaser that would not have been granted or imposed by this Agreement or by applicable law in the absence of this Section 14.

14.02. Standard of Care. The powers conferred on the Purchaser hereunder are solely to protect its interest in the Collateral and shall not impose any duty upon it to exercise any such powers. Except for the exercise of reasonable care in the custody of any Collateral in its possession and the accounting for moneys actually received by it hereunder, the Purchaser shall have no duty as to any Collateral or as to the taking of any necessary steps to preserve rights against prior parties or to protect, preserve, vote or exercise any rights pertaining to any Collateral. The Purchaser shall be deemed to have exercised reasonable care in the custody and preservation of Collateral in its possession if such Collateral is accorded treatment substantially equal to that which the Purchaser accords its own property or if it selects, with reasonable care, a custodian to hold such Collateral on its behalf.

Section 15. WAIVERS BY GRANTOR; OBLIGATIONS ABSOLUTE.

15.01. Specific Waivers. Each Grantor waives demand, notice, protest, notice of acceptance of this Agreement, notice of any purchase pursuant to the terms of the Purchase Agreement, Collateral received or delivered or other action taken in reliance hereon and all other demands and notices of any description other than those required pursuant to the Purchase Agreement or any other Transaction Documents to which such Grantor is a party.

15.02. Obligations Absolute. All rights of the Purchaser hereunder, the Security Interest and all obligations of the Grantors hereunder shall be absolute and unconditional irrespective of (a) any lack of validity or enforceability of the Purchase Agreement, any other Transaction Document, any agreement with respect to any of the Secured Obligations or any other agreement or instrument relating to any of the foregoing; (b) any change in the time, manner or place of payment of, or in any other term of, all or any of the Secured Obligations, or any other amendment or waiver of or any consent to any departure from the Purchase Agreement, any other Transaction Document, or any other agreement or instrument; (c) any exchange, release or non-perfection of any Lien on other collateral, or any release or amendment or waiver of or consent under or departure from or any acceptance of partial payment thereon and or settlement, compromise or adjustment of any Secured Obligation or of any guarantee, securing or guaranteeing all or any of the Secured Obligations; or (d) any other circumstance that might otherwise constitute a defense available to, or a discharge of, any Grantor in respect of the Secured Obligations or this Agreement other than the prompt and complete performance and payment in full of the Secured Obligations.

Section 16. MARSHALLING. The Purchaser shall not be required to marshal any present or future collateral security (including but not limited to this Agreement and the Collateral) for, or other assurances of payment of, the Secured Obligations or any of them or to resort to such collateral security or other assurances of payment in any particular order, and all of its rights hereunder and in respect of such collateral security and other assurances of payment shall be cumulative and in addition to all other rights, however existing or arising. To the extent

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that it lawfully may, each Grantor hereby agrees that it shall not invoke any law relating to the marshalling of collateral which might cause delay in or impede the enforcement of the Purchaser's rights under this Agreement or under any other instrument creating or evidencing any of the Secured Obligations or under which any of the Secured Obligations is outstanding or by which any of the Secured Obligations is secured or payment thereof is otherwise assured, and, to the extent that it lawfully may, each Grantor hereby irrevocably waives the benefits of all such laws.

Section 17. INTEREST. Until paid, all amounts due and payable by each Grantor hereunder shall be deemed to be a debt secured by the Collateral and shall bear, whether before or after judgment, interest at a rate equal to the lower of (i) the highest rate permitted by applicable law, and (ii) one and one-half percent (1.5%) per month, compounded monthly.

Section 18. REINSTATEMENT. The obligations of each Grantor pursuant to this Agreement shall continue to be effective or automatically be reinstated, as the case may be, if at any time payment of any of the Secured Obligations is rescinded or otherwise must be restored or returned by the Purchaser upon the insolvency, bankruptcy, dissolution, liquidation or reorganization of such Grantor or any other obligor or otherwise, all as though such payment had not been made.

Section 19. MISCELLANEOUS.

19.01. Notices. All notices, requests and demands to or upon the Purchaser or any Grantor hereunder shall be effected in the manner provided for in Section 7.03 of the Purchase Agreement.

19.02. GOVERNING LAW; CONSENT TO JURISDICTION; SERVICE OF PROCESS. THIS AGREEMENT SHALL BE A CONTRACT MADE UNDER AND GOVERNED BY THE INTERNAL LAWS OF THE STATE OF NEW YORK APPLICABLE TO CONTRACTS MADE AND TO BE PERFORMED ENTIRELY WITHIN SUCH STATE, WITHOUT REGARD TO CONFLICT OF LAWS PRINCIPLES (OTHER THAN SECTION 5-1401 OF THE NEW YORK GENERAL OBLIGATIONS LAW). ANY LITIGATION BASED HEREON, OR ARISING OUT OF, UNDER, OR IN CONNECTION WITH THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT, MAY BE BROUGHT IN ANY STATE OR FEDERAL COURT OF COMPETENT JURISDICTION IN THE STATE OF NEVADA, WASHOE COUNTY AND CITY OF RENO; PROVIDED THAT ANY SUIT SEEKING ENFORCEMENT AGAINST ANY COLLATERAL OR OTHER PROPERTY MAY BE BROUGHT, AT PURCHASER'S OPTION, IN THE COURTS OF ANY JURISDICTION WHERE SUCH COLLATERAL OR OTHER PROPERTY MAY BE FOUND. EACH PARTY HERETO HEREBY EXPRESSLY AND IRREVOCABLY SUBMITS TO THE JURISDICTION OF THE COURTS OF THE STATE OF NEVADA, WASHOE COUNTY AND CITY OF RENO FOR THE PURPOSE OF ANY SUCH LITIGATION AS SET FORTH ABOVE. EACH PARTY HERETO FURTHER IRREVOCABLY CONSENTS TO THE SERVICE OF PROCESS BY REGISTERED MAIL, POSTAGE PREPAID, OR BY PERSONAL SERVICE WITHIN OR WITHOUT THE STATE OF NEVADA. EACH PARTY HERETO HEREBY EXPRESSLY AND IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY OBJECTION WHICH IT MAY NOW OR HEREAFTER HAVE TO THE LAYING OF VENUE OF ANY SUCH LITIGATION BROUGHT IN ANY SUCH COURT REFERRED TO ABOVE AND ANY CLAIM THAT ANY SUCH LITIGATION HAS BEEN BROUGHT IN AN INCONVENIENT FORUM.

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19.03. WAIVER OF JURY TRIAL, ETC. EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING, CLAIM OR COUNTERCLAIM ARISING OUT OF OR RELATING TO ANY TRANSACTION DOCUMENT OR THE TRANSACTIONS CONTEMPLATED UNDER ANY TRANSACTION DOCUMENT. THIS WAIVER SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO ANY TRANSACTION DOCUMENT.

19.04. Counterparts. This Agreement may be executed in counterparts (and by different parties hereto in different counterparts), each of which shall constitute an original, but all of which when taken together shall constitute a single contract.

19.05. Headings. The headings of each section of this Agreement are for convenience only and shall not define or limit the provisions thereof.

19.06. No Strict Construction. The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

19.07. Severability. The illegality or unenforceability of any provision of this Agreement or any instrument or agreement required hereunder shall not in any way affect or impair the legality or enforceability of the remaining provisions of this Agreement or any instrument or agreement required hereunder.

19.08. Survival of Agreement. All representations, warranties and agreements made by or on behalf of any in this Agreement and in the other Transaction Documents shall survive the execution and delivery hereof or thereof and the payment of the Secured Obligations. In addition, notwithstanding anything herein or under applicable law to the contrary, the provisions of this Agreement and the other Transaction Documents relating to indemnification or payment of costs and expenses, including, without limitation, the provisions of Sections 7.05 and 7.14 of the Purchase Agreement, shall survive the payment in full of the Secured Obligations and any termination of this Agreement or any of the other Transaction Documents.

19.09. Fees and Expenses; Indemnification.

(a) The Grantors, jointly and severally, agree to pay upon demand the amount of any and all reasonable expenses, including the fees, disbursements and other charges of counsel and of any experts or Purchasers, which (i) the Purchaser may incur in connection with (x) collecting against any Grantor or otherwise enforcing or preserving any rights under this Agreement and the other Transaction Documents, (y) the exercise, enforcement or protection of any of the rights of the Purchaser hereunder or (z) the failure of any Grantor to perform or observe any of the provisions hereof, and (ii) the Purchaser may incur in connection with (x) the administration of this Agreement (including the customary fees and charges for any audits conducted by it or on its behalf with respect to the accounts receivable) or (y) the custody or preservation of, or the sale of, collection from or other realization upon any of the Collateral.

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Each Grantor agrees to pay, and to save the Purchaser harmless from, any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind or nature whatsoever with respect to the execution, delivery, enforcement, performance and administration of this Agreement to the extent the Seller would be required to do so pursuant to Section 7.05 of the Purchase Agreement.

(b) The agreements in this Section shall survive repayment of the Secured Obligations and all other amounts payable under the Purchase Agreement and the other Transaction Documents.

(c) Each Grantor agrees that the provisions of Article III of the Purchase Agreement are hereby incorporated herein by reference, mutatis mutandis, and the Purchaser shall be entitled to rely on each of them as if they were fully set forth herein.

19.10. Binding Effect; Several Agreement. This Agreement is binding upon each Grantor and the Purchaser and their respective successors and permitted assigns, and shall inure to the benefit of the Grantors, the Purchaser and their respective successors and permitted assigns, except that no Grantor shall have any right to assign or transfer its rights or obligations hereunder or any interest herein, except as specifically permitted by the Purchase Agreement, without the prior written consent of the Purchaser (and any such assignment or transfer shall be void).

19.11. Waivers; Amendment.

(a) No failure or delay of the Purchaser in exercising any power or right hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right or power, or any abandonment or discontinuance of steps to enforce such a right or power, preclude any other or further exercise thereof or the exercise of any other right or power. The rights and remedies of the Purchaser hereunder and of the Purchaser under the Purchase Agreement and other Transaction Documents are cumulative and are not exclusive of any rights or remedies that it would otherwise have. No waiver of any provisions of this Agreement or consent to any departure by any Grantor therefrom shall in any event be effective unless the same shall be permitted by paragraph (b) below, and then such waiver or consent shall be effective only in the specific instance and for the purpose for which given. No notice to or demand on any Grantor in any case shall entitle such or any other Grantor to any other or further notice or demand in similar or other circumstances.

(b) Neither this Agreement nor any provision hereof may be waived, amended or modified except pursuant to an agreement or agreements in writing entered into by the Purchaser and each affected Grantor.

19.12. Set Off. Each Grantor hereby irrevocably authorizes the Purchaser at any time and from time to time while an Event of Default shall have occurred and be continuing, without notice to such Grantor or any other Grantor, any such notice being expressly waived by each Grantor, to set off and appropriate and apply any and all deposits (general or special, time or demand, provisional or final), in any currency, and any other credits, indebtedness or claims, in any currency, in each case whether direct or indirect, absolute or contingent, matured or unmatured, at any time held or owing by the Purchaser to or for the credit or the account of such Grantor, or any part thereof in such amounts as the Purchaser may elect, against and on account of the obligations and liabilities of such Grantor to the Purchaser hereunder and claims of every

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nature and description of the Purchaser against such Grantor, in any currency, whether arising hereunder, under the Purchase Agreement, any other Transaction Document or otherwise, as the Purchaser may elect. The Purchaser shall notify such Grantor promptly of any such set-off and the application made by the Purchaser of the proceeds thereof; provided that the failure to give such notice shall not affect the validity of such set-off and application. The rights of the Purchaser under this Section are in addition to other rights and remedies (including, without limitation, other rights of set-off) which the Purchaser may have.

19.13. Integration. This Agreement and the other Transaction Documents constitute the entire contract among the parties relating to the subject matter hereof and supersede any and all previous agreements and understandings, oral or written, relating to the subject matter hereof.

19.14. Acknowledgments. Each Grantor hereby acknowledges that:

(a) it has been advised by counsel in the negotiation, execution and delivery of this Agreement and the other Transaction Documents to which it is a party;

(b) the Purchaser does not have any fiduciary relationship with or duty to any Grantor arising out of or in connection with this Agreement or any of the other Transaction Documents, and the relationship between the Grantors, on the one hand, and the Purchaser, on the other hand, in connection herewith or therewith is solely that of seller and purchaser (or, in the case that a Grantor owes Secured Obligations to the Purchaser, that of debtor and creditor); and

(c) no joint venture is created hereby or by the other Transaction Documents or otherwise exists by virtue of the transactions contemplated hereby among the Grantors and the Purchaser.

19.15. Additional Grantors and Guarantors. Each subsidiary of the Seller that is required to become a party to this Agreement pursuant to Section 5.10(b) of the Purchase Agreement shall become a Grantor and Guarantor for all purposes of this Agreement upon execution and delivery by such subsidiary of an Assumption Agreement in the form of Annex I hereto.

[Remainder of Page Intentionally Left Blank; Signature Pages Follow]

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IN WITNESS WHEREOF, each of the undersigned has caused this Guarantee and Collateral Agreement to be duly executed and delivered as of the date first above written.

GRANTORS:

AXOGEN, INC.

By: /s/ Karen Zaderej

Name: Karen Zaderej

Title: CEO

AXOGEN CORPORATION.

By: /s/ Karen Zaderej

Name: Karen Zaderej

Title: CEO

[Collateral Agreement – Signature Page]



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PDL BIOPHARMA, INC.,  
as Purchaser

By: /s/ John P. McLaughlin  
Name: John P. McLaughlin  
Title: President and Chief Executive Officer

[Guarantee and Collateral Agreement – Signature Page]

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## Annex A to Guarantee and Collateral Agreement

ASSUMPTION AGREEMENT, dated as of \_\_\_\_\_, 20\_\_\_\_, made by \_\_\_\_\_, a \_\_\_\_\_ (the "Additional Grantor"), in favor of PDL Biopharma, Inc., as Purchaser (the "Purchaser") party to the Purchase Agreement referred to below. All capitalized terms not defined herein shall have the meaning ascribed to them in such Purchase Agreement.

### WITNESSETH:

WHEREAS, AxoGen, Inc. ("Seller") and the Purchaser have entered into the Revenue Interests Purchase Agreement, dated as of October 5, 2012 (as amended, supplemented, replaced or otherwise modified from time to time, the "Purchase Agreement");

WHEREAS, in connection with the Purchase Agreement, the Seller and certain of its Affiliates (other than the Additional Grantor) have entered into a Guarantee and Collateral Agreement, dated as of October 5, 2012 (as amended, supplemented or otherwise modified from time to time, the "Guarantee and Collateral Agreement") in favor of the Purchaser;

WHEREAS, the Purchase Agreement requires the Additional Grantor to become a party to the Guarantee and Collateral Agreement; and

WHEREAS, the Additional Grantor has agreed to execute and deliver this Assumption Agreement in order to become a party to the Guarantee and Collateral Agreement;

### NOW, THEREFORE, IT IS AGREED:

1. Guarantee and Collateral Agreement. By executing and delivering this Assumption Agreement, the Additional Grantor, as provided in Section 19.15 of the Guarantee and Collateral Agreement, hereby becomes a party to the Guarantee and Collateral Agreement as a Grantor and Guarantor thereunder with the same force and effect as if originally named therein as a Grantor and Guarantor and, without limiting the generality of the foregoing, hereby expressly assumes all obligations and liabilities of a Grantor and Guarantor thereunder. The information set forth in Annex I-A hereto is hereby added to the information set forth in the update to the Schedules to the Purchase Agreement most recently delivered pursuant to the terms of the Guarantee and Collateral Agreement. The Additional Grantor hereby represents and warrants that each of the representations and warranties as to the Additional Grantor contained in Section 6 of the Guarantee and Collateral Agreement is true and correct on and as the date hereof (after giving effect to this Assumption Agreement) as if made on and as of such date.

2. GOVERNING LAW. THIS ASSUMPTION AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK.

IN WITNESS WHEREOF, the undersigned has caused this Assumption Agreement to be duly executed and delivered as of the date first above written.

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[ADDITIONAL GRANTOR]

By: \_\_\_\_\_  
Name:  
Title:

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Schedule 6.01

Name: AxoGen, Inc.

Jurisdiction of Organization: Minnesota

Identification Number: 41-1301878

Chief Executive Office: 13859 Progress Boulevard, Suite 100  
Alachua, Florida 32615

Prior Organizational Names: LecTec Corporation

Name: AxoGen Corporation

Jurisdiction of Organization: Delaware

Identification Number: 55-0805988

Chief Executive Office: 13859 Progress Boulevard, Suite 100  
Alachua, Florida 32615

Prior Organizational Names: None

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Schedule 6.06  
Deposit Accounts

Guarantor	Bank	Account Number
AxoGen, Inc.	Silicon Valley Bank	***
AxoGen Corporation	Silicon Valley Bank	***

**SECOND AMENDMENT TO LEASE**

This Second Amendment to Lease (this "Second Amendment") is entered into as of February 27, 2013 by and between SNH Medical Office Properties Trust, a Maryland real estate investment trust ("Landlord") and AXOGEN CORPORATION, a Delaware corporation ("Tenant").

WHEREAS, Wigshaw, LLC ("Original Landlord") and Tenant entered into that certain Lease dated February 6, 2007 (the "Original Lease") for certain premises in the building known as the Progress One Building and located at 13859 Progress Boulevard, Alachua, Florida; and

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

WHEREAS, the Lease is scheduled to expire on April 30, 2013; and

WHEREAS, Landlord and Tenant have agreed to amend the Lease to extend the term thereof, subject to and upon the terms and conditions hereinafter provided;

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

1. Capitalized terms used and not otherwise defined herein shall have the meanings ascribed to such terms in the Lease.
2. The Term of the Lease is hereby extended and shall expire on April 30, 2014.
3. For the period commencing on May 1, 2013 and ending on April 30, 2014, Annual Gross Rent shall be \$94,840.00 per annum, payable in equal monthly installments of \$7,903.33, in advance.
4. Tenant acknowledges that it is currently in possession of the Leased Premises and is agreeing to an extension of the Term with the Leased Premises being accepted in "as is" condition as of the date of this Second Amendment.
5. Tenant warrants and represents that it has dealt with no broker in connection with the consummation of this Second Amendment, other than Coldwell Banker Commercial/M.M. Parish Realtors ("Broker"), and in the event of any brokerage claims or liens, other than by Broker, against Landlord or the Building predicated upon or arising out of prior dealings with Tenant, Tenant agrees to defend the same and indemnify and hold Landlord harmless against any such claim, and to discharge any such lien.
6. As amended hereby, the Lease is hereby ratified and confirmed.

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

**LANDLORD:**

SNH Medical Office Properties Trust

By: Reit Management & Research LLC,  
its managing agent

By: /s/ David M. Lepore

David M. Lepore  
Senior Vice President

**TENANT:**

Axogen Corporation

By: /s/ Karen Zaderej

Name: Karen Zaderej  
Title: CEO

SUBSIDIARY OF AXOGEN, INC.

As of December 31, 2012, AxoGen Inc.'s sole subsidiary was AxoGen Corporation, a Delaware corporation.



**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements of AxoGen, Inc. on Form S-8 (File No. 333-177980, effective November 14, 2011) of our report dated March 12, 2013, appearing in this annual report on form 10-K of AxoGen, Inc. for the years ended December 31, 2012 and 2011.

/s/ LURIE BESIKOF LAPIDUS & COMPANY, LLP

Minneapolis, Minnesota  
March 12, 2013

**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 12, 2013

/s/ Karen Zaderej

Karen Zaderej

Chief Executive Officer

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

I, Gregory G. Freitag, certify that:

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

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

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

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

- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2013

/s/ Gregory G. Freitag

Gregory G. Freitag  
Chief Financial Officer

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

In connection with the Annual Report of LecTec Corporation (the "Company") on Form 10-K for the year ended December 31, 2012 as filed with the Securities and Exchange Commission (the "Report"), I, Karen Zaderej, Chief Executive Officer and Gregory G. Freitag, Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Karen Zaderej

Karen Zaderej  
Chief Executive Officer  
March 12, 2013

/s/ Gregory G. Freitag

Gregory G. Freitag  
Chief Financial Officer  
March 12, 2013



## **AxoGen, Inc. Reports Record 2012 Revenues**

### **Full Year 2012 Highlights**

- Revenue for full year 2012 increased 59% to \$7.69 million from \$4.85 million for full year 2011
- Gross profit for full year 2012 increased \$3.31 million, or 136%, to \$5.73 million compared with full year 2011
- Gross margins for full year 2012 were 75%

### **Fourth Quarter 2012 Highlights**

- Revenue for 4Q12 was \$2.04 million, a 50% increase over 4Q11.
- Gross profit for 4Q12 was \$1.58 million versus \$0.83 million for 4Q11.

**ALACHUA, FL – March 12, 2013** – AxoGen, Inc. (OTCBB: AXGN) a leading regenerative medicine company focused on the commercialization of proprietary products and technologies for peripheral nerve reconstruction and regeneration, today reported revenues for the year ended December 31, 2012 of \$7.69 million, a 59% increase over the \$4.85 million reported during the same period in 2011. In addition, the Company reported a net loss for 2012 of \$9.42 million, or (\$0.85) per common share, compared to a net loss of \$10.25 million, or (\$2.77) per common share, reported during the same period in 2011.

“AxoGen’s revenue growth is an affirmation of market demand and the direct result of an increase in the number of surgeons and hospitals using our peripheral nerve repair technologies,” stated Karen Zaderej, Chief Executive Officer of AxoGen. “Our strategy is to provide education and clinical evidence to surgeons on the value of new peripheral nerve treatment options to drive adoption of our products. That strategy was evident with the publication of data for Avance® Nerve Graft from the Ranger® Study in two leading, peer-reviewed journals, *Microsurgery* and *The Journal of Hand Surgery*. Further, expanded data from the RANGER® Study was presented at the American Association for Hand Surgery conference in January 2013, which received strong visibility among hand surgeons.”

Ms. Zaderej continued, “In 2012, we successfully completed a \$20.8 million financing with PDL that strengthened our balance sheet, and provided the funds to expand training of our sales team, to increase our marketing efforts and add additional sales associates. We believe these initiatives position AxoGen well for acceleration of growth in 2013.

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## Revenue

Revenues for the year ended December 31, 2012 increased 59% to approximately \$7,692,000 as compared to approximately \$4,849,000 for the year ended December 31, 2011 principally due to a greater number of customers utilizing AxoGen products.

## Gross Profit

Gross profit for the year ended December 31, 2012 reached \$5.73 million, a 136% increase, compared to \$2.42 million for the same period in 2011. This increase is due, in part, to increased revenues and gross margins, and not incurring the \$0.8 million in inventory and raw-materials write-offs experienced in 2011. Also, in 2011 we had higher processing and testing fees, travel costs and temporary labor costs due to the resumption of the manufacturing of Avance® Nerve Graft that were not incurred in 2012. Gross profit margin for 2012 was 75%.

## Sales and Marketing Expenses

Sales and marketing expenses increased 57.2% to approximately \$6,884,000 for the year ended December 31, 2012 as compared to approximately \$4,379,000 for the year ended December 31, 2011. This increase was primarily due to expanded marketing activity and an increase in the number of direct representatives. As a percentage of revenues, sales and marketing expenses were 89.4% for the year ended December 31, 2012 compared to 90.3% for the year ended December 31, 2011. Sales and marketing expenses as a percentage of revenue remaining flat between yearly periods was primarily a result of revenue increases in 2012 being offset by increased expenses.

## General and Administrative Expenses

General and administrative expenses increased 21.0% to approximately \$5,221,000 for the year ended December 31, 2012 as compared to approximately \$4,316,000 for the year ended December 31, 2011. As a percentage of revenues, general and administrative expenses decreased to 67.9% for the year ended December 31, 2012 compared to 89.0% the year ended December 31, 2011. The increase in aggregate dollars spent was a result of hiring and costs related to being a public company, offset by a savings in certain professional fees and finance costs. As a percentage of revenue, general and administrative expenses decreased as the increase in aggregate dollars spent was absorbed by the increase in revenues.

## Research and Development

Research and development expenses increased to approximately \$1,427,000 in the year ended December 31, 2012 as compared to approximately \$697,000 for the year ended December 31, 2011. Development includes AxoGen's clinical efforts and other investments in data that help support the value of our products. A large portion of the increase in research and development expenses from 2011 to 2012 related to expenditures for such clinical activity.

## Financial Liquidity

At December 31, 2012, the Company had approximately \$13.91 million in cash and cash equivalents and approximately \$21.58 million in long-term debt outstanding.

On October 5, 2012, the Company entered into a Revenue Interests Purchase Agreement with PDL BioPharma Inc., under which the Company received \$20.8 million in cash, certain proceeds of which were used to repay existing debt and expenses related to the transaction.

Greg Freitag, AxoGen's CFO and General Counsel stated, "The PDL transaction provided capital to the Company without the issuance of any dilutive equity. By leveraging this capital into our sales and marketing organization, we expect to see the continued increase of shareholder value. The structure of the PDL transaction was intended to maximum available funds in the near term and allow for flexibility in the longer term."

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## Earnings Call Information

As previously announced, AxoGen, Inc. management will review its year end 2012 and fourth quarter 2012 financials during a conference call scheduled for March 13, 2013 at 10:00 AM Eastern Time. The conference call information is as follows:

Conference dial-in: 877-709-8150  
International dial-in: 201-689-8354  
Conference Name: AxoGen 2012 Fourth Quarter & Year End Results  
Conference ID: 00409696  
Conference Call Webcast: [www.axogeninc.com/investors.html](http://www.axogeninc.com/investors.html)

Following the live call, a replay will be available on the Company's website, [www.axogeninc.com](http://www.axogeninc.com), under the "Investors" page.

## About AxoGen, Inc.

AxoGen (OTCBB: AXGN) is a regenerative medicine company dedicated to advancing the science and commercialization of peripheral nerve repair solutions. The Company's innovative approach to regenerative medicine has resulted in first-in-class products that will define their product categories. AxoGen's products offer a full suite of surgical nerve reconstruction solutions including Avance® Nerve Graft, the only commercially available processed nerve allograft for bridging severed nerves without the comorbidities associated with a second surgical site, AxoGuard® Nerve Connector, a porcine submucosa 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. For more information, visit our website at [www.axogeninc.com](http://www.axogeninc.com).

AxoGen is the parent of its wholly owned operating subsidiary, AxoGen Corporation. AxoGen's principal executive office and operations are located in Alachua, FL. To receive email alerts directly from AxoGen, please click here [www.axogeninc.com/emailalerts.html](http://www.axogeninc.com/emailalerts.html).

## Cautionary Statements Concerning Forward-Looking Statements

This Press Release contains "forward-looking" statements as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations or predictions of future conditions, events or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as "expects", "anticipates", "intends", "plans", "believes", "seeks", "estimates", "projects", "forecasts", "continue", "may", "should", "will" 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, financial performance, sales growth, product adoption, market awareness of our products and data

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validation. The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the statements. Forward-looking statements in this release should be evaluated together with the many uncertainties that affect AxoGen's business and its market, particularly those discussed in the risk factors and cautionary statements in AxoGen's filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made, and AxoGen assumes no responsibility to update any forward-looking statements, whether as a result of new information, future events or otherwise.

**Contact:**

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AxoGen, Inc.  
Greg Freitag, Chief Financial Officer  
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[InvestorRelations@AxoGenInc.com](mailto:InvestorRelations@AxoGenInc.com)  
[www.axogeninc.com](http://www.axogeninc.com)



AXOGEN, INC.

CONSOLIDATED BALANCE SHEETS

December 31, 2012 and 2011

	December 31, 2012	December 31, 2011
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 13,907,401	\$ 8,190,781
Accounts receivable	1,050,089	797,654
Inventory	3,151,109	1,760,540
Prepaid expenses and other	187,256	133,500
<b>Total current assets</b>	18,295,855	10,882,475
<b>Property and equipment, net</b>	108,534	247,824
<b>Goodwill</b>	—	169,987
<b>Intangible assets</b>	573,731	899,480
<b>Deferred financing costs</b>	1,252,443	295,276
	\$ 20,230,563	\$ 12,495,042
<b>Liabilities and Shareholders' Equity (Deficit)</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 1,479,752	\$ 1,585,100
Current portion of long-term debt	—	434,734
<b>Total current liabilities</b>	1,479,752	2,019,834
<b>Long-term debt</b>	—	4,403,737
<b>Note Payable – Revenue Interest Purchase Agreement</b>	21,580,252	—
<b>Total liabilities</b>	23,060,004	6,423,571
<b>Shareholders' equity (deficit):</b>		
Common stock, \$.01 par value; 50,000,000 shares authorized; 11,122,573 and 11,062,188 shares issued and outstanding	111,226	110,622
Additional paid-in capital	54,908,226	54,391,784
Accumulated deficit	(57,848,893)	(48,430,935)
<b>Total shareholders' equity (deficit)</b>	(2,829,441)	6,071,471
	\$ 20,230,563	\$ 12,495,042

AXOGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

Years ended December 31, 2012 and 2011

	2012	2011
<b>Revenues</b>	\$ 7,691,704	\$ 4,849,470
<b>Cost of goods sold</b>	1,961,877	2,426,544
<b>Gross profit</b>	5,729,827	2,422,926
<b>Costs and expenses:</b>		
Sales and marketing	6,883,953	4,378,694
Research and development	1,427,211	697,355
General and administrative	5,220,599	4,315,604
<b>Total costs and expenses</b>	13,531,763	9,391,653
<b>Loss from operations</b>	(7,801,936)	(6,968,727)
<b>Other income (expense):</b>		
Interest expense	(1,391,342)	(1,094,657)
Interest expense – deferred financing costs	(986,844)	(1,223,126)
Change in fair value of warrant liability	—	62,305
Other income	23,972	4,985
<b>Total other income (expense)</b>	(2,354,214)	(2,250,493)
<b>Loss before income taxes</b>	(10,156,150)	(9,219,220)
<b>Income tax benefit</b>	738,192	—
<b>Net Loss</b>	(9,417,958)	(9,219,220)
Preferred Stock dividends (assumes all paid)	—	(1,028,351)
Net loss available to common shareholders	\$ (9,417,958)	\$ (10,247,571)
Weighted Average Common Shares outstanding – basic and diluted	11,089,425	3,697,390
Loss Per Common share – basic and diluted	\$ (0.85)	\$ (2.77)

AXOGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2012 and 2011

	2012	2011
<b>Cash flows from operating activities:</b>		
Net loss	\$ (9,417,958)	\$ (9,219,220)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	187,749	273,528
Amortization of intangible assets	127,080	67,147
Loss on impairment	299,654	—
Loss on abandonment of license	147,826	—
Amortization of deferred financing costs	352,667	1,223,126
Amortization of debt discount	161,529	23,643
Stock-based compensation	495,077	250,044
Directors Stock Compensation	—	15,000
Stock grant for service	21,375	—
Cancellation of shares	(14,999)	—
Change in fair value of warrant liability	—	(62,305)
Interest added to note payable	780,252	55,562
Change in assets and liabilities:		
Accounts receivable	(252,435)	(368,954)
Inventory	(1,390,570)	142,249
Prepaid expenses and other	(53,757)	20,070
Accounts payable and accrued expenses	(105,348)	500,820
<b>Net cash used for operating activities</b>	<u>(8,661,858)</u>	<u>(7,079,290)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(48,459)	(20,610)
Acquisition of intangible assets	(78,825)	(68,856)
Cash acquired with Merger	—	7,201,638
<b>Net cash (used for) provided by investing activities</b>	<u>(127,284)</u>	<u>7,112,172</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of long-term debt	—	10,500,000
Proceeds from issuance of note payable	15,961,294	—
Proceeds from issuance of common stock	—	1,000,000
Repayments of long-term debt	(161,292)	(4,732,857)
Debt issuance costs	(1,309,834)	(434,772)
Proceeds from exercise of stock options	15,652	26,480
Merger	(58)	—
<b>Net cash provided by financing activities</b>	<u>14,505,762</u>	<u>6,358,851</u>
Net increase in cash and cash equivalents	5,716,620	6,391,733
<b>Cash and cash equivalents, beginning of year</b>	<u>8,190,781</u>	<u>1,799,048</u>
<b>Cash and cash equivalents, end of period</b>	<u>\$13,907,401</u>	<u>\$ 8,190,781</u>
<b>Supplemental disclosures of cash flow activity:</b>		
Cash paid for interest	\$ 649,108	\$ 1,029,753
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Payments of long term debt with proceeds from note payable	\$ 4,838,706	\$ —
Conversion of preferred stock, convertible debt and accrued interest into common stock	—	21,497,955
Accretion of dividends of Series B preferred stock	—	292,330
Accretion of dividends of Series C preferred stock	—	515,577
Accretion of dividends of Series D preferred stock	—	220,444
Preferred stock dividend payable forfeited with the Merger	—	7,076,729
Warrant Liability forfeited with the Merger	—	2,607,510
Debt discount related to warrants issued with debt	—	173,736
Net assets acquired on Merger	—	11,847,916
Note and accrued interest retired with the Merger	—	4,555,562
Directors stock compensation included in prepaid expenses	—	60,000