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**Filed Pursuant to Rule 424(b)(4)**
**Registration No. 333-188597**

**Prospectus**

# 6,000,000 Shares

# AXOGEN, INC.

## Common Shares

We are offering 6,000,000 common shares, par value $0.01 per share, at a public offering price per share of $3.00. Our common shares currently trade on the OTCQB Marketplace, operated by OTC Markets Group, under the symbol "AXGN." The last reported sale price of our common shares on the OTCQB Marketplace on August 8, 2013 was $3.85 per share. We have been approved to list our common shares on the NASDAQ Capital Market under the symbol "AXGN."

**Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 8.**

| | Per Share | Total |
|---|---|---|
| Public offering price | $ 3.00 | $18,000,000 |
| Underwriting discounts and commissions(1) | $ 0.21 | $ 1,260,000 |
| Proceeds, before expenses, to us | $ 2.79 | $16,740,000 |

**(1) See "Underwriting" in this prospectus for a description of compensation payable to the underwriters.**

We have granted to the underwriters an option to purchase up to 900,000 additional common shares to cover over-allotments, if any, exercisable at any time until 30 days after the date of this prospectus. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $1,449,000 and the total proceeds to us, before expenses, will be $19,251,000.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The underwriters expect to deliver the common shares on or about August 14, 2013.

**JMP Securities**

**Ladenburg Thalmann & Co.**

The date of this prospectus is August 8, 2013.

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**Neither we nor any of the underwriters has authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. Neither we nor any of the underwriters is making an offer to sell or seeking offers to buy these securities in any jurisdiction where, or to any person to whom, the offer or sale is not permitted. The information in this prospectus is accurate only as of its date regardless of the time of delivery of this prospectus or of any sale of our common shares. Our business, financial condition, results of operations and future growth prospects may have changed since those dates.**

**For investors outside the United States: neither we nor any of the underwriters has done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus outside of the United States.**

**This prospectus includes estimates, statistics and other industry and market data that we obtained from industry publications, research, surveys and studies conducted by third parties and publicly available information. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. This prospectus also includes data based on our own internal estimates. We caution you not to give undue weight to such projections, assumptions and estimates.**

## PROSPECTUS SUMMARY

*This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in our securities and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read the entire prospectus carefully, especially the section entitled "Risk Factors" and our consolidated financial statements and related notes, before deciding to buy our securities. Unless otherwise stated, all references to "us," "our," "we," "AxoGen," the "Company" and similar designations refer to AxoGen, Inc. and its subsidiary AxoGen Corporation.*

### Company Overview

We are 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 muscle function and/or feeling.

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

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

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 complex brachial plexus (an injury to the network of nerves that originate in the neck). The Avance® Nerve Graft provides surgeons with a three-dimensional structure of a natural nerve. This structure is essential and allows for bridging nerve gaps or discontinuities in the range of 5mm to 70mm.

The January 2012 edition of Microsurgery and November 2012 edition of The Journal of Hand Surgery each contain an article summarizing study results from patients included in our ongoing RANGER® study, an observational study of outcomes from the use of Avance® Nerve Graft. The most recent presentation of data from the RANGER® study found that in 113 nerve repairs, the use of Avance® Nerve Graft has been associated with meaningful motor and sensory recovery in 87% of nerve discontinuities between 5 and 50 mm. According to Brooks, et al., "outcomes of Avance® Nerve Graft compare favorably with those reported in the literature for nerve autograft and the processed nerve allograft returned a higher rate of meaningful functional recovery than those reported in the literature for nerve conduits."[1] Additionally, no implant related adverse events have been reported.

Our Avance® Nerve Graft has beneficial product and sales synergies with the AxoGuard® Nerve Protector and AxoGuard® Nerve Connector. Complementary to our Avance® Nerve Graft, our AxoGuard® Nerve Connector is used to align and connect nerves with less than a 5mm gap between the severed nerve ends. Our AxoGuard® Nerve Protector is designed to protect and isolate the nerve during the healing process after surgery. Furthermore, our 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 product to remodel and form a tissue similar to the nerve epineurium.

[1] See "Business— Sales and Marketing — Avance® Nerve Graft Performance" for full citation information.

Avance® Nerve Graft has been processed and distributed since 2007 as a human cell, tissue, and cellular and tissue-based product, hereafter referred herein as HCT/P, pursuant to section 361 of the Public Health Service Act and 21 CFR § 1271 controls, based on AxoGen's good faith belief that the Avance Nerve Graft was a HCT/P tissue product. In 2010, the Food and Drug Administration, or FDA, determined that the Avance® Nerve Graft was a biological product that would be reviewed and regulated by the Center for Biologics Evaluation and Research, or CBER, under the biologics licensing provision of the Public Health Service, or PHS, Act. We subsequently agreed with the FDA on a transition plan for Avance® Nerve Graft from a HCT/P product to a licensed biological product. We are able to continue to sell Avance® Nerve Graft pursuant to a November 2010 letter from the FDA stating the agency's intent to exercise enforcement discretion with respect to the introduction or delivery for introduction into interstate commerce of the Avance® Nerve Graft provided we meet the conditions for the transition specified in the letter. One such condition is that we conduct a phase 3 clinical trial to demonstrate the safety, purity and potency of the Avance® Nerve Graft under a Special Protocol Assessment, or SPA, and the FDA has subsequently agreed to our SPA. In accordance with FDA regulations in 21 CFR §312, we submitted an Investigational New Drug Application, or IND, to the FDA in April 2013 and we are currently responding to FDA comments regarding it. We expect that enrollment of patients into the phase 3 clinical trial will occur later this year following approval of the IND.

AxoGuard® products are manufactured by Cook Biotech Incorporated, referred to herein as Cook Biotech. Under the license agreement with Cook Biotech, we are the exclusive worldwide distributor of the AxoGuard® products for use in the peripheral and central nervous system, but excluding use of the AxoGuard® product in the oral cavity for endodontic and periodontal applications and oral and maxillofacial surgery solely as they relate to dental, soft or hard, tissue repair or reconstruction. The exclusion results in certain areas of AxoGen's market expansion into the oral surgery market being limited to the Avance® Nerve Graft. The AxoGuard® products are Class II medical devices that FDA found substantially equivalent to class II predicate devices, and thus, cleared for marketing under FDA's 510(k) program.

On October 5, 2012, we entered into a Revenue Interests Purchase Agreement, which we refer to as the Royalty Contract, with PDL BioPharma, Inc., or PDL, pursuant to which we sold to PDL the right to receive specified royalties on our Net Revenues, as defined in the Royalty Contract, generated by the sale, distribution or other use of our products Avance® Nerve Graft, AxoGuard® Nerve Connector and AxoGuard® Nerve Protector, referred to as the Assigned Interests. The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments based on a 9.95% royalty rate of our Net Revenues, as defined in the Royalty Contract, subject to certain agreed upon minimum payment requirements of approximately $1.3 to $2.5 million per quarter which begin in the fourth quarter of 2014 as provided in the Royalty Contract. The total consideration PDL paid to AxoGen was $20,800,000, or the Funded Amount. The Royalty Contract also contains certain call provisions, including a call right by PDL in connection with a change of control, is secured by our Net Revenues, restricts our ability to pay dividends and grants PDL a right to a designee on our Board of Directors. Further, on October 5, 2016, or in the event of the occurrence of a material adverse event, our transfer of revenue interest or substantially all of our interest in the products or our bankruptcy or material breach of the Royalty Contract, PDL may require us to repurchase the Assigned Interests, referred to herein as the Put, at the Put Price which is equal to the sum of (i) an amount that, when paid to PDL, would generate a 20% internal rate of return to PDL, called the Put Rate, on the Funded Amount, taking into consideration payments made to PDL by us, and (ii) any Delinquent Assigned Interests Payment, as defined in the Royalty Contract, we owed to PDL. The arrangement was entered into because we could not obtain debt financing under a traditional credit facility with a lender to the extent of the Funded Amount and we believed the cost of capital for an equity transaction at the time was prohibitive.

We currently promote, market and sell our family of products through our own direct sales force and independent sales representatives. Following the publication of results from our RANGER® study in 2012, we invested in expanding our commercial capabilities and implemented a number of sales initiatives which we believe position us to further build awareness and drive sales growth of our Avance® Nerve Graft and AxoGuard® products. For the three months ended March 31, 2013, our total revenue was approximately $2.1 million and our net loss was approximately $3.4 million, with a gross margin of approximately 74%. For the twelve months ended December 31, 2012, our total revenue was approximately $7.7 million and our net loss was approximately $9.4 million, with a gross margin of approximately 75%. For the year ended December 31, 2011, our total revenue was approximately $4.8 million, and our net loss was approximately $10.2 million, with a gross margin of approximately 50%.

**Risks Associated with Our Business**

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are described in more detail in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks include the following:

- 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'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's revenue depends solely on three products.
- AxoGen is a party to the Royalty Contract with PDL which requires it to pay royalty fees that could materially adversely affect its financial position.
- 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.
- Failure to protect AxoGen's Intellectual Property rights could result in costly and time consuming litigation and its loss of any potential competitive advantage.
- The price of AxoGen's common shares could be highly volatile due to a number of factors, which could lead to losses by investors and costly securities litigation.

**Recent Developments**

On July 11, 2013, we announced the following operating results for the quarter ended June 30, 2013. The following results have been prepared by, and are the responsibility of, management and have not been reviewed or audited by our independent registered public accounting firm. We believe the following results constitute a fair representation of the financial status of AxoGen. Our financial statements for the 2013 second quarter have not yet been finalized and therefore are not available at this time.

*Revenue*

Revenues for the second quarter 2013 were $2.86 million, up 42.2% compared to $2.01 million in the second quarter 2012, driven by an increase in the number of facilities utilizing our products and increased penetration of existing accounts.

*Gross Profit*

Gross profit for the second quarter 2013 was $2.23 million, up 47.6% compared to $1.51 million in the second quarter 2012. Gross profit margin for the second quarter 2013 was 77.9%, up 2.8% compared to 75.1% in the second quarter 2012. The year-over-year improvement in gross profit and gross margin was primarily attributable to revenue growth and a product price increase implemented during the first quarter 2013, respectively.

*Operating Expenses*

Total operating expenses in the second quarter 2013 were $4.42 million, up 42.8% compared to $3.10 million in the second quarter 2012. As a percentage of revenues, operating expenses were up 0.73% in the second quarter 2013 as compared to the same period in 2012.

Second quarter 2013 sales and marketing expense was $2.53 million, up 60.0% compared to $1.58 million in the second quarter 2012. The increase was primarily attributable to increased commissions due to higher sales and the expansion of the Company's marketing efforts and direct sales force. Direct sales force personnel require time to become effective in the territory and new sales personnel hired during the first and second quarters of 2013 are not expected to contribute significantly to revenue in the third quarter of this year.

Second quarter 2013 general and administrative expense was $1.40 million, up 21.8% compared to $1.15 million in the second quarter 2012. The increase was primarily attributable to increased salary expense and benefits, travel and public company expenses.

Second quarter 2013 research and development expense was $0.50 million, up 35.7% compared to $0.37 million in the second quarter 2012. The increase was primarily attributable to costs associated with the Company's investment in clinical studies that support the use and regulatory position of the Company's products.

*Loss from Operations and Net Loss*

Operating loss in the second quarter 2013 was $2.20 million, compared to $1.59 million in the second quarter 2012. Net loss in the second quarter 2013 was $3.45 million, or ($0.31) per share, compared to net loss of $1.03 million, or ($0.09) per share, in the second quarter 2012.

*Balance Sheet*

As of June 30, 2013, the Company had $8.69 million in cash and cash equivalents and approximately $23.38 million in long-term note payable – revenue interest purchase agreement. AxoGen had working capital of approximately $12.22 million and a current ratio of 8.7 at June 30, 2013, compared to working capital of $16.82 million and a current ratio of 12.4 at December 31, 2012.

**Corporate Information**

We were incorporated under the laws of Minnesota in 1977. Our principal executive offices are located at 13859 Progress Blvd., Suite 100, Alachua, Florida 32615 and our telephone number is (386) 462-6800. Our website address is www.axogeninc.com. We have included our website address in this prospectus solely as an inactive textual reference. The information contained on, or that can be accessed through, our website is not part of this prospectus.

| The Offering | |
|---|---|
| **Common shares offered by us** | 6,000,000 shares (or 6,900,000 shares if the underwriters' over-allotment option is exercised in full) |
| **Common shares outstanding after this offering** | 17,139,939 shares (or 18,039,939 shares if the underwriters' over-allotment option is exercised in full) |
| **Use of proceeds** | We estimate that the net proceeds to us from the sale of common shares in this offering will be approximately $16,180,000 or approximately $18,691,000 if the underwriters exercise their over-allotment option in full, in each case at the public offering price of $3.00 per common share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to continue our product commercialization and marketing efforts, development of our product pipeline, including product line extensions, and for general working capital purposes. See "Use of Proceeds." |
| **Current trading on OTCQB Marketplace** | Our common shares currently trade on the OTCQB Marketplace under the symbol "AXGN." |
| **Listing** | In connection with this offering we have been approved to list our common shares on the NASDAQ Capital Market under the symbol "AXGN." |
| **Risk factors** | You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in our common shares. |

(1) The number of our common shares outstanding after this offering is based on 11,139,939 common shares outstanding as of August 8, 2013 and assumes no exercise of the underwriter's option to purchase an additional 900,000 shares to cover over-allotments, and excludes:

- 1,986,276 common shares issuable upon the exercise of options outstanding as of August 8, 2013 at a weighted average exercise price of $2.67 per share;
- 89,686 common shares issuable upon the exercise of warrants outstanding as of August 8, 2013 at an exercise price of $2.23 per share; and
- 602,914 additional common shares available for future issuance as of August 8, 2013 under our AxoGen 2010 Stock Incentive Plan.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the outstanding options or the warrants described above.

**Summary Consolidated Financial Data**

The summary financial data below as of and for the years ended December 31, 2012, 2011 and 2010 have been derived from our audited consolidated financial statements. Our audited consolidated financial statements as of December 31, 2012 and 2011 and for the years ended December 31, 2012 and 2011 are included elsewhere in this prospectus. Our audited consolidated financial statements as of December 31, 2010 and for the year ended December 31, 2010 are not included in this prospectus. The summary financial data as of March 31, 2013 and 2012 and for the three months ended March 31, 2013 and 2012 have been derived from our consolidated financial statements included elsewhere in this prospectus. You should read the summary financial data together with "Capitalization," "Management's Discussion and Analysis of Financial Condition" and "Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

| Statement of operations data: | Three months ended March 31, | | Years ended December 31, | | |
|---|---|---|---|---|---|
| | 2013 | 2012 | 2012 | 2011 | 2010 |
| | (in thousands, except share and per share data) | | | | |
| Revenues | $ 2,143 | $ 1,653 | $ 7,692 | $ 4,849 | $ 3,004 |
| Cost of goods sold | 560 | 439 | 1,962 | 2,427 | 1,379 |
| Gross Profit | 1,583 | 1,214 | 5,730 | 2,422 | 1,625 |
| Costs and expenses: | | | | | |
| Sales and marketing | 1,894 | 1,629 | 6,884 | 4,379 | 3,007 |
| Research and development | 407 | 296 | 1,427 | 697 | 436 |
| General and administrative | 1,606 | 1,230 | 5,221 | 4,316 | 2,664 |
| Total Costs and Expenses | 3,907 | 3,155 | 13,532 | 9,392 | 6,107 |
| Loss from operations | (2,324) | (1,941) | (7,802) | (6,970) | (4,482) |
| Total other income (expense) | (1,114) | (168) | (2,354) | (2,250) | (942) |
| Net Loss | (3,438) | (2,109) | (10,156) | (9,220) | (5,424) |
| Net loss available to common shareholders | $ (3,438) | $ (2,109) | $ (9,418) | $ (10,248) | $ (6,990) |
| Weighted average basic and diluted common shares outstanding | 11,124,633 | 11,062,339 | 11,089,425 | 3,697,390 | 836,645 |
| Loss Per Common Share – basic and diluted | $ (0.31) | $ (0.19) | $ (0.85) | $ (2.77) | $ (8.35) |

| Balance sheets data: | As of March 31, 2013 | As of March 31, 2012 | As of December 31, 2012 | As of December 31, 2011 | As of December 31, 2010 |
|---|---|---|---|---|---|
| | | | (in thousands) | | |
| Cash and Cash equivalents | $ 11,200 | $ 5,642 | $ 13,907 | $ 8,191 | $ 1,799 |
| Total assets | $ 17,852 | $ 10,477 | $ 20,231 | $ 12,495 | $ 6,406 |
| Total liabilities | $ 23,857 | $ 6,357 | $ 23,060 | $ 6,424 | $ 18,105 |
| Temporary equity | — | — | — | — | 15,412 |
| Total shareholders' equity (deficit) | $ (6,005) | $ 4,120 | $ (2,829) | $ 6,071 | $ (27,111) |

| Statements of cash flows data: | Three months ended March 31, 2013 | Three months ended March 31, 2012 | Years ended December 31, 2012 | Years ended December 31, 2011 | Years ended December 31, 2010 |
|---|---|---|---|---|---|
| | | | (in thousands) | | |
| Net cash used for operating activities | $ (2,651) | $ (2,478) | $ (8,662) | $ (7,079) | $ (3,943) |
| Net cash (used for) provided by investing activities | (57) | (71) | (127) | 7,112 | (72) |
| Net cash provided by financing activities | $ 2 | $ 0 | $ 14,506 | $ 6,359 | $ 5,531 |

## RISK FACTORS

*Investing in our common shares involves a high degree of risk. Before you decide to invest in our securities, you should consider carefully the risks described below, as well as the other information contained in this prospectus. The risks described below are not the only ones facing us. Additional risks not presently known to us or that we currently deemed immaterial may also impair our business operations.*

*If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common shares could decline, and you may lose all or part of your investment.*

### Risks Related To Company

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

AxoGen has historically operated with negative cash flow from its operations. As of March 31, 2013, AxoGen had an accumulated deficit of approximately $61.0 million. If AxoGen product sales do not increase as anticipated, then it will continue to experience negative cash flows and adverse operating conditions. AxoGen's continuing capital needs and other factors, could cause the Company to raise additional funds through public or private equity offerings, debt financings or from other sources. The sale of additional equity may result in dilution to AxoGen's shareholders. There is no assurance that AxoGen will be able to secure funding on terms acceptable to it, or at all.

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

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

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

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

The AxoGuard® products are only available through an exclusive distribution agreement with Cook Biotech. Such contract is for an initial seven year term and following such initial term, the agreement automatically renews for an additional seven (7) year period provided that the parties agree to meet at least ninety (90) days before the end of such initial term to review whether the purchase price of the products obtained from Cook Biotech need to be adjusted and reasonably agree to such adjustment in writing, where such agreement shall not be unreasonably withheld. However, there are conditions for continuation of the agreement, including payment terms and minimum purchase requirements, that if breached could result in an earlier termination of the agreement; except that through mutual agreement the parties have not established such minimums and to date have not enforce such minimum purchase provision. Additionally, in the event that AxoGen and Cook Biotech were to fail to reach an agreement as to minimum purchase

quantities, Cook Biotech could terminate the agreement if it was deemed that AxoGen had failed to generate commercially reasonable sales of AxoGuard® as measured by sales similar to a competitive product at the same stage in its commercial launch as verified by a mutually acceptable third-party. Although there are products that AxoGen believes it could develop or obtain that would replace the AxoGuard® products, the loss of the ability to sell the AxoGuard® products could have a material adverse effect on AxoGen's business until other replacement products are available.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

AxoGen products compete with autograft and hollow-tube conduits, as well as with alternative medical procedures. For the foreseeable future, AxoGen believes a significant number of surgeons will continue to choose to perform autograft procedures when feasible, despite the necessity of performing a second operation and its drawbacks. In addition, many members of the medical community will continue to prefer the use of hollow-tube conduits due in part to their familiarity with these products and the procedures required for their use. Also, steady 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 the United Kingdom, the Netherlands, 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, quantity and timing of donor medical releases, such as effectiveness of donor screening (currently performed by donor recovery groups), the effective recovery of tissue, the timely receipt, recording and review of required medical documentation, and employee loss and turnover in AxoGen's and its contractor's recovery department. AxoGen can provide no assurance that tissue recovery or donor medical releases will occur at levels that will maximize processing efficiency and minimize AxoGen's cost per allograft processed.

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

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

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

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

During 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. The increasing need for capital as the PDL transaction matures could also make it more difficult to obtain funding through either equity or debt. See "Notes to Consolidated Financial Statements – Footnote 7 Long-Term Debt/Note Payable."

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

In the event of a "Change of Control" (as defined in the Royalty Contract), AxoGen must repurchase the Assigned Interests from PDL for a repurchase price equal to the "Change of Control Price" on or prior to the third business day after the occurrence of the Change of Control. The Change of Control Price is the sum of (i) an amount that, when paid to PDL, would generate an internal rate of return to PDL of

thirty-two and one half percent (32.5%) on all payments made by PDL pursuant to the Royalty Contract as of the date of the Change of Control Payment (as defined in the Royalty Contract), taking into account the amount and timing of all payments made by AxoGen to PDL (and retained by PDL) prior to and as of the date of payment of the Change of Control Payment, plus (ii) any Delinquent Assigned Interests Payment owed. For purposes of example only, the Change of Control payment at March 31, 2013 would have been $23,439,186. Payment of the Change of Control Price could materially reduce the consideration to be received by AxoGen shareholders if the Change of Control event was in conjunction with the acquisition of the Company.

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

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

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

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

In our annual report for the period ended December 31, 2011, we reported a material weakness in our internal control over financial reporting, which related to an instance in which the accounting for a contract was inappropriately treated as an expense as opposed to a prepaid asset. 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. 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, 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 most recent evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2012.

Although we believe we took appropriate actions to remediate the control deficiencies we identified and to strengthen our internal control over financial reporting, we cannot assure you that we will not discover other material weaknesses in the future or that no material weakness will result from any difficulties, errors, delays or disruptions while we implement and transition to new internal systems. The existence of one or more material weaknesses could result in errors in our financial statements, and substantial costs and resources may be required to rectify these or other internal control deficiencies. If we cannot produce reliable financial reports, investors could lose confidence in our reported financial information, the market price of our common stock could decline significantly, we may be unable to obtain additional financing to operate and expand our business, and our business and financial condition could be harmed.

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

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

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

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

The use, misuse or off-label use of AxoGen's products may harm its reputation or the image of its products in the marketplace, or result in injuries that lead to product liability suits, which could be costly to AxoGen's business or result in FDA sanctions if the company is deemed to have engaged in off-label promotion. AxoGen is seeking a biologics license through the BLA process for specific uses of Avance® Nerve Graft under specific circumstances. Its promotional materials and training methods must comply with FDA requirements and other applicable laws and regulations, including the prohibition against off-label promotion. AxoGen's promotion of the AxoGuard® products, which are regulated as medical devices, also must comply with FDA's requirements and must only use labeling that is consistent with the specific indication(s) for use included in FDA's substantial equivalence order that results in marketing the devices. The FDA does not restrict or regulate a physician's use of a medical product within the practice of medicine, and AxoGen cannot prevent a physician from using its products for an off-label use. However, the Federal Food, Drug, and Cosmetic Act, referred to herein as the FD&C Act, and the FDA's regulations restrict the kind of promotional communications that may be made about AxoGen's products and if the

FDA determines that AxoGen's promotional or training materials constitute the unlawful promotion of an off-label use, it could request that AxoGen modify its training or promotional materials and/or subject the Company to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, civil money penalties, or criminal fines and penalties. Other federal, state or foreign governmental authorities might also take action if they consider AxoGen promotion or training materials to constitute promotion of an uncleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement, or exclusion from participation in federal health programs. In that event, AxoGen's reputation could be damaged and the use of its products in the marketplace could be impaired.

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

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

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

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

AxoGen's AxoGuard® product line is regulated as a medical device under the FD&C Act and subject to premarket notification and clearance requirements under section 510(k) of the FD&C Act, 21 CFR Part 820 (Quality System Regulation) and other FDA regulations. AxoGen distributes for Cook Biotech Incorporated the AxoGuard® product line and Cook Biotech is responsible for the regulatory compliance of the AxoGuard® product line. Cook Biotech has obtained a 510(k) premarket clearance from the FDA for porcine 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 or withdraw 510(k) clearance for the AxoGuard® products, or impose civil penalties, including fines, product seizures or product recalls and, in certain cases, criminal sanctions.

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

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

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

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

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

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

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

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

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

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

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

AxoGen will rely on third parties, such as contract research organizations ("CROs"), medical institutions, clinical investigators and contract laboratories to conduct its clinical trial and certain nonclinical studies. AxoGen and its CROs are required to comply with all applicable regulations governing clinical research, including good clinical practice, or GCP. The FDA enforces these regulations through periodic inspections of trial sponsors, principal investigators, CROs and trial sites. If AxoGen or its CROs fail to comply with applicable FDA regulations, the data generated in its clinical trials may be deemed unreliable and the FDA may require AxoGen to perform additional clinical trials before approving its applications. AxoGen cannot be certain that, upon inspection, the FDA and similar foreign regulatory authorities will determine that AxoGen's clinical trial complies or complied with clinical trial regulations, including GCP. In addition, AxoGen's clinical trial must be conducted with product produced under applicable current Good Manufacturing Practice, or GMP, regulations. Failure to comply with the clinical trial regulations may require AxoGen to repeat clinical trials, which would delay the regulatory approval process. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data

they obtain is compromised due to the failure to adhere to AxoGen's clinical protocols or regulatory requirements or for other reasons, AxoGen's non-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and it would not be able to obtain regulatory approval for, its products on a timely basis, if at all, and its business, results of operations, financial condition and growth prospects would be adversely affected. Furthermore, AxoGen's third-party clinical trial investigators may be delayed in conducting its clinical trials for reasons outside of their control.

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

In addition to the FDA requirements for biological products, the Avance® Nerve Graft will continue to be subject to various requirements for human tissue under 21 CFR Part 1271 controls. Human tissues intended for transplantation have been regulated by the FDA since 1993. In May 2005, three new comprehensive regulations went into effect that address manufacturing activities associated with HCT/P. The first requires that companies that produce and distribute HCT/Ps register with the FDA. The second provides criteria that must be met for donors to be eligible to donate tissues and is referred to as the "Donor Eligibility" rule. The third rule governs the processing and distribution of the tissues and is often referred to as the Current Good Tissue Practices rule. The Current Good Tissue Practices rule covers all stages of allograft processing, from procurement of tissue to distribution of final allografts. Together, they are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients. These regulations increased regulatory scrutiny within the industry in which AxoGen operates and have led to increased enforcement action, which affects the conduct of its business. See "Business — Government Regulations." These regulations can also increase the cost of tissue recovery activities. Additionally, the Avance® Nerve Graft is subjected to certain state and local regulations, as well as compliance to the standards of the tissue bank industry's accrediting organization, the American Association of Tissue Banks ("AATB").

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

AxoGen's 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.

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

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

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

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

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

***AxoGen depends on maintenance of exclusive licenses.***

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

**Risk Related to this Offering**

***Until our common stock is listed on a qualified national securities exchange or our common stock price exceeds $5 per share, our common stock will be considered a "penny stock" and will not qualify for exemption from the "penny stock" restrictions, which may make it more difficult for you to sell your shares.***

Prior to this offering, our common shares have traded on the OTCQB Marketplace at a price of less than $5.00 per share and, as a result, is considered as a "penny stock" by the SEC and subject to rules adopted by the SEC regulating broker-dealer practices in connection with transactions in "penny stocks." The SEC has adopted regulations which generally define a "penny stock" to be any equity security that is not listed on a qualified national securities exchange and that has a market price of less than $5.00 per share, or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, these rules require delivery, prior to any transaction in a penny stock, of a disclosure schedule relating to the penny stock market. Disclosure is also required to be made about current quotations for the securities and commissions payable to both the broker-dealer and the registered representative. Finally, broker-dealers must send monthly statements to purchasers of penny stocks disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. As a result of our common shares being subject to the rules on penny stocks, the liquidity of our common shares may be adversely affected.

In connection with this offering, we have been approved to list our common shares on the NASDAQ Capital Market. To the extent that our common shares continue to be listed on the NASDAQ Capital Market, and we meet certain minimum financial metrics, our common shares will no longer be considered as a "penny stock."

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

Prior to this offering, our common shares have traded on the OTCQB Marketplace in limited volumes. In connection with this offering, we have been approved to list our common shares on the NASDAQ Capital Market. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on that stock exchange or any other exchange in the future. The trading price of our common shares has experienced substantial volatility while trading on the OTCQB Marketplace and is likely to continue to be highly volatile in response to a number of factors including, without limitation, the following:

- trading of AxoGen common shares on the OTCQB;
- limited daily trading volume resulting in the lack of a liquid market;

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

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

***Prior to this offering, AxoGen did not meet the criteria to list its common shares on an exchange such as the NYSE — MKT or NASDAQ Stock Market and its common shares lack liquidity and may be difficult to sell.***

Prior to this offering, trading of AxoGen's common stock has been conducted on the OTCQB. Generally, securities that are quoted on the OTCQB lack liquidity and analyst coverage. This may result in lower prices for its common shares and a larger spread between the bid and asked prices for its common shares than might otherwise be obtained if it met the criteria to list its securities on a larger or more established exchange. We have been approved to list our common shares on the NASDAQ Capital Market and anticipate that simultaneously with the closing of the sale of the shares pursuant to this Prospectus our common stock will trade on such exchange. The NASDAQ Capital Market has provided us requirements necessary to obtain such listing, which include completion of this offering and payment of the applicable listing entry fee. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on that stock exchange or any other exchange in the future. Additionally, listing on an exchange will result in increased costs and regulatory requirements.

***Our use of the offering proceeds may not yield a favorable return on your investment.***

We currently anticipate that the net proceeds from this offering will be used primarily for continued product commercialization and marketing efforts, development of product pipeline, including product line extension, and for general working capital purposes. Pending the application of the net proceeds, we intend to invest the net proceeds in investment-grade, interest-bearing securities. Our management has broad discretion over how these proceeds are used and could spend the proceeds in ways with which you may not agree, and the proceeds may not be invested in a manner that yields a favorable or any return.

***As a new investor, you will incur substantial dilution as a result of this offering and future equity issuances, and as a result, our share price could decline.***

The offering price will be substantially higher than the net tangible book value per share of our outstanding common shares. As a result, based on our capitalization as of March 31, 2013, investors purchasing common shares in this offering will incur immediate and substantial dilution of $1.85 per share, based on the offering price of $3.00 per share. In addition to this offering, subject to market conditions and other factors, we likely will pursue raising additional funds in the future, as we continue to build our business. In future years, we will likely need to raise significant additional funding to finance our operations and to fund clinical trials, regulatory submissions and the development, manufacture and marketing of other products under development and new product opportunities. Accordingly, we may conduct substantial future offerings of equity or debt securities. The exercise of outstanding options and warrants and future equity issuances, including future public offerings or future private placements of equity securities and any additional shares issued in connection with acquisitions, will also result in dilution to investors. In addition, the market price of our common shares could fall as a result of resales of any of these shares of common stock due to an increased number of shares available for sale in the market.

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

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

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

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

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

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

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

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

From time to time, in reports filed with the Securities and Exchange Commission (including this registration statement), 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 registration statement 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 this registration statement. 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.

You should read this prospectus and the documents that we reference in this prospectus and have been filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any issuance or sale of our common shares. Except as required by law, we do not assume any obligation to update any forward-looking statements.

## USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of common shares in this offering will be approximately $16,180,000 or approximately $18,691,000 if the underwriters exercise their over-allotment option in full, at the public offering price of $3.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering for continued product commercialization and marketing efforts, development of product pipeline, including product line extension, and for general working capital purposes. We have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures.

Therefore, investors will be relying on the judgment of our management, who will have broad discretion regarding the application of the proceeds of this offering. The amounts and timing of our actual expenditures will depend upon numerous factors, including the amount of cash generated by our operations, our cash needs, the rate of adoption of our products by the medical community and efficiency of our product development. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes.

Pending the application of the net proceeds, we intend to invest the net proceeds in investment-grade, interest-bearing securities. Our management has broad discretion over how these proceeds are used and could spend the proceeds in ways with which you may not agree, and the proceeds may not be invested in a manner that yields a favorable or any return.

## 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 additional, the PDL Royalty Contract places certain restrictions on AxoGen's ability to pay dividends.

## COMMON SHARE PRICE RANGE

Prior to this offering, our common shares have been traded on the OTCQB Marketplace 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 our common shares quoted on the OTCQB Marketplace. The prices in the table represent prices between dealers and do not include adjustments for retail mark-up, markdown or commission and may not represent actual transactions.

| | January 1, 2013 through August 8, 2013 | | Year Ended December 31, 2012 | | Year Ended December 31, 2011 | |
|---|---|---|---|---|---|---|
| | High | Low | High | Low | High | Low |
| First Quarter | $ 4.25 | $ 2.75 | $ 3.49 | $ 2.60 | $ 4.00 | $ 2.75 |
| Second Quarter | $ 5.08 | $ 3.66 | $ 3.99 | $ 2.51 | $ 3.37 | $ 2.17 |
| Third Quarter (through August 8, 2013) | $ 4.45 | $ 3.70 | $ 3.25 | $ 2.50 | $ 3.00 | $ 2.00 |
| Fourth Quarter | — | — | $ 3.10 | $ 2.25 | $ 3.10 | $ 2.05 |

The last reported sale price for our common shares on August 8, 2013 was $3.85 per share. As of June 14, 2013, there were approximately 303 registered holders of record of our common shares, 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. We believe that there are a significantly larger number of beneficial owners of our common shares than the number of record holders. In connection with this offering, we have been approved to list our shares on the NASDAQ Capital Market under the symbol "AXGN."

## CAPITALIZATION

The following table describes our capitalization as of March 31, 2013:

- on an actual basis; and
- on an as adjusted basis to give effect to the sale of 6,000,000 of our shares in this offering at the public offering price of $3.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses.

You should read this capitalization table together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Use of Proceeds," "Summary Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections and other financial information included in this prospectus.

| | As of March 31, 2013 | |
|---|---|---|
| | Actual | As Adjusted |
| | (in thousands, except share and per share data) | |
| Long-term debt | 22,438 | 22,438 |
| Shareholders' equity (deficit): | | |
| Common Share, $.01 par value; 50,000,000 shares authorized, 11,127,869 shares issued and outstanding | 111 | 171 |
| Additional paid-in capital | 55,170 | 71,290 |
| Accumulated deficit | (61,286) | (61,286) |
| Total shareholders' equity (deficit) | (6,005) | 10,175 |
| Total capitalization | $ 16,433 | $ 32,613 |

The number of our common shares outstanding after this offering is based on 11,139,939 common shares outstanding as of August 8, 2013 and assumes no exercise of the underwriter's option to purchase an additional 900,000 shares to cover over-allotments, and excludes:

- 1,986,276 common shares issuable upon the exercise of options outstanding as of August 8, 2013 at a weighted average exercise price of $2.67 per share;
- 89,686 common shares issuable upon the exercise of warrants outstanding as of August 8, 2013 at an exercise price of $2.23 per share; and
- 602,914 additional common shares available for future issuance as of August 8, 2013 under our AxoGen 2010 Stock Incentive Plan.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the outstanding options or the warrants described above.

## DILUTION

Our net tangible book value as of March 31, 2013 was approximately $(6.6) million, or $(0.59) per common share. Net tangible book value per share is determined by dividing our total tangible assets less total liabilities by the actual number of outstanding shares of our common shares. After giving effect to our issuance of 6,000,000 shares at the public offering price of $3.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of March 31, 2013 would have been $9.6 million or $0.56 per common share. This represents an immediate increase in pro forma net tangible book value of $1.15 per share to our existing shareholders and an immediate dilution of $1.85 per share to new investors in this offering. The following table illustrates this per share dilution:

| | | |
|---|---|---|
| Public offering price per share | | $ 3.00 |
| Net tangible book value per share as of March 31, 2013 | $ (0.59) | |
| Increase per share attributable to new investors | $ 0.56 | |
| Pro forma net tangible book value per share after this offering | | $ 1.15 |
| Dilution per share to new investors | | $ 1.85 |

Information in the above table is based on 11,127,869 shares of common stock outstanding as of March 31, 2013, and excludes:

- 1,943,689 common shares issuable upon the exercise of options outstanding as of March 31, 2013 at a weighted average exercise price of $2.60 per share;
- 89,686 common shares issuable upon the exercise of warrants outstanding as of March 31, 2013 at an exercise price of $2.23 per share; and
- 657,571 additional common shares available for future issuance as of March 31, 2013 under our AxoGen 2010 Stock Incentive Plan.

Dilution per share to new investors is determined by subtracting pro forma net tangible book value per share after this offering from the public offering price per share paid by a new investor. If any shares are issued in connection with outstanding options or the underwriter's over-allotment option, you will experience further dilution.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes, and the financial and other information included elsewhere in this prospectus. Among other things, those financial statements include more detailed information regarding the basis of presentation for the following information. The financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, and are presented in U.S. dollars.*

*This discussion contains forward-looking statements that involve risks and uncertainties based on assumptions about our future business. Our actual results may differ from those contained in the forward-looking statements and such differences may be material as a result of a number of factors. Please read "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements."*

### Overview

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. 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 years ended December 31, 2011 and 2010 include the operations and cash flows of AC through September 30, 2011 and the combined operations and cash flows of 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 muscle function and feeling. In order to improve the options available for the surgical repair and regeneration of peripheral nerves, AxoGen has developed and licensed patented and patent pending technologies. AxoGen's innovative approach to regenerative medicine has resulted in first-in-class products that it believes will define their product categories. AxoGen's products offer a full suite of surgical nerve repair solutions including Avance® Nerve Graft, the only off-the-shelf commercially available processed nerve allograft, human nerve tissue obtained from a donor, for bridging severed nerves without the comorbidities of an autograft second surgical site, such as loss of feeling where the nerve was removed and potential pain at the donor site. The Company's AxoGuard® line of products are a natural scaffold ExtraCellular Matrix, or ECM, derived from pig tissue. AxoGuard® Nerve Connector is used to facilitate the tensionless repair of severed nerves and AxoGuard® Nerve Protector is used to wrap and protect injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments.

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 first quarter of 2013 and the twelve months of 2012 compared to the first quarter 2012 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 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.

*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 F-7 of this registration statement. We have identified the following policies as critical to our business operations and the understanding of our consolidated results of operations:

Accounts Receivable and Concentration of Credit Risk – Doubtful Accounts

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. If deemed necessary we maintain an allowance for doubtful accounts for estimated losses inherent in our accounts receivable portfolio. In establishing the required allowance, management considers customers' financial condition, credit history and current economic conditions. To date, we have not reserved for doubtful accounts as they have been immaterial both in number and dollar amount. Account balances are charged off after all means of collection have been exhausted and the potential for recovery is considered remote. Our internal financial operations have primary responsibility for billing and collecting our accounts receivable. We utilize various processes and procedures in our collection efforts; these efforts include monthly statements, written collection notices and telephonic follow-ups. In the event the current conditions as to doubtful accounts negatively changes, management will consider reserving for doubtful accounts. Management judgment as to identifying negative trends is important in its assumption of exposure to uncollectable receivables requiring a reserve and if revenues expand as expected accounts receivable will rise potentially causing management to reevaluate its underlying assumptions.

Goodwill

Goodwill represents the excess of the purchase price over the net tangible and intangible assets acquired in business combinations. The Company is required to perform a review for impairment of goodwill in accordance with FASB ASC 350, Intangibles — Goodwill and Other. Goodwill is considered to be impaired if it is determined that the carrying value of goodwill exceeds its fair value. The Company conducts an impairment test of goodwill each year end. In addition to the annual review, an interim review is required if an event occurs or circumstances change that would more likely than not reduce the fair value of the goodwill below its carrying amount.

Effective Interest Rate on Note Payable

The PDL Royalty Contract is accounted for as long-term debt. The Company records interest using its best estimate of the effective interest rate. This estimate takes into account both the internal rate of return (IRR) of the PDL agreement and the rate of return as the result of exercise of the Put option. The IRR of the PDL Royalty Contract is based on the actual payments to date, projected future revenues and required minimum payments, and is calculated at 19.85%. The PDL Royalty Contract Put option provides PDL a 20% return, if exercised. As a result of the return of the Put option being higher than the IRR of the PDL agreement, management believes the best estimate of the effective interest rate on this instrument would be the Put rate. As a result, the Company is accruing interest using the specified internal rate of return for the Put which is 20%. We currently have no knowledge of PDL's intent to exercise the Put, but will monitor this on an ongoing basis. From time to time, the Company will reevaluate the expected cash flows and may adjust the effective interest rate. Since inception of the Royalty Contract, if the interest rate utilized were to change by 1% the effect on interest expense through March 31, 2013 would increase or decrease by approximately $110,000. Determining the effective interest rate requires judgment and is based on significant assumptions related to estimates of the amounts and timing of future revenue streams and PDL's ultimate decision to exercise the Put. Determination of these assumptions is highly subjective and different assumptions could lead to materially different outcomes.

Income Taxes

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

**Results of Operations**

***Comparison of Three Months Ended March 31, 2013 and 2012 and the Years Ended December 31, 2012 and 2011***

Revenues

Revenues for the three months ended March 31, 2013 increased 29.6% to approximately $2,143,000 as compared to approximately $1,653,000 for the three months ended March 31, 2012. Additionally, 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. Such increases were principally due to a greater number of customers utilizing AxoGen products and increased product usage by existing accounts. For the three months ended March 31, 2013, new AxoGen customers in that quarter represented approximately $149,000 of total revenue for such quarter or approximately 7%. For the year ended December 31, 2012 new customers in 2012 represented approximately $859,000 of total revenue in 2012 or approximately 11%. Each new customer in a defined period has the potential to become an established customer that increases its purchasing. As such, revenue growth occurs from both new customers who purchase for the first time in a period and increased purchasing from established customers. Each new period of measurement is thus benefited from the additional new customers added in the prior period.

Gross Profit

Gross profit for the three months ended March 31, 2013 increased 30.4% to approximately $1,583,000 as compared to approximately $1,214,000 for the three months ended March 31, 2012, primarily attributable to the increased revenues in the first quarter of 2013, manufacturing efficiencies and a product price increase instituted in March 2013 which contributed approximately $30,000 or approximately 1.5%, partially offset by an increase in the inventory reserve. 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 in the aggregate amount of $828,000 or higher processing and testing fees, travel costs and temporary labor costs due to the resumption of the manufacturing of Avance® Nerve Graft as experienced in 2011. The 2011 inventory write-offs consisted of two items. The first item was approximately $614,000 for Avance® Nerve Graft finished goods inventory and the second was related to $214,000 of raw materials related to the Avance® Nerve Graft, both of these items were deemed to be excess inventory. During the third quarter of 2011 management made certain strategic decisions in response to market demand, and anticipated trends, that resulted in a portion of the finished goods and raw materials inventory to become excess.

Costs and Expenses

Total cost and expenses increased 23.8% to approximately $3,906,000 for the three months ended March 31, 2013 as compared to approximately $3,155,000 for the three months ended March 31, 2012. 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 in the first quarter 2013 and the 2012 fiscal year were primarily due to increasing sales and marketing activities and increases in salaries as AxoGen hired additional personnel to meet its current and expected growth. To a lesser extent, these increases were also attributable to expenses associated with being a public company and research and development costs associated with the Company's preparation for its clinical trial. For the fiscal year 2012 these increases were partially offset by decreases in certain professional services and financing costs.

As a percentage of revenues, total operating expenses were 182.3% for the three months ended March 31, 2013 compared to 190.9% for the three months ended March 31, 2012. 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 in the first quarter 2013 and the 2012 fiscal year were primarily a result of the Company's revenue increase outpacing costs and expenses increase.

Sales and marketing expenses increased 16.3% to approximately $1,894,000 for the three months ended March 31, 2013 as compared to approximately $1,629,000 for the three months ended March 31, 2012. 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. The increases in the first quarter 2013 and the 2012 fiscal year were 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 in fiscal year 2012 increasing the number of its direct sales representatives. As a percentage of revenues, sales and marketing expenses were 88.4% for the three months ended March 31, 2013 compared to 98.5% for the three months ended March 31, 2012. 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. Such lower sales and marketing expenses as a percentage of revenue were a result of the revenue increases outpacing costs and expenses increases.

General and administrative expenses increased 30.5% to approximately $1,606,000 for the three months ended March 31, 2013 as compared to approximately $1,231,000 for the three months ended March 31, 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 74.9% for the three months ended March 31, 2013 compared to 74.5% for the three months ended March 31, 2012. As a percentage of revenues, general and administrative expenses were 67.9% for the year ended December 31, 2012 compared to 89.0% for the year ended December 31, 2011.

The increase in aggregate dollars spent in the first quarter 2013 and the 2012 fiscal year were a result of increased payroll and benefits, public company related expenditures, travel and other general expenses. As a percentage of revenue, general and administrative expenses decreased in the 2012 fiscal year as the increase in aggregate dollars spent were absorbed by the increase in revenues. In the first quarter 2013 as a percentage of revenue, general and administrative expenses were slighter higher as the percentage increase rise in revenue was similar to the percentage increase rise in general and administrative expenses.

Research and development expenses increased 37.5% to approximately $407,000 in the three months ended March 31, 2013 as compared to approximately $296,000 for the three months ended March 31, 2012. 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 the first quarter 2013 and the 2012 fiscal year in research and development expenses over the comparable periods 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 754% to approximately $1,068,000 in the three months ended March 31, 2013 as compared to approximately $125,000 for the three months ended March 31, 2012. 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 $895,000 of non-cash expense that is expected to be paid in the future based upon the terms of the PDL transaction and increases in AxoGen revenues. The $895,000 of non cash expense was derived from taking the total amount of imputed interest for the quarter on the PDL agreement less the actual cash payment made to PDL in the quarter. Other than the $895,000 non-cash expense, the remaining $173,000 in interest expense for the three months ended March 31, 2013 is related to cash paid for interest on the note payable. The $125,000 interest expense for the three months ended March 31, 2012 was cash paid for interest on the previous debt.

Interest expense increased 27% to approximately $1,391,000 for the year ended December 31, 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. The $780,000 of non cash expense was derived from taking the total amount of imputed interest for the year ended December 31, 2012 on the PDL agreement less the actual cash payment made to PDL for that period. Excluding this non-cash component, cash paid for interest decreased in 2012 by approximately $381,000 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 increased 25.7% to approximately $44,000 for the three months ended March 31, 2013 as compared to approximately $35,000 for the three months ended March 31, 2012. This increase is primarily due to higher deferred financing cost amortization associated with the PDL agreement when compared to the previous bank debt. 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.

Income Taxes

The Company had no income tax expenses or income tax benefit for each of the three months ended March 31, 2013 and 2012 due to incurrence of net operating loss in each of these periods. Income tax benefit of approximately $738,000 for the year ended December 31, 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.

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

of the Change of Control Payment, taking into account the amount and timing of all payments made by AxoGen to PDL (and retained by PDL) prior to and as of the date of payment of the Change of Control Payment, plus (ii) any Delinquent Assigned Interests Payment owed. The total consideration PDL paid to 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 shares at $2.23 per share. Proceeds from the PDL transaction were used to fully repay the MidCap Loan, along with a $172,581 prepayment penalty, and extinguish AxoGen's obligations thereunder.

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

On June 11, 2010, AxoGen entered into Convertible Debt Agreements for an aggregate principal amount of $3.7 million with 8% interest and principal and interest payable in full on June 30, 2013, as amended. The Convertible Debt Agreements were collateralized by a third lien on certain property and were subordinated to the 2008 Loan and Security Agreement. Immediately prior to the closing of the Merger, the Convertible Debt Agreements pursuant to their terms automatically converted into AC common stock which was then exchanged for Company common shares 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 March 31, 2013 or December 31, 2012 or 2011. Under the Royalty Contract, the Company sold to PDL the Acquired Revenues and PDL is to receive for eight years the Assigned Interests, i.e., a royalty payment based on a 9.95% royalty rate of the Company's Net Revenues, subject to certain agreed upon minimum payments of approximately $1.3 to $2.5 million per quarter, and was provided the Put and receives certain payments in the event of a

Change of Control. 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 where used to fully repay the MidCap Loan and extinguish AxoGen's obligations thereunder. There are no financial covenants or other restrictions on the use of capital by AxoGen as a result of the Royalty Contract, however, PDL has a first perfected security interest in the Assigned Interests. In the event that the Company is unable to generate revenue in excess of its PDL Assigned Interests payments and other expenses, or PDL were to exercise the Put at a time when the Company did not have sufficient capital to pay the Put Price, AxoGen would need to raise additional capital. There is no assurance that if AxoGen is required to secure funding it can do so on terms acceptable to it, or at all, and its liquidity would be severely compromised.

**Cash Flow Information**

AxoGen had working capital of approximately $14.5 million and a current ratio of 11.23 at March 31, 2013, compared to working capital of $16.8 million and a current ratio of 12.4 at December 31, 2012. The decrease in working capital and the current ratio at March 31, 2013 as compared to December 31, 2012 was primarily due to the use of working capital for operations in excess of revenues. 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, and the corresponding royalty payments of approximately $1.3 to $2.5 million per quarter due to PDL and pursuant to AxoGen's licensing agreements in connection with Avance® Nerve Graft, cost of products and acquisition and/or development of new products. In particular, if revenue does not increase by fourth quarter 2014 to a level whereby the 9.95% royalty owed to PDL on AxoGen's gross revenues exceeds the PDL minimum royalty payments at such time of approximately $1.3 million, and such differential continues, or grows larger as the PDL minimum royalty payments increase, AxoGen would face increasing capital needs. Such capital needs could be substantial depending on the extent to which AxoGen is unable to increase revenue.

As a result of AxoGen's continuing capital needs and other factors, it has decided to raise additional funds through this registration statement. The sale of additional equity may result in dilution to AxoGen's shareholders. There is no assurance that AxoGen will be able to secure funding on terms acceptable to it, or at all. The increasing need for capital as the PDL transaction matures could also make it more difficult to obtain funding through either equity or debt. Should additional capital not become available to AxoGen as needed, AxoGen may be required to take certain action, such as, slowing sales and marketing expansion, delaying regulatory approvals or reducing headcount. During the three months ended March 31, 2013, the Company had a net decrease in cash and cash equivalents of approximately $2,707,000 as compared to a net decrease of cash and cash equivalents of approximately $2,549,000 in the three months ended March 31, 2012. The Company's principal sources and uses of funds are explained below:

Cash used in operating activities

The Company used approximately $2,651,000 of cash for operating activities in the three months ended March 31, 2013, as compared to using approximately $2,478,000 of cash for operating activities in the three months ended March 31, 2012. This increase in cash used in operating activities is primarily attributed to the net loss generated in the three months ended March 31, 2013, along with an increase in our accounts receivable and inventory.

Cash used for investing activities

Investing activities for the three months ended March 31, 2013 used approximately $57,000 of cash as compared to using approximately $71,000 of cash in the three months ended March 31, 2012. This increase in use is principally attributable to the purchase of certain fixed and intangible assets.

Cash provided by financing activities

Financing activities in the three months ended March 31, 2013 provided $1,654 of cash as compared to providing $0 of cash in the three months ended March 31, 2012. The Company did not incur any debt issuance costs in 2013.

**Off-Balance Sheet Arrangements**

AxoGen does not have any off-balance sheet arrangements.

# BUSINESS

## General

We are 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 muscle function and/or feeling.

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

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

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 complex brachial plexus (an injury to the network of nerves that originate in the neck). The Avance® Nerve Graft provides surgeons with a three-dimensional structure of a natural nerve. This structure is essential and allows for bridging nerve gaps or discontinuities the range of 5mm to 70mm. 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 outermost layer of the nerve (nerve epineurium).

*Regenerative Medical Products Industry*

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

We believe the primary driver of sustained growth in the regenerative medical product market is continued favorable efficacy as compared to autograft 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 and rely on:

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

ii. Cells to regenerate or recellularize the scaffold.

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

*Peripheral Nerves and Their Regeneration*

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

Given the right conditions, peripheral nerves have the ability to regenerate. Regenerating axons require the proper environmental conditions including; structure and guidance of axons in a tension and compression free environment. In an untreated severe crush injury or transected nerve, errant axons that are not guided by the nerve sheath structure, or other mechanism, can form painful and ineffective nerve proliferation (neuromas). This can then require revision surgery to relieve pain or bring back sensory and/or motor functionality. Therefore, the surgical treatment of nerve injuries is typically focused on restoring nerve functionality by providing structural guidance to regenerating axons while 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 1.4 million people suffer traumatic injuries to peripheral nerves resulting in at least 700,000 nerve repair procedures in the U.S. annually. ("Health", United States, 2011, Publication of U.S. Department of Health & Human Services; Noble, et al. J of Trauma Injury Infection and Critical Care 1998).

Beyond traumatic injury to nerves, nerve damage also occurs due to surgical intervention. 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.

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 – the surgeon can attempt to fix the damaged nerve but must create an additional nerve deficit. For example, a patient may opt to get movement and feeling back in their finger while losing some sensation in their foot. Additionally, the secondary surgery to obtain the needed autograft also increases operating time, and thus medical expenses, and increases the risk of surgical infection and other complications. In the case of extreme trauma where multiple nerves need to be repaired, it may not be possible to recover enough nerve from the patient to complete the repair.

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, we believe 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.

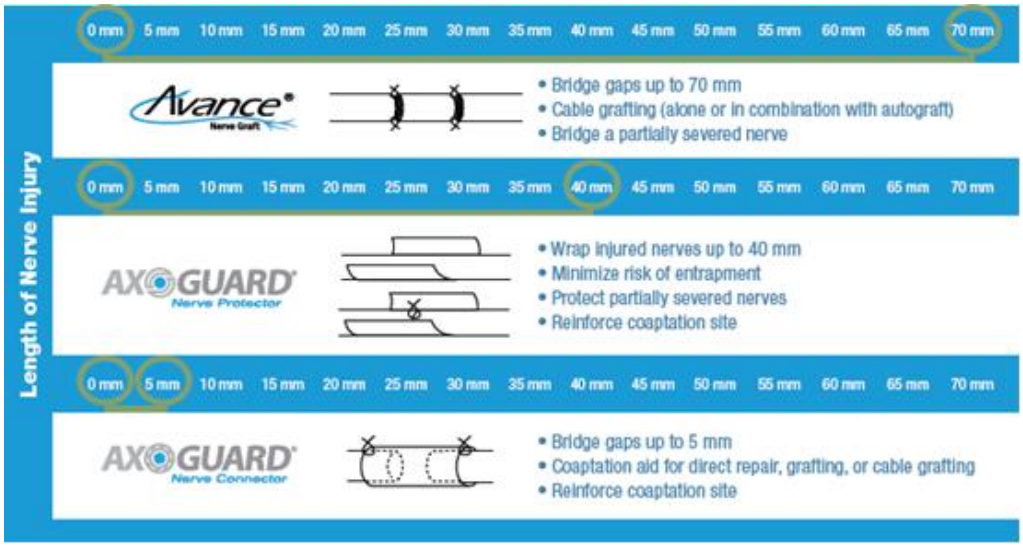
The growth of hollow-tube conduit use demonstrates there is market demand for products that do not have the drawbacks of autografting. However, as stated above, the shortcomings of conduits limit where they may be used effectively. Thus, the nerve repair market needs an alternative off-the-shelf product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

**AxoGen's Product Portfolio**

*Overview of AxoGen's Products*

AxoGen's proprietary products and technologies are designed to overcome fundamental challenges in nerve repair. AxoGen's Avance® Nerve Graft is an 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. 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.

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




*Avance® Nerve Graft*

Avance® Nerve Graft is intended for the surgical repair of peripheral nerve discontinuities to support regeneration across the defect (a gap created when the nerve is severed). It is intended to act as a bridge in order to guide and structurally support axonal regeneration across a nerve gap caused by traumatic injury or surgical intervention. Avance® Nerve Graft is decellularized and sterile extracellular matrix (ECM) processed from human peripheral nerve tissue. AxoGen developed the Avance® Nerve Graft by following the guiding principle that the human body created the optimal nerve structure. AxoGen, through its licensing efforts and research, developed the Avance® Process, a proprietary method for processing recovered human peripheral nerve tissue in a manner that preserves the essential structure of the ECM while cleansing away cellular and noncellular debris. Avance® Nerve Graft provides the natural nerve structure of an autograft and the ease and availability of an off-the-shelf product. AxoGen believes that Avance® Nerve Graft is the first and only off-the-shelf commercially available allograft nerve for bridging nerve discontinuities. The Avance® Nerve Graft is comprised of bundles of small diameter endoneurial tubes that are held together by an outer sheath called the epineurium. Avance® Nerve Graft has

been processed to remove cellular and noncellular factors such as cells, fat, blood, axonal debris and chondroitin sulfate proteoglycans, ("CSPG"), while preserving the three-dimensional 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.

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

The Avance® Nerve Graft provides the following key advantages:

- Provides a three-dimensional bioscaffold for bridging a nerve gap;
- No patient donor-nerve surgery, therefore no comorbidities associated with a secondary surgical site;
- Available in a variety of 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 an ECM for tensionless repair of severed nerves. AxoGuard® Nerve Connector is a tubular, multilaminar extracellular matrix with an open lumen where the severed nerve ends are placed. 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 product to remodel and form a tissue similar to the outermost layer of the nerve (nerve epineurium). AxoGuard® Nerve Connector is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs.

AxoGuard® Nerve Connector can be used 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 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.

*AxoGuard® Nerve Protector*

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

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

AxoGen's Avance® Process 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 AATB standards. As an FDA registered tissue establishment, AxoGen utilizes both its own personnel and a variety of subcontractors for recovery, storage, testing, processing and sterilization of the donated peripheral nerve tissue. Additionally, independent certified laboratories have been contracted by AxoGen and its subcontractors to perform testing. The safety of Avance® Nerve Graft is supported by donor screening, process validation, process controls, and validated terminal sterilization methods. The AxoGen Quality System has built in redundancies so that each Avance® Nerve Graft released for implantation meets AxoGen's stringent quality control and product requirements.

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

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

***Avance® Nerve Graft Packaging***

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

***Avance® Nerve Graft Sterilization and Labeling***

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

The agreement has an initial seven-year term from the date of the original agreement and following such initial term, the agreement automatically renews for an additional seven (7) year period provided that the parties agree to meet at least ninety (90) days before the end of such initial term to review whether the purchase price of the products obtained from Cook Biotech need to be adjusted and reasonably agree to such adjustment in writing, where such agreement shall not be unreasonably withheld. The Cook Biotech agreement also requires certain minimum purchases, although through mutual agreement the parties have not established such minimums and to date have not 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 repair needs. AxoGen is focused on the developing market of peripheral nerve repair and regeneration and is committed to improving awareness of new surgical peripheral nerve repair options, as well as building additional scientific and clinical data to assist surgeons and patients in making informed choices. AxoGen believes 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*

Prior to the introduction of AxoGen's portfolio of products, surgeons had a limited number of options available for the surgical repair of nerve injuries. AxoGen entered the market to improve the standard of care for patients. It has brought the science of nerve repair to life by developing 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 and in conformity with AxoGen's agreement with Cook Biotech restricting certain use of the AxoGuard® Products, 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.

*AxoGen Strengths*

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

Established Surgical Nerve Repair and Regeneration Expertise

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

Surgical Implant Commercialization Experience

The AxoGen commercialization team consists of sales, marketing, and customer service professionals with backgrounds in the medical device and biotechnology industries. The 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 surgical peripheral nerve repair. To date, AxoGen's RANGER® study (defined below in "Government Regulations") is the largest multi-center clinical study conducted in peripheral nerve gap repair. AxoGen's RECON study will also continue AxoGen's clinical work, providing a new multi-center, prospective, randomized, clinical study on the Avance® Nerve Graft. The January, 2012 edition of Microsurgery and November 2012 edition of The Journal of Hand Surgery each contain an article summarizing the RANGER® study results. The publication reported on 55 Avance® Nerve Graft nerve repairs and resulted in meaningful motor and sensory recovery in 87% of nerve discontinuities between 5 and 50 mm. Additionally no implant related adverse events have been reported. (Brooks, D. N., Weber, R. V., Chao, J. D., Rinker, B. D., Zoldos, J., Robichaux, M. R., Ruggeri, S. B., Anderson, K. A., Bonatz, E. E., Wisotsky, S. M., Cho, M. S., Wilson, C., Cooper, E. O., Ingari, J. V., Safa, B., Parrett, B. M. and Buncke, G. M. (2012), Processed nerve allografts for peripheral nerve reconstruction: A multicenter study of utilization and outcomes in sensory, mixed, and motor nerve reconstructions. Microsurgery, 32: 1–14. doi: 10.1002/micr.20975 and Cho, et al. 2012, J Hand Surg Am 37(11):2340-9). A meta-analysis of available clinical outcomes data from published papers on the leading synthetic collagen conduit showed meaningful improvement in only 53% of cases bridging a gap in the nerve. A similar meta-analysis for nerve autograft reported meaningful improvement in 60-88% of nerve repairs.

*International Opportunity for Product Sales*

AxoGen currently focuses on the U.S. market, with additional limited foreign sales in the United Kingdom, the Netherlands, Canada, Italy, Austria and Switzerland. The need for the surgical repair of injured nerves is a global issue. Through its foreign sales, AxoGen has shown the capability to take its current product offering into new geographical markets. AxoGen does not currently have E.U.-wide approval for the Avance® Nerve Graft, but received its CE Mark for AxoGuard® products in April 2013.

**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 three months ended March 31, 2013 and 2012 AxoGen spent approximately $406,000, and $296,000, respectively, and for the years ended December 31, 2012 and 2011, AxoGen spent $1,427,211, and $697,355, respectively, on research and development expenses.

**Competition**

The medical device and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. As such, AxoGen cannot predict what products may be offered in the future that may compete with AxoGen's

products. Currently, AxoGen competes primarily against 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 NeuraWrapTM, 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 comorbidities of an autograft second surgical site. AxoGuard® Nerve Protector and AxoGuard® Nerve Connector provide the unique features of pliability, suturability, and translucence for visualization of the underlying nerve while also allowing the patient's own cells to incorporate into the extracellular matrix to remodel and form a tissue similar to the outermost layer of the nerve (nerve epineurium).

AxoGen believes any current or future competitors face the following important barriers to entry as it relates to the market for its products. AxoGen's intellectual property, and that of its partners, including patents and patents-pending, is believed to be an important barrier. Additionally, AxoGen has developed knowledge and experience in understanding and meeting FDA regulatory requirements for Avance® Nerve Graft, including having made a substantial investment in validating, testing for, and meeting and preparing a submission for FDA 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 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 the UFRF and UT. Under the terms of these license agreements, AxoGen has exclusive worldwide licenses for the underlying technologies used by AxoGen in repairing and regenerating nerves. The license agreements include both the right to issued patents and patents pending in the U.S. and international markets. The effective term of the license agreements extends through the term of the related patents. In the event of default, licensors may also terminate an agreement (after written notice) if AxoGen fails to cure a breach. The license agreements contain the following key terms:

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

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

***Patents***

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

| Patent No. | Description | Estimated expiration date |
|---|---|---|
| US 6,972,168 | Materials and Methods for Nerve Grafting, Selection of Nerve Grafts, and in vitro Nerve Tissue Culture | August 13, 2021 |
| US 7,402,319 | Cell Free Tissue Replacement for Tissue Engineering | September 26, 2023 |
| US 7,732,200 | Materials and Methods for Nerve Grafting, Selection of Nerve Grafts, and in vitro Nerve Tissue Culture | December 21, 2022 |
| US 6,696,575 | Biodegradable, electrically conducting polymer for tissue engineering applications | March 27, 2021 |
| US 7,851,447 | Materials and Methods for Nerve Repair | November 18, 2023 |

Additionally, AxoGen entered into an exclusive distribution agreement with Cook Biotech in August 2008, as subsequently amended in March 2012, to distribute its ECM technology in the form of the Surgisis® Nerve Cuff, the form of a nerve wrap or patch, or the form of any other mutually-agreed-to configuration in the field of peripheral nervous system and central nervous system use, but excluding use of the AxoGuard® product in the oral cavity for endodontic and periodontal applications and oral and maxillofacial surgery solely as they relate to dental, soft or hard, tissue repair or reconstruction. AxoGen has subsequently rebranded the Surgisis products under the AxoGuard® name. Cook Biotech holds multiple issued and pending U.S. and international patents covering its ECM technology. The following table illustrates the two

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

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

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

Finally, 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 premarket notification classification requirements under section 510(k) of the FD&C Act that usually result in the marketing of devices, 21 CFR § 820 ("Quality System Regulation") and related laws and regulations. Cook Biotech has obtained a 510(k) premarket clearance from the FDA for the use of porcine (pig) small intestine submucosa for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. We sell the 510(k)-cleared device under the trade name AxoGuard®.

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

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

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

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

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

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

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

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

***FDA — General***

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

- product design, development and manufacture;
- product safety, testing, labeling and storage;

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

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

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

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

***FDA's Premarket Approval Requirements—Biologic Products***

Biologics License Application Pathway

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

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

- completion of preclinical laboratory tests, animal studies and formulation studies under the FDA's good laboratory practices regulations;
- submission to the FDA of an IND, for human clinical testing, which must become effective before human clinical trials may begin and which must include independent Institutional Review Board, or IRB, approval at each clinical site before the trials may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with Good Clinical Practices to establish the safety and efficacy of the product for each indication;
- submission to the FDA of a BLA, which contains detailed information about the CMC for the product, reports of the outcomes and full data sets of the preclinical testing and 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 current good manufacturing practice, or cGMP, regulations, to assure that the facilities, methods and controls are adequate to ensure the product's identity, strength, quality and purity; and
- FDA approval of the BLA including agreement on post-marketing commitments, if applicable.

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

Biosimilar Biological Products

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

and can be expected to produce the same clinical results as the reference product in any given patient, and a demonstration that the risk in terms of safety or diminished efficacy of alternating or switching between the use of the interchangeable and reference product is not greater than the risk of using the reference product without such alternation or switch. Several states have enacted or are considering laws that also regulate the use and substitution of biosimilar drugs. For example, Virginia requires licensure as interchangeable by FDA for a pharmacist to dispense a biosimilar in place of a prescribed biological product
(Virginia § 54.1-3408.04).

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

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

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

Post-Approval Requirements

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

Future FDA inspections may identify compliance issues at AxoGen's facilities or at the facilities of its contract manufacturers that may disrupt production or distribution, or require substantial resources to correct and prevent recurrence of any deficiencies. In addition, discovery of problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could

delay or prohibit further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Finally, new government requirements, including those resulting from new legislation, may be established that could delay or prevent regulatory approval of AxoGen products that are currently under development or regulatory activity.

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

Clinical Trials

Clinical trials are required to support a BLA and are sometimes required for 510(k) clearance. Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under strict requirements to ensure the protection of human subjects participating in the trial and under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring and safety, and the effectiveness criteria to be evaluated. Clinical trials for biological products require the submission and FDA approval of an IND and clinical trials for medical devices require the submission and FDA approval of an Investigational Device Exemption application, or IDE, unless the device regulations would not require an IDE for a study. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND or IDE, for significant risk devices. In addition, for these studies, an IRB at each site at which the study is conducted must approve the protocol, subject consent form and any amendments for each site at which the study is conducted. All research subjects must be informed, among other things, about the risks and benefits of the investigational product and provide their informed consent in writing.

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

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

Phase 3 clinical trials usually further evaluate clinical efficacy and test further for safety in an expanded patient population (e.g., a hundred to several thousand). Phase 3 clinical trials usually involve comparison with placebo, standard treatments or other comparators. Usually at least one well-controlled large Phase 3 or pivotal clinical trial demonstrating safety and efficacy is required to support a BLA. These trials are intended to establish the overall risk-benefit profile of the

product and provide an adequate basis for physician labeling. Phase 3 trials are almost always larger, more time consuming, complex and costly than Phase 1 and Phase 2 clinical trials. Phase 1, Phase 2 and Phase 3 clinical testing may not be completed successfully within any specified period, if at all. Furthermore, the FDA or AxoGen may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk, have experienced a serious and unexpected adverse event, or that continued use in an investigational setting may be unethical. Similarly, an IRB can suspend or terminate approval of research if the research is not being conducted in accordance with the IRB's requirements or if the research has been associated with unexpected serious harm to patients.

Investigational New Drug Application

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

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

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

***AxoGen Clinical Trials***

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

The RANGER® study is an observational study in current enrollment. It is designed to allow enrollment of up to a total of 1000 subjects over the next several years. The follow-up for the RANGER® study is standard of care up to 36 months post nerve repair. At the time of the BLA submission, if 1000 subjects have not been enrolled and follow-up completed, AxoGen will submit an interim report in the BLA for the enrolled subjects.

The CHANGE study is being run as a pilot comparative study and enrollment was completed November 2011. The study has a 12 month follow-up post nerve repair. After the completion of the follow-up period, data management and report development are anticipated to take an additional 9 months.

The study regarding prostatectomy has also completed enrollment as of the first quarter 2013. The study has a 24 month follow-up post nerve repair. After the completion of the follow-up period, data management and report development are anticipated to take an additional 9 months.

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

Pervasive and Continuing Regulation

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

- to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

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

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

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

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

- warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, repair, replacement, refunds, recall or seizure of our products;

- operating restrictions, partial suspension or total shutdown of production;
- suspension or termination of our clinical trials;
- refusing our PMA or BLA for new products, new intended uses or modifications to existing products;
- withdrawing premarket approvals that have already been granted; and criminal prosecution.

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

Educational Grants

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

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

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

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

Fraud, Abuse and False Claims

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

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

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

procedures and sponsorship of third-party conferences. In addition, AxoGen has conducted training sessions on these principles. However, AxoGen cannot provide any assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws.

***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 E.U., which has adopted numerous directives and promulgated voluntary standards regulating the design, manufacture and labeling of, and clinical trials and adverse event reporting for, medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the E.U. and other countries that comply with or mirror these directives. The method for assessing conformity varies depending on the type and class of the product, but normally involves an assessment by the manufacturer and a third-party assessment by a notified body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's device. Such an assessment is required for a manufacturer to commercially distribute the product throughout these countries. AxoGen has prepared the Quality System and is ready for an assessment by the International Organization for Standardization, (ISO) 13485:2003 Quality Management System. If a country or international customer requires AxoGen to have its quality system registered for compliance to ISO 13485, AxoGen will begin the registration process (selecting a registering body, scheduling audits and report completion). This process is expected to take less than 9 months.

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

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

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

The FDA and international regulatory bodies conduct periodic compliance inspections of AxoGen's U.S. processing facilities. AxoGen's operations are registered with the 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 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 Connector and AxoGuard® Nerve Protector. The Royalty Contract has a term of eight years. Under the Royalty Contract, PDL is to receive royalty payments based on a 9.95% royalty rate of AxoGen's Net Revenues, subject to certain agreed upon minimum payment requirements of approximately $1.3 to $2.5 million per quarter, which begin in the fourth quarter of 2014 as provided in the Royalty Contract. The total consideration PDL paid to AxoGen was the Funded Amount of $20,800,000, including $19,050,000 PDL paid to AxoGen on October 5, 2012, and $1,750,000 PDL paid to AxoGen on August 14, 2012 pursuant to an Interim Revenue Interest Purchase Agreement between AxoGen and PDL, dated August 14, 2012 (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.

*Put Option*

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

*Change of Control; Call Option*

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

*Board Designee*

Under the Royalty Contract, during the term of the Royalty Contract, PDL is entitled to designate, and AxoGen shall appoint an individual designated by PDL, who shall serve on the Board of Directors of AxoGen (the "Board") until AxoGen'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 AxoGen's shareholders at any annual or special meeting of AxoGen's shareholders and where no other individual is elected to such vacancy, PDL shall have the right to designate an individual to fill such vacancy, and AxoGen shall take such actions necessary to appoint, such individual to the Board. AxoGen was required to have taken all actions necessary at or prior to the Closing to ensure there is a vacancy on the Board as of the Closing to permit the appointment of the PDL designee to the Board as of the Closing. PDL has exercised this right and nominated John P. McLaughlin, PDL's President and Chief Executive Officer. On October 5, 2012, upon the Closing, the Board approved to increase its size from seven directors to eight directors, and Mr. McLaughlin was elected to the Board 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, subject to certain restrictions, including restrictions regarding issuance of securities in a registered public offering by the Company. Therefore, due to such restrictions, the preemptive right does not apply to this offering.

*Restriction on Dividends*

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

*Guarantee and Collateral Agreement*

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

**Employees**

At August 8, 2013, AxoGen had 67 full time employees which included 13 in administration, information technology and finance, 9 in manufacturing and quality control, 9 in research and development and regulatory and 36 in sales and marketing. As of the date of this registration statement 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.

**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 AxoGen's prior corporate headquarters at 1407 South Kings Highway, Texarkana, Texas 75501. AxoGen'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.

**Legal Proceedings**

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

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

We have completed, through settlement, our previous material legal action against the five defendants. We currently have no active or pending material legal proceedings.

## MANAGEMENT

### Executive Officers and Directors

*Executive Officers*

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 31, 2013, executive officers of the Company:

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

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. Prior to founding FreiMc, LLC, Mr. Freitag was a Director of Business Development at Pfizer Health Solutions, a former subsidiary of Pfizer, Inc., from January 2006 to May 2009. From July 2005 to January 2006, Mr. Freitag worked for Guidant Corporation in their business development group. Prior to Guidant Corporation, Mr. Freitag was the Chief Executive Officer of HTS Biosystems, a biotechnology tools start-up company, from March 2000 until its sale in early 2005. Mr. Freitag was the Chief Operating Officer, Chief Financial Officer and General Counsel of Quantech, Ltd., a public point of care diagnostic company, from December 1995 to March 2000. Prior to that time, Mr. Freitag practiced corporate law in Minneapolis, Minnesota. Mr. Freitag is also a director of the Foundation Board of HealthEast Care System, a health care system in Minnesota.

John P. Engels, Vice President (Age 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 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. McCarrey held multiple escalating positions with Possis Medical, Inc., a company that developed, manufactured, and marketed medical devices for the cardiovascular and vascular treatment markets, and served as Director or Sales, VP of US Sales, VP of Worldwide Sales and EVP of Worldside Sales & Marketing. For more than 15 years prior to joining Possis, Mr. McCarrey served in a series of progressively responsible roles with two divisions of C.R. Bard, United States Catheter and Instrument Corporation (USCI) which specialized in the treatment of coronary disease in the cardiac catheterization laboratory and Davol, an operating room division that promoted Thoraclex and Simpulse to cardiovascular and orthopedic surgeons. Mr. McCarrey holds a Bachelor of Science degree in Marketing from Central Michigan University.

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

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."

*Directors*

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 May 10, 2013,

| Name | Age | Title |
|---|---|---|
| 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 "—Executive Officers."

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

Mr. Freitag's biographical information is provided above under "—Executive Officers."

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.

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 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–led 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.

John P. 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.

**Director Independence**

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

In connection with this offering, we have been approved to list our common shares on the NASDAQ Capital Market and will be subject to certain rules of such exchange. Although we are not currently subject to director independence requirements, we have, nevertheless, in determining whether our directors and director nominees are independent, used the definition of independence provided in Rule 5605 (a)(2) of The NASDAQ Stock Market's Marketplace Rules. Under this definition of independence, directors Jamie Grooms, Robert Rudelius, John Harper, Joe Mandato and Dr. Mark Gold 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, 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 as to Audit Committee consideration and the Board has not otherwise deemed him independent. The Company believes it complies with applicable independence standards of the NASDAQ Capital Market.

**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), Grooms and Harper are the members of the Audit Committee. Messrs. Harper (Chairman), Rudelius 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, Grooms and Harper is an "audit committee financial expert" as such term is defined in Item 407(d)(5) of Regulation S-K promulgated by the SEC.

**Compensation Committee**

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

**Governance and Nominating Committee**

The Governance and Nominating Committee is responsible to provide oversight in relation to the corporate governance of AxoGen and also identifies director nominees for election to fill vacancies on the AxoGen Board of Directors. Nominees are approved by the AxoGen Board of Directors on recommendation of the Governance and Nominating Committee. In evaluating nominees, the Governance and Nominating Committee particularly seeks candidates of high ethical character with significant business experience at the senior management level who have the time and energy to attend to board responsibilities. Candidates should also satisfy such other particular requirements that the Governance and Nominating Committee may consider important to AxoGen's business at the time. When a vacancy occurs on the AxoGen Board of Directors, the Governance and Nominating Committee will consider nominees from all sources, including shareholders, nominees recommended by other parties, and candidates known to the directors or AxoGen's management. The best candidate from all evaluated will be recommended to the AxoGen Board of Directors to consider for nomination. Shareholders who wish to recommend candidates for consideration as nominees should on or before January 1 of each year furnish in writing detailed biographical information concerning the candidate to the Governance and Nominating Committee addressed to the Corporate Secretary of AxoGen at 13859 Progress Blvd., Suite 100, Alachua, FL 32615. No material changes have been made to the procedures by which security holders may recommend nominees to AxoGen's Board of Directors.

## EXECUTIVE COMPENSATION

### Executive Compensation

***Summary Compensation Table***

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").

| 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.

***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 Shares. 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 shares on the date of grant.

(2) Ms. Zaderej received this option to purchase 275,000 shares of the Company's common shares. 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 shares on the date of grant.

(3) Ms. Zaderej received this option to purchase 100,000 shares of the Company's common shares. 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 shares 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 shares on the date of grant.

(5) Mr. Freitag received this option to purchase 92,000 shares of the Company's common shares. 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 shares 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 shares. 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 shares on the date of grant.

(7) Mr. Engels received this option to purchase 65,000 shares of the Company's common shares. 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 shares on the date of grant.

(8) Ms. Schiaparelli received this option to purchase 90,913 shares of the Company's common shares. 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 shares 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, Jill Schiaparelli, effective February 27, 2012 and Shawn McCarrey, effective February 25, 2013. 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, Messrs. Freitag and McCarrey and Ms. Schiaparelli employment are at will. In the event Messrs. Freitag or McCarrey 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. Messrs. Freitag and McCarrey and Ms. Schiaparelli are also entitled to severance of twelve months of base salary if the person leaves AxoGen for "good reason" (as defined below) within 180 days following a change of control.

In addition, Ms. Zaderej is entitled to full vesting of her outstanding stock options that were granted prior to the Merger upon a change of control, regardless of whether her employment terminates on or following the change of control. With respect to Ms. Zaderej's, Ms. Schiaparelli's and Messrs. Freitag's, Engel's and McCarrey'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 shares 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 shares immediately prior to the merger have the same proportionate ownership of common shares 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 Messrs. Freitag's and McCarrey'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, which for Mr. McCarrey includes the failure of gross revenue in a calendar quarter exceed 80% of budgeted gross revenue.

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

For purposes of Messrs. Freitag's and McCarrey'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 shares on the date of grant. Such stock options are for a term of seven years and are fully vested upon grant.

***Director Compensation Table***

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

| 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.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

One of our directors, Joe Mandato, is a Managing Partner of DeNovo Ventures II, L.P. which is a greater than 5% shareholder of the Company's common shares. Another director of ours, John McLaughlin, is an executive officer of PDL, with which the Company has entered into the Royalty Contract. See "Business— PDL BioPharma, Inc. Revenue Interests Purchase Agreement"

## PRINCIPAL SHAREHOLDERS

The following table sets forth, as of August 8, 2013, certain information with respect to the beneficial ownership of our common shares (the only voting class outstanding), (i) by each director, (ii) by each of the named executive officers and (iii) by all officers and directors as a group.

| Name of Beneficial Owner | Shares Beneficially Owned Before Offering (1) | Percentage of Outstanding Shares Beneficially Owned Before Offering (1) | Shares Beneficially Owned After Offering | Percentage of Outstanding Shares Beneficially Owned After Offering |
|---|---|---|---|---|
| DeNovo Ventures II, LP(2)<br>2180 Sand Hill Rd.<br>Suite 200<br>Menlo Park, CA 94025 | 1,426,392 | 12.8% | 1,426,392 | 7.91% |
| AMV Partners I, L.P.<br>2750 Premier Parkway<br>Suite 200<br>Duluth, GA 30097 | 1,017,904 | 9.1% | 1,017,904 | 5.64% |
| Utility Service Holding Company, Inc. | 972,127 | 8.7% | 972,127 | 5.39% |
| CHP II, L.P.<br>230 Nassau St.<br>Princeton, NJ 08542<br>Attn: John Park | 886,556 | 8.0% | 886,556 | 4.91% |
| Karen Zaderej | 278,208 | 2.5% | 278,208 | 1.53% |
| Jamie M. Grooms(3) | 473,032 | 4.3% | 473,032 | 2.60% |
| John P. Engels | 154,189 | 1.4% | 154,189 | 0.85% |
| Mark Gold, M.D.(4) | 277,697 | 2.5% | 277,697 | 1.54% |
| John Harper | 184,371 | 1.7% | 184,371 | 1.02% |
| Joe Mandato(2) | 25,000 | 0.2% | 25,000 | 0.14% |
| Robert Rudelius | 68,273 | 0.6% | 68,273 | 0.38% |
| Greg Freitag | 183,818 | 1.7% | 183,818 | 1.01% |
| All directors and executive officers as a group (11 persons) (2)(3)(4)(5) | 1,723,695 | 14.6% | 1,723,695 | 9.20% |

(1) Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In general, a person is deemed to be the beneficial owner of (i) any of our common shares over which such person has sole or shared voting power or investment power, plus (ii) any shares which such person has the right to acquire beneficial ownership of within 60 days, whether through the exercise of options, warrants or otherwise. The percentage of ownership set forth above is based on 11,139,939 common shares outstanding as of August 8, 2013. Our common shares issuable upon the exercise of stock options exercisable currently or within 60 days of August 8, 2013 are deemed outstanding and to be beneficially owned by the person holding such option for purposes of computing such person's percentage ownership, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

(2) Mr. Mandato is a Managing Partner of this venture capital fund. Mr. Mandato disclaims beneficial ownership of the shares owned by the fund.
(3) 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.
(4) 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.
(5) 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, 21,311 and 23,653, for Jill Schiaparelli, Mark Friedman and Dave Hansen, respectively.

## DESCRIPTION OF COMMON SHARES

### General

The following description does not purport to be complete and is subject in all respects to applicable Minnesota law and to the provisions of the AxoGen Amended and Restated Articles of Incorporation and bylaws, as amended to the date of this prospectus. AxoGen shareholders are urged to read the Amended and Restated Articles of Incorporation and bylaws for a more complete description of these provisions and other information that may be important to AxoGen shareholders.

### Capital Stock

AxoGen'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 shares. The holders of AxoGen common shares: (1) have equal ratable rights to dividends from funds legally available therefor, when, as and if declared by the AxoGen Board of Directors; (2) are entitled to share ratably in all assets available for distribution to holders of AxoGen common shares upon liquidation, dissolution or winding up of its affairs; (3) do not have preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions applicable thereto; and (4) are entitled to one vote per share on all matters which shareholders may vote on at all meetings of shareholders.

All shares of AxoGen common shares now outstanding are fully paid and nonassessable. The holders of shares of AxoGen common shares do not have cumulative voting rights, which means that the holders of more than 50% of the outstanding shares voting for the election of directors can elect all of AxoGen's directors to be elected, if they so choose. In such event, the holders of the remaining shares will not be able to elect any directors.

After consummation of this offering, AxoGen will have 17,139,939 common shares outstanding, or 18,039,939 common shares if the underwriters' overallotment option is exercised in full.

Wells Fargo Bank, N.A. is the transfer agent for AxoGen common shares.

### Minnesota Anti-Takeover Laws

AxoGen is governed by the provisions of Sections 302A.671, 302A.673 and 302A.675 of the Minnesota Business Corporation Act. These provisions may discourage a negotiated acquisition or unsolicited takeover of AxoGen and deprive AxoGen security holders of an opportunity to sell their shares at a premium over the market price. In general, Section 302A.671 provides that a corporation's shares acquired in a control share acquisition have no voting rights unless voting rights are approved in a prescribed manner. A "control share acquisition" is a direct or indirect acquisition of beneficial ownership of shares that would, when added to all other shares beneficially owned by the acquiring person, entitle the acquiring person to have voting power of 20% or more in the election of directors.

In general, Section 302A.673 prohibits a public Minnesota corporation from engaging in a business combination with an interested shareholder for a period of four years after the date of the transaction in which the person became an interested shareholder, unless the business combination is approved in a prescribed manner. The term "business combination" includes mergers, asset sales and other transactions resulting in a financial benefit to the interested shareholder. An "interested shareholder" is a person who is the beneficial owner, directly or indirectly, of 10% or more of a corporation's voting stock, or who is an affiliate or associate of the corporation, and who, at any time within four years before the date in question, was the beneficial owner, directly or indirectly, of 10% or more of the corporation's voting stock. Section 302A.673 does not apply if a committee of the AxoGen Board of Directors consisting of all of its disinterested directors (excluding current and former officers) approves the proposed transaction or the interested shareholder's acquisition of shares before the interested shareholder becomes an interested shareholder. If a tender offer is made for AxoGen common stock, Section 302A.675 of the Minnesota

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

**Trading**

Our common shares currently trade on the OTCQB Marketplace under the symbol “AXGN” In connection with this offering, we have been approved to list our common shares on the NASDAQ Capital Market under the symbol “AXGN.”

**Transfer Agent and Registrar**

The transfer agent and registrar for our common shares is Wells Fargo Shareowner Services.

## UNDERWRITING

We and the underwriters for the offering named below have entered into an underwriting agreement with respect to the shares of common shares being offered. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase from us the number of common shares set forth opposite its name below. JMP Securities is the representative of the underwriters.

| Underwriters | Number of Shares |
|---|---|
| JMP Securities LLC. | 5,400,000 |
| Ladenburg Thalmann & Co., Inc. | 600,000 |
| Total | 6,000,000 |

The underwriters are offering the common shares subject to each underwriter's acceptance of the shares of common stock from us and subject to prior sale. The underwriting agreement provides that the obligation of each underwriter to pay for and accept delivery of the shares of common stock offered by this prospectus is subject to the approval of certain legal matters by its counsel and to certain other conditions. Each underwriter is obligated to take and pay for all of the shares of common stock if any such shares are taken. However, the underwriters are not required to take or pay for the shares of common stock covered by the underwriters' over-allotment option described below.

The public offering price was determined through negotiations between us and the representative. In addition to prevailing market conditions, the factors considered in determining the public offering price were:

- the reported price of our common shares on the OTCQB Marketplace;
- the closing valuation multiples of publicly traded companies that the representative believes to be comparable to us;
- our financial information;
- the history of, and the prospects for, our company and the industry in which we compete;
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

### Over-Allotment Option

We have granted the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of 900,000 additional shares of common stock to cover over-allotments, if any, at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus.

### Commission and Expenses

The shares of common stock are offered by the underwriters subject to various conditions as stated herein, including receipt and acceptance by it and its right to reject any order in whole or in part. The underwriters have informed us that they do not intend to confirm sales to any accounts over which they exercise discretionary authority.

The following table shows the underwriting discounts and commissions payable to the underwriter by us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriter's over-allotment option to purchase additional shares.

| | Per Common Share | Total Without Exercise of Over-Allotment Option | Total With Exercise of Over-Allotment Option |
|---|---|---|---|
| Public offering price | $ 3.00 | $ 18,000,000 | $ 20,700,000 |
| Underwriting discounts and commissions payable by us | $ 0.21 | $ 1,260,000 | $ 1,449,000 |

We estimate that expenses payable by us in connection with this offering (including the reimbursement of the underwriters' expenses described in this paragraph), other than the underwriting discounts and commissions referred to above, will be approximately $560,000. We have agreed to reimburse the underwriters for reasonable fees and other disbursements of counsel to the underwriters and other reasonable out-of-pocket expenses actually incurred by the underwriters in an amount not to exceed $150,000 in the aggregate.

**Indemnification**

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

**Lock-up Agreements**

We, our officers and directors and holders of 3,330,852 shares of our common stock have agreed, subject to limited exceptions, for a period of 90 days after the date of the underwriting agreement, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any shares of common stock or any securities convertible into or exchangeable for our common stock either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent of JMP Securities LLC. This 90-day period may be extended if (1) during the last 17 days of the 90-day period, we issue an earnings release or material news or a material event regarding us occurs or (2) prior to the expiration of the 90-day period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 90-day period, then the period of such extension will be 18 days, beginning on the issuance of the earnings release or the occurrence of the material news or material event. JMP Securities LLC may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

**Electronic Distribution**

This prospectus in electronic format may be made available on websites or through other online services maintained by the underwriters, or by their affiliates. Other than this prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by any underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriters in their capacity as underwriters, and should not be relied upon by investors.

**Price Stabilization, Short Positions and Penalty Bids**

In connection with the offering the underwriters may engage in stabilizing transactions, over-allotment transactions and syndicate covering transactions in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

- Over-allotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any covered short position by either exercising their over-allotment option and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of shares of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. If the underwriters sell more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor the underwriters make any representations that the underwriters will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

### Listing and Transfer Agent

We have been approved to list our common shares on the NASDAQ Capital Market under the symbol “AXGN.” The transfer agent of our common shares is Wells Fargo Bank, N.A.

### Other

The underwriter and/or their affiliates have provided, and may in the future provide, various investment banking and other financial services for us for which services they have received and, may in the future receive, customary fees.

## LEGAL MATTERS

Certain legal matters in connection with the securities offered hereby will be passed upon for us by Morgan, Lewis & Bockius LLP, Philadelphia, Pennsylvania and Kaplan, Strangis and Kaplan, P.A., Minneapolis, Minnesota. Certain legal matters in connection with this offering will be passed upon for the underwriters by Orrick, Herrington & Sutcliffe LLP, San Francisco, California.

## EXPERTS

The financial statements of the Company as of December 31, 2012 and 2011, and for the years then ended included in this prospectus and registration statement, have been included in reliance of the reports on Lurie Besikof Lapidus & Company, LLP, an independent registered public accounting firm, given on the authority of said firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement under the Securities Act of 1933 that registers the distribution of the common shares offered under this prospectus. The registration statement contains additional relevant information about us and the common shares. The rules and regulations of the SEC allow us to omit from this prospectus certain information included in the registration statement. Statements contained in this prospectus as to the contents of any documents that we have filed as an exhibit to the registration statement are qualified in their entirety by reference to the exhibits for a complete statement of their terms and conditions.

In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy this information and the registration statement at the SEC public reference room located at 100 F Street, N.E., Washington D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Any information we file with the SEC is also available on the SEC's website at http://www.sec.gov. We also maintain a website at http://www.axogeninc.com/secfilings.html through which you can access our SEC filings. We have included our website address in this prospectus solely as an inactive textual reference. The information contained on, or that can be accessed through, our website is not part of this prospectus.

**AXOGEN, INC.**

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**Audited Consolidated Financial Statements**



**Unaudited Condensed Consolidated Financial Statements**

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

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

| | December 31, 2012 | December 31, 2011 |
|---|---|---|
| **Assets** | | |
| **Current assets:** | | |
| 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 |
| **Total current assets** | 18,295,855 | 10,882,475 |
| **Property and equipment, net** | 108,534 | 247,824 |
| **Goodwill** | — | 169,987 |
| **Intangible assets** | 573,731 | 899,480 |
| **Deferred financing costs** | 1,252,443 | 295,276 |
| | $ 20,230,563 | $ 12,495,042 |
| **Liabilities and Shareholders' Equity (Deficit)** | | |
| **Current liabilities:** | | |
| Accounts payable and accrued expenses | $ 1,479,752 | $ 1,585,100 |
| Current portion of long-term debt | — | 434,734 |
| **Total current liabilities** | 1,479,752 | 2,019,834 |
| **Long-term debt** | — | 4,403,737 |
| **Note Payable — Revenue Interest Purchase Agreement** | 21,580,252 | — |
| **Total liabilities** | 23,060,004 | 6,423,571 |
| **Shareholders' equity (deficit):** | | |
| 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) |
| **Total shareholders' equity (deficit)** | (2,829,441) | 6,071,471 |
| | $ 20,230,563 | $ 12,495,042 |

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

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

| | 2012 | 2011 |
|---|---|---|
| **Revenues** | $ 7,691,704 | $ 4,849,470 |
| **Cost of goods sold** | 1,961,877 | 2,426,544 |
| **Gross profit** | 5,729,827 | 2,422,926 |
| **Costs and expenses:** | | |
| 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 |
| **Total costs and expenses** | 13,531,763 | 9,391,653 |
| **Loss from operations** | (7,801,936) | (6,968,727) |
| **Other income (expense):** | | |
| 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 |
| **Total other income (expense)** | (2,354,214) | (2,250,493) |
| **Loss before income taxes** | (10,156,150) | (9,219,220) |
| **Income tax benefit** | 738,192 | — |
| **Net Loss** | (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.

**AXOGEN, INC.**
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)**
**Years ended December 31, 2012 and 2011**

| | *Series A Convertible Preferred Stock* | | *Common Stock* | | *Additional Paid-in Capital* | *Accumulated Deficit* | *Total Stockholders' Deficit* |
|---|---|---|---|---|---|---|---|
| | *Shares* | *Amount* | *Shares* | *Amount* | | | |
| **Balance,** December 31, 2010 | 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) |
| **Balance,** December 31, 2011 | — | — | 11,062,188 | $110,622 | $54,391,784 | $(48,430,935) | $ 6,071,471 |
| Stock-based compensation | — | — | — | — | 495,077 | — | 495,077 |
| Exercise of stock options | — | — | 58,340 | 583 | 15,069 | — | 15,652 |
| Stock Grant for Services | — | — | 7,500 | 75 | 21,300 | — | 21,375 |
| Cancellation of shares | — | — | (5,455) | (54) | (14,946) | — | (14,999) |
| Merger Closing — Fractional shares | — | — | — | — | (58) | — | (58) |
| Net loss | — | — | — | — | — | (9,417,958) | (9,417,958) |
| **Balance,** December 31, 2012 | — | — | 11,122,573 | $111,226 | $54,908,226 | $(57,848,893) | $ (2,829,441) |

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

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

| | 2012 | 2011 |
|---|---|---|
| **Cash flows from operating activities:** | | |
| 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 |
| **Net cash used for operating activities** | (8,661,858) | (7,079,290) |
| **Cash flows from investing activities:** | | |
| Purchase of property and equipment | (48,459) | (20,610) |
| Acquisition of intangible assets | (78,825) | (68,856) |
| Cash acquired with Merger | — | 7,201,638 |
| **Net cash (used for) provided by investing activities** | (127,284) | 7,112,172 |
| **Cash flows from financing activities:** | | |
| 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) | — |
| **Net cash provided by financing activities** | 14,505,762 | 6,358,851 |
| Net increase in cash and cash equivalents | 5,716,620 | 6,391,733 |
| **Cash and cash equivalents,** beginning of year | 8,190,781 | 1,799,048 |
| **Cash and cash equivalents,** end of period | $13,907,401 | $ 8,190,781 |
| **Supplemental disclosures of cash flow activity:** | | |
| Cash paid for interest | $ 649,108 | $ 1,029,753 |
| **Supplemental disclosure of non-cash investing and financing activities:** | | |
| Payments of long term debt with proceeds from note payable (this amount represents a payment made by PDL directly to MidCap Financial SBIC, LP) | $ 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

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 manufactured products and products sold under a distribution agreement are recognized when the product 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 shipping are recognized as revenues when products are 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.

**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 |
| | $3,151,109 | $1,760,540 |

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.

**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.

**Fair Value of Financial Instruments**

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

**Stock-Based Compensation**

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

| Years ended December 31, | 2012 | 2011 |
|---|---|---|
| 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:

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

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.

**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 |

## 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 | $ 108,534 | $ 247,824 |

## 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) |
| **Intangible assets, net** | $ 573,731 | $ 899,480 |

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.

- 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 for aggregate of $20,800,000 with amounts payable monthly at 9.95% of Net Revenues through September 2014; and the greater of (i) 9.95% of product revenue or (ii) specific quarterly amounts varying from approximately $1.3 million to $2.5 million per quarter through September 2020. The minimum annual payment amounts are as follows: 2014 - $1,250,805, 2015 - $6,781,440, 2016 - $9,232,642, 2017 and 2018 - $9,000,000, 2019 - $9,063,000 and 2020 - $6,939,000. | 21,580,252 | — |
| Total debt | 21,580,252 | 5,000,000 |
| Less unamortized debt discount | — | (161,529) |
| Less current portion | — | (434,734) |
| **Long-term portion** | $21,580,252 | $4,403,737 |

**Note Payable**

On October 5, 2012, AxoGen entered into a Revenue Interests Purchase Agreement (the “Royalty Contract”) with PDL, pursuant to which the Company sold to PDL the right to receive specified royalties of 9.95% 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 royalty rate of 9.95% 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,

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

The Company records interest using its best estimate of the effective interest rate, currently the Company is accruing interest using the specified internal rate of return of the put option of 20%. From time to time, the Company will reevaluate the expected cash flows and may adjust the effective interest rate. Determining the effective interest rate requires judgment and is based on significant assumptions related to estimates of the amounts and timing of future revenue streams. Payments made to PDL consist of interest and principal. Based on current calculations of repayments, using actual payments to date, an estimate of future revenue streams and an estimated effective rate of 20% (calculated using the put rate in the agreement), principal payments are scheduled to begin in April 2015. All payments made prior to this date are interest only payments.

*Put Option*

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

*Change of Control; Call Option*

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

*Board Designee*

Under the Royalty Contract, during the term of the Royalty Contract, PDL is entitled to designate, and AxoGen shall appoint an individual designated by PDL, who shall serve on the Board of Directors of the Company (the "Board") 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 certain new issuances of AxoGen's equity securities and securities convertible, exchangeable or exercisable into such equity securities.

*Restriction on Dividends*

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

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

*Guarantee and Collateral Agreement*

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

**Long-Term Debt**

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

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

The MidCap Loan was secured by all of AxoGen's assets. The lenders also received a ten-year warrant to purchase 89,686 shares of AxoGen's common stock at $2.23 per share. The fair value of the warrant was $173,736 and was recorded as debt discount and was being amortized through interest expense using the

effective interest method over the term of the debt. Amortization of debt discount was $12,207 for 2011. The Company also recorded $317,990 in deferred financing costs which were being amortized over the term of the loan. Amortization of the deferred financing cost was $22,714 for 2011.

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.

**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.

***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.

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.

## 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:

| Warrants | Remaining Number Outstanding | Exercise Price |
|---|---|---|
| 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-1st Amendment | 6,243,362 | $ 0.1198 |
| *Series D Warrants-2nd Amendment | 8,694,558 | $ 0.1198 |
| *Series D Warrants-3rd Amendment | 4,462,227 | $ 0.1198 |
| *Series D Warrants-5th Amendment | 2,260,440 | $ 0.1198 |
| *Series D Warrants-6th Amendment | 6,900,685 | $ 0.1198 |
| Total | 41,558,259 | |

* 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:

| | 2011 |
|---|---|
| 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.

**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.

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 | (9,223) | (0.004) |
| Nonvested options — December 31, 2011: | 1,263,205 | 1.41 |
| Granted | 267,576 | 2.99 |
| Vested | (317,734) | (1.92) |
| Forfeited | (354,932) | (2.48) |
| Nonvested options — December 31, 2012 | 858,115 | 2.36 |

## 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 |
|---|---|---|
| **Deferred tax assets:** | $ | $ |
| 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 | 52,300 | 361,000 |
| Total deferred tax assets | 18,602,700 | 15,592,000 |
| **Deferred tax liabilities:** | | |
| Depreciation | (154,900) | (160,000) |
| Amortization | (51,700) | (51,000) |
| Total deferred tax liabilities | (206,600) | (211,000) |
| Net deferred tax assets | 18,396,100 | 15,381,000 |
| Valuation allowance | (18,396,100) | (15,381,000) |

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.

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 | 34,015 |
| TOTAL | $179,979 |

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.

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.

**AXOGEN, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**

| | March 31, 2013 (unaudited) | December 31, 2012 |
|---|---|---|
| **Assets** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 11,200,447 | $ 13,907,401 |
| Accounts receivable | 1,179,138 | 1,050,089 |
| Inventory | 3,420,253 | 3,151,109 |
| Prepaid expenses and other | 142,033 | 187,256 |
| **Total current assets** | 15,941,871 | 18,295,855 |
| **Property and equipment, net** | 111,401 | 108,534 |
| **Intangible assets** | 590,458 | 573,731 |
| **Deferred financing costs** | 1,208,227 | 1,252,443 |
| | $ 17,851,957 | $ 20,230,563 |
| **Liabilities and Shareholders' Equity (Deficit)** | | |
| **Current liabilities:** | | |
| Accounts payable and accrued expenses | $ 1,418,938 | $ 1,479,752 |
| **Total current liabilities** | 1,418,938 | 1,479,752 |
| **Note Payable — Revenue Interest Purchase Agreement** | 22,438,404 | 21,580,252 |
| **Total liabilities** | 23,857,342 | 23,060,004 |
| **Commitments and contingencies** | | |
| **Shareholders' equity (deficit):** | | |
| Common stock, $.01 par value; 50,000,000 shares authorized; 11,127,869 and 11,122,573 shares issued and outstanding | 111,279 | 111,226 |
| Additional paid-in capital | 55,169,737 | 54,908,226 |
| Accumulated deficit | (61,286,401) | (57,848,893) |
| **Total shareholders' equity (deficit)** | (6,005,385) | (2,829,441) |
| | $ 17,851,957 | $ 20,230,563 |

*See notes to condensed consolidated financial statements.*

**AXOGEN, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
**(UNAUDITED)**

| | Three Months Ended | |
|---|---|---|
| | March 31, 2013 | March 31, 2012 |
| **Revenues** | $ 2,142,932 | $ 1,653,430 |
| **Cost of goods sold** | 560,243 | 439,158 |
| **Gross profit** | 1,582,689 | 1,214,272 |
| **Costs and expenses:** | | |
| Sales and marketing | 1,893,541 | 1,628,608 |
| Research and development | 406,943 | 296,131 |
| General and administrative | 1,605,759 | 1,230,608 |
| **Total costs and expenses** | 3,906,243 | 3,155,347 |
| **Loss from operations** | (2,323,554) | (1,941,075) |
| **Other income (expense):** | | |
| Interest expense | (1,067,621) | (125,125) |
| Interest expense — deferred financing costs | (44,216) | (34,951) |
| Other income (expense) | (2,117) | (8,174) |
| **Total other income (expense)** | (1,113,954) | (168,250) |
| **Net loss** | (3,437,508) | (2,109,325) |
| Net loss available to common shareholders | $ (3,437,508) | $ (2,109,325) |
| Weighted Average Common Shares outstanding — basic and diluted | 11,124,633 | 11,062,339 |
| Loss Per Common share — basic and diluted | $ (0.31) | $ (0.19) |

*See notes to condensed consolidated financial statements.*

**AXOGEN, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(UNAUDITED)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| **Cash flows from operating activities:** | | |
| Net loss | $ (3,437,508) | $(2,109,325) |
| Adjustments to reconcile net loss to net cash used for operating activities: | | |
| Depreciation | 23,140 | 55,691 |
| Amortization of intangible assets | 14,687 | 29,419 |
| Amortization of deferred financing costs | 44,216 | 22,713 |
| Amortization of debt discount | — | 12,238 |
| Share-based compensation | 259,912 | 157,860 |
| Interest added to note | 858,151 | — |
| Change in assets and liabilities: | | |
| Accounts receivable | (129,049) | (96,329) |
| Inventory | (269,144) | (365,796) |
| Prepaid expenses and other | 45,223 | (106,033) |
| Accounts payable and accrued expenses | (60,814) | (78,727) |
| **Net cash used for operating activities** | (2,651,186) | (2,478,289) |
| **Cash flows from investing activities:** | | |
| Purchase of property and equipment | (26,007) | (29,313) |
| Acquisition of intangible assets | (31,415) | (41,236) |
| **Net cash used for investing activities** | (57,422) | (70,549) |
| **Cash flows from financing activities:** | | |
| Proceeds from exercise of stock options | 1,654 | 63 |
| Payment of fractional shares from Merger | — | (59) |
| **Net cash provided by financing activities** | 1,654 | 4 |
| **Net decrease in cash and cash equivalents** | (2,706,954) | (2,548,834) |
| **Cash and cash equivalents,** beginning of year | 13,907,401 | 8,190,781 |
| **Cash and cash equivalents,** end of period | $11,200,447 | $ 5,641,947 |
| **Supplemental disclosures of cash flow activity:** | | |
| Cash paid for interest | $ 172,527 | $ 125,125 |

*See notes to condensed consolidated financial statements.*

**AXOGEN, INC.**
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**(UNAUDITED)**

## 1. Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of AxoGen, Inc. (the "Company" or "AxoGen") and its wholly owned subsidiary AxoGen Corporation ("AC") as of March 31, 2013 and December 31, 2012 and for the three month periods ended March 31, 2013 and 2012. The Company's condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and should be read in conjunction with the audited financial statements of the Company for the year ended December 31, 2012, which are included in the Annual Report on Form 10-K for the year ended December 31, 2012. The interim condensed consolidated financial statements are unaudited and in the opinion of management, reflect all adjustments necessary for a fair presentation of results for the periods presented. Results for interim periods are not necessarily indicative of results for the full year. All significant intercompany accounts and transactions have been eliminated in consolidation

## 2. Organization and Business

### Business Summary

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, which the Company believes is 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.

## 3. Summary of Significant Accounting Policies

### Revenue Recognition

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

### Cash and Cash Equivalents and Concentration

For purposes of the statement of cash flows, the Company considers all highly liquid debt instruments purchased with a maturity of three months or less to be cash equivalents. Cash and cash equivalents are maintained at financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances and does not believe it is exposed to any significant credit risk on cash and cash equivalents.

**Accounts Receivable and Concentration of Credit Risk**

Accounts receivable are carried at the original invoice amount less an estimate made for doubtful accounts based on a review of all outstanding amounts on a monthly basis. Management determines the allowance for doubtful 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 March 31, 2013 and December 31, 2012, there were no amounts deemed uncollectible and there was no allowance for doubtful accounts recorded.

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

**Inventories**

Inventories are comprised of implantable tissue, nerve grafts, Avance® Nerve Graft, 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:

| | March 31, 2013 (unaudited) | December 31, 2012 |
|---|---|---|
| Finished goods | $2,246,213 | $2,143,176 |
| Work in process | 149,561 | 145,156 |
| Raw materials | 1,024,479 | 862,777 |
| | $3,420,253 | $3,151,109 |

Inventories were net of reserve of approximately $459,000 and $538,000 at March 31, 2013 and December 31, 2012, respectively.

**Income Taxes**

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

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; currently there are no examinations in process.

**Share-Based Compensation**

AxoGen's 2010 Stock Incentive Plan 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 October 1, 2011, and based on the Company's common stock for periods subsequent to that date. 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 during the periods reflected herein 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 three months ended March 31:

| Three months ended March 31, | 2013 | 2012 |
|---|---|---|
| Expected term (in years) | 4.0 | 4.0 |
| Expected volatility | 84.90% | 118.17% |
| Risk free rate | 0.56% | 0.62% |
| 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 three months ended March 31, 2013 and 2012 as they were deemed insignificant.

**Use of Estimates**

The preparation of 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 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. Intangible Assets**

The Company's intangible assets consist of the following:

| | March 31, 2013 (unaudited) | December 31, 2012 |
|---|---|---|
| License agreements | $ 802,994 | $ 772,230 |
| Patents | 64,079 | 63,429 |
| Less: accumulated amortization | (276,615) | (261,928) |
| **Intangible assets, net** | $ 590,458 | $ 573,731 |

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 the three months ended March 31, 2013 and 2012 was approximately $15,000 and $29,000, respectively. As of March 31, 2013, future amortization of license agreements is expected to be approximately $44,000 for the remainder of fiscal 2013, $55,000 for 2014, $46,000 each year for 2015 through 2018.

**License Agreements**

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

- AxoGen pays royalty fees ranging from 1% to 3% under the License Agreements based on net sales of licensed products. One of the agreements also contains a minimum royalty of $12,500 per quarter, which may include a credit in future quarters in the same calendar year for the amount the minimum royalty exceeds the royalty fees. Also, when AxoGen pays royalties to more than one licensor for sales of the same product, a royalty stack cap applies, capping total royalties at 3.75%;
- If AxoGen sublicenses technologies covered by the License Agreements to third parties, AxoGen would pay a percentage of sublicense fees received from the third party to the licensor. Currently, AxoGen does not sublicense any technologies covered by License Agreements. The Company is not considered a sub-licensee under the License Agreements and does not owe any 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 $47,031 and $37,265 during the three months ended March 31, 2013 and 2012, respectively, and are included in sales and marketing expense on the accompanying condensed consolidated statements of operations.

**5. Notes Payable**

Notes Payable consists of the following:

| | March 31, 2013 (unaudited) | December 31, 2012 |
|---|---|---|
| Revenue Interest Purchase Agreement with PDL for aggregate of $20,800,000 with amounts payable monthly at 9.95% of Net Revenues through September 2014; and the greater of (i) 9.95% of product revenue or (ii) specific quarterly amounts varying from approximately $1.3 million to $2.5 million per quarter through September 2020. The minimum annual payment amounts are as follows: 2014 - $1,250,805, 2015 - $6,781,440, 2016 - $9,232,642, 2017 and 2018 - $9,000,000, 2019 - $9,063,000 and 2020 - $6,939,000. | $22,438,404 | $21,580,252 |
| **Long-term Notes Payable** | $22,438,404 | $21,580,252 |

**Notes Payable**

On October 5, 2012, AxoGen entered into a Revenue Interests Purchase Agreement (the "Royalty Contract") with PDL, pursuant to which the Company sold to PDL the right to receive specified royalties of 9.95% 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 royalty rate of 9.95% 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, 2012 (the "Interim Royalty Contract"). Upon the closing (the "Closing") of PDL's purchase of the specified royalties described above, which was concurrent with the execution of the Royalty Contract, the Interim Royalty Contract was terminated.

The Company records interest using its best estimate of the effective interest rate, currently the Company is accruing interest using the specified internal rate of return of the put option of 20%. From time to time, the Company will reevaluate the expected cash flows and may adjust the effective interest rate. Determining the effective interest rate requires judgment and is based on significant assumptions related to estimates of the amounts and timing of future revenue streams. Payments made to PDL consist of interest and principal. Based on current calculations of repayments, using actual payments to date, an estimate of future revenue streams and an estimated effective rate of 20% (calculated using the put rate in the agreement), principal payments are scheduled to begin in April 2015. All payments made prior to this date are interest only payments.

*Put Option*

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

*Change of Control; Call Option*

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

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

*Board Designee*

Under the Royalty Contract, during the term of the Royalty Contract PDL is entitled to designate, and AxoGen shall appoint an individual designated by PDL, who shall serve on the Board of Directors of the Company (the "Board") 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 certain new issuances of AxoGen's equity securities and securities convertible, exchangeable or exercisable into such equity securities.

*Restriction on Dividends*

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

*Guarantee and Collateral Agreement*

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

**6. Stock Options**

The Company granted 153,000 shares of stock options pursuant to its 2010 Stock Incentive Plan for the three months ended March 31, 2013. Stock-based compensation expense was $259,912 and $157,860 for the three months ended March 31, 2013 and 2012, respectively. Total future stock compensation expense related to nonvested awards is expected to be approximately $1,437,000 at March 31, 2013.

Table of Contents

# 6,000,000 Shares

# AXOGEN, INC.

**Common Shares**

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**Prospectus**

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**August 8, 2013**

## JMP Securities

## Ladenburg Thalmann & Co.