June 21, 2013

VIA EDGAR AND FEDEX

Amanda Ravitz
Assistant Director
United States Securities and Exchange Commission
Division of Corporate Finance
100 "F" Street, N.E.
Washington, D.C. 20549

Re: AxoGen, Inc.
Registration Statement on Form S-1
Filed May 14, 2013
File No. 333-188597
Form 10-K for Fiscal Year Ended
December 31, 2012
Filed March 12, 2013
File No. 000-16159

Dear Ms. Ravitz:

On behalf of our client, AxoGen, Inc. ("we" or the "Company"), set forth below is the Company's response to the letter dated June 10, 2013 (the "June 10 Comment Letter") from the staff (the "Staff") of the Securities and Exchange Commission (the "Commission"), which relates to the Company's Registration Statement on Form S-1, File No. 333-188597 (the "Registration Statement") filed with the Commission on May 14, 2013 (the "Initial Filing") and the Company Form 10-K for the fiscal year ended December 31, 2012 (File No. 000-16159). The Company is filing Amendment No. 1 to the Registration Statement ("Amendment No. 1"), which includes revisions made to the Initial Filing in response to the June 10 Comment Letter, and to reflect certain additional information. An electronic version of Amendment No. 1 has been filed concurrently with the Commission through its EDGAR system. The enclosed copy of Amendment No. 1 has been marked to reflect changes made to the Registration Statement.

The numbered paragraphs and headings below correspond to the headings set forth in the June 10 Comment Letter. Each of the Staff's comments is set forth in bold, followed by the Company's response to each comment. The page numbers in the bold captions refer to pages in the Initial Filing, while the page numbers in the Company's responses refer to page numbers in Amendment No. 1. Capitalized terms used in this letter but not defined herein have the meaning given to such terms in Amendment No. 1.

Form S-1 filed May 14, 2013

Prospectus Cover Page

1. **We note your disclosure on page 20 that you do not meet listing criteria for any national securities exchange. Please continue to update your cover page disclosure to provide a realistic picture of your efforts to list on a national exchange. See Note to Item 202 of Regulation S-K.**

   Response:

   The Company advises the Staff that it has applied for listing on the NYSE — MKT and NASDAQ Stock Market and the Company plans to be approved for listing on one of these exchanges on the effective date of the Registration Statement. Both exchanges are reviewing the Company's applications, and MKT is preparing to bring the Company's application to their committee for approval. From the Company's discussions and review of applicable listing criteria, the Company believes that it has reasonable assurance that the securities to be offered will be acceptable to one of the securities exchanges for listing. In response to the Staff's comment, the Company proposes to revise the risk factor referenced above on page 23 of Amendment No. 1 to now state:

   AxoGen does 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 applied to list our common shares on 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. has provided us requirements necessary to obtain such listing which include, completion of this offering and . 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.

In addition, the Company proposes to update the fourth sentence of the first paragraph on the cover page of the prospectus to Amendment No. 1 to now read:

We have applied to list our common shares on and expect that, after the pricing of this offering, our common shares will trade on the under the symbol

The Company will continue to update these disclosures as it receives new information.

Prospectus Summary, page 1

2. Please revise your disclosure in the summary to avoid medical jargon that is only defined later in the prospectus and instead describe your business in concrete, everyday terms. We note for example your last sentence in the first paragraph describing the Avance product as an "allograft" and the description of the AxoGuard products as "porcine submucosa ExtraCellular matrix coaptation aid." Similarly, please do not use acronyms before you have defined them. As an example, reference the acronym "CMC" appearing in your last risk factor on page 14.

Response:

In response to the Staff's comment, the Company has attempted to remove medical jargon from the Registration Statement. Consistent with that approach, the Company proposes to restate the beginning of the "Company Overview" section in the prospectus to Amendment No. 1 to avoid the medical jargon, where possible, as follows:

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. To date, 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.

3. Please revise here to disclose the status of regulatory approvals required to commercialize each of your highlighted products. Include a brief discussion of the fact that the Avance Nerve Graft is commercially available on a transitional basis and has not yet received final FDA approval.

Response:

In response to the Staff's comment, the Company proposes to add the following paragraph to page 2 of Amendment No. 1 to clarify to the current status of regulatory approvals required to commercialize its products:

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, etermined 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.

4. Revise here to clarify your relationship with Cook Biotech Incorporated and to their products.

Response:

In response to the Staff's comment, the Company proposes to add the following language to page 2 of Amendment No. 1 to clarify its relationship with Cook Biotech Incorporated:

AxoGuard® products are manufactured by Cook Biotech Incorporated, referred to herein as Cook Biotech. We are the exclusive worldwide distributor. 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.

5. Please provide us copies of the articles cited in the third paragraph of Company Overview that were published in the journals Microsurgery and The Journal of Hand Surgery.

Response:

In response to the Staff's comment, the Company has provided the sited journals to the Staff simultaneously herewith.

Risk Factors, page 6

6. Please include a risk factor discussing the internal control deficiency discussed in your 10-K.

Response:

In response to the Staff's comment, the Company proposes to add the following risk factor to the Amendment No. 1 on page 13:

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.

AxoGen relies on third party suppliers; AxoGen relies on third parties to perform, page 8

7. Please tell us whether you have a written contract with any single source supplier or contractor on whom you are dependent and if so disclose the termination provisions of such contract and file it as an exhibit to the registration statement.

Response:

The Company does not have written contracts with its single source suppliers. In response to the Staff's comment, the Company has revised the Risk Factor on page 9 of Amendment No. 1 to include the following sentence to provide further information regarding its suppliers:

We do not have written contracts with any of our single source suppliers, and at any time they could stop supplying our orders.

Healthcare policy changes, page 16

8. Please revise to explain and quantify, to the extent possible, how the medical device excise tax applies to you and each of your products.

Response:

In response to the Staff's comment, the Company proposes to add the following language to the Risk Factor on page 19 of Amendment No. 1 to explain how the excise tax applies to the Company and its products:

Because the Avance® Nerve Graft is a tissue 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.

Capitalization, page 26

9. Please remove the cash and cash equivalents line item from your capitalization table as this is not part of your capitalization.

Response:

In response to the Staff's comment, the Company has removed the cash and cash equivalents from the capitalization table on page 28 of Amendment No. 1.

Management's Discussion and Analysis, page 28

Critical Accounting Policies, page 29

10. **We note your disclosure that your significant accounting policies are described in Note 3 to the financial statements. Please revise to provide a discussion of your critical accounting policies including judgments and uncertainties affecting the application of those policies, and the likelihood that materially different amounts would be reported under different conditions or using different assumptions. Such disclosure should supplement, not duplicate, the description of accounting policies that are already disclosed in the notes to the financial statements. The disclosure should provide greater insight into the quality and variability of information regarding financial condition and operating performance. Please note that while accounting policy notes in the financial statements generally describe the method used to apply an accounting principle, the discussion in MD&A should present a company's analysis of the uncertainties involved in applying a principle at a given time or the variability that is reasonably likely to result from its application over time. Refer to FR-72 and SEC Release No. 33-8040.**

Response:

In response to the Staff's comment, the Company proposes to add the following disclosure to page 31 of Amendment No. 1 to provide a more insightful discussion of the Company's critical accounting policies:

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. Company goodwill represents certain IP and a licensing royalty arrangement related to the LecTec business prior to the Merger. The value of such IP is based on patent life, likelihood of obtaining patent protection and the ability to commercialize the IP. The future royalties expected from the license are considered in valuing the license component of goodwill. Such factors are subjective and could result in different values being reported if different assumptions were used.

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. Currently the Company is accruing interest using the specified internal rate of return of the put option. From time to time, the Company will reevaluate the expected cash flows and may adjust the effective interest rate. Determining the effective interest rate requires judgment and is based on significant assumptions related to estimates of the amounts and timing of future revenue streams. Determination of future revenue streams is highly subjective and different assumptions could lead to materially different outcomes. The Company believes, however, that the minimum royalty aspects of the PDL Royalty Contract will minimize variability in determination of the effective rate over time.

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.

Revenues, page 29

11. We see that revenues increased almost 30% in the three months ended March 31, 2013 as compared to the three months ended March 31, 2012 and revenues increased year over year by approximately 59% and your disclosure indicates that the increases are primarily due to a greater number of customers utilizing your products. We also note your discussion regarding the change in gross profit that there were price increases during the period. Please revise to further discuss the underlying reasons for significant changes in your results of operations and quantify the effect of each material factor contributing to the significant change between periods. For further guidance, please refer to Item 303 and the related instructions in Regulations S-K as well as SEC Interpretive Release No. 33-8350.

Response:

In response to the Staff's comment, the Company proposes to add the following disclosure to page 32 of Amendment No. 1 to further discuss the reasons for such changes:

For the three months ended March 31, 2013, new AxoGen customers in that quarter represented approximately $80,000 of total revenue for such quarter or approximately 4%. For the year ended December 31, 2012 new customers in 2012 represented approximately $770,000 of total revenue in 2012 or approximately 10%. 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, page 30

12. Please revise to explain the nature of and reason for the inventory write-off for expiring inventory discussed on page 30.

Response:

In response to the Staff's comment, the Company proposes to add the following language to page 33 of Amendment No. 1 to further explain the inventory write-offs:

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.

Other Income and Expense, page 31

13. Please revise to disclose the nature of non-cash expense from the PDL transaction discussed on page 31 and clarify how this amount was determined.

Response:

In response to the Staff's comment, the Company proposes to add the following disclosure regarding the non-cash expense from the PDL transaction to page 34 of Amendment No. 1:

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.

Liquidity and Capital Resources, page 32

14. We see the discussion on page 32 that the MidCap loan was subject to prepayment penalties. Please revise to disclose the amount of any prepayment penalties that resulted from the repayment of this loan in fiscal 2012.

Response:

In response to the Staff's comment, the Company has revised the MidCap loan discussion on page 36 of Amendment No. 1 to provide that the repayment penalty was $172,581.

15. Clarify the nature of the "Acquired Revenues" sold to PDL referenced on page 33.

Response:

In response to the Staff's comment, the Company proposes to delete the current third sentence of the first paragraph below the heading "Long-Term Debt / Note Payable" on page 35 of Amendment No. 1 and insert the following disclosure to the end of the same paragraph:

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.

Competition, page 45

16. With a view toward disclosure, please tell us, if possible, what share of the market for nerve repair each of the three methods you describe occupies—allograft, hollow conduit and autograft.

Response:

Unfortunately, the Company has been unable to find the third-party information requested. It does not appear as though this market share research regarding nerve repair for each of the three methods the Company describes has been conducted by any third party. To the extent the Company is able to find this information in the future, it may update our disclosure.

Intellectual Property, page 47

17. It appears that Cook Biotech's patents relating to the AxoGuard products you distribute expire in three years. Please tell us what consideration you have given to adding additional risk factor disclosure regarding the expiration of these patents.

Response:

In response to the Staff's comment, the Company proposes to add the following risk factor to the Amendment No. 1 on page 21:

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.

Government Regulations, page 48

18. Refer to your fourth paragraph under this caption on page 48. Revise your disclosure to explain what the FDA's "intent to exercise enforcement discretion" means with respect to sales of your product and further explain what is required of AxoGen for it to be in compliance with the regulations cited in the bullet points of that paragraph. Finally, explain how the FDA monitors your compliance with the cited regulations.

Response:

In response to the Staff's comment, the Company proposes to add the following disclosure in place of the current fourth paragraph on page 52 of Amendment No. 1:

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 quality system is being updated and is expected to meet the applicable regulations when required;
- AxoGen conduct 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 NDA. We expect enrollment of patients into the phase 3 clinical trial later this year; and
- AxoGen continues to comply with the regulations and standard for 21 CFR § 1271 and exercises due diligence in executing the transition;
    - AxoGen was audited by the FDA in March 2013, and the quality system was found to be in compliance with 21 CFR §1271.

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

19. Please tell us what factors determine the amount of the user fee payment you will owe the FDA upon approval of the Avance Nerve Graft.

Response:

In response to the Staff's comment, the Company proposes to add the following disclosure regarding the factors that determine the amount of the user fee payment that the Company will owe the FDA upon approval of its product to page 53 of Amendment No. 1:

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) is 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.

20. Please disclose in more detail the status of the Phase 3 clinical trials for your Avance Nerve Graft product. Specifically with respect to your two trials that are fully enrolled, provide a realistic picture of the general timeframe for completion of trials of this type and the additional steps you would need to take to complete the BLA and further your FDA approval.

Response:

In response to the Staff's comment, please see the Company's revised disclosure set forth in response to Comment 18.

Regulation Outside of the United States, page 57

20. Revise to provide a realistic estimate of the average time to approval by the ISO and describe any additional steps you need to take to achieve that approval for each of your offered products.

Response:

In response to the Staff's comment, the Company proposes to add the following disclosure to page 62 of Amendment No. 1 to provide an estimate of the time required for approval by the ISO and to describe the Company's required steps to obtain such approval:

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.

PDL Biopharma, Inc. Revenue Interests Purchase Agreement, page 59

21. Please disclose whether PDL BioPharma has waived its preemptive rights with respect to the offering contemplated by this registration statement.

Response:

PDL has not waived its rights with respect to this offering and to the Company's knowledge they wish to maintain their rights pursuant to the PDL agreement. In response to the Staff's comment, the Company proposes to add the following additional disclosure regarding PDL's preemptive rights to page 65 of Amendment No. 1:

The Company will supply its required notice to PDL upon final pricing this offering and PDL will have five days to exercise or waive their right. PDL has not waived its rights with respect to this offering.

Financial Statements, page F-1

Note 3. Summary of Significant Accounting Policies

Revenue Recognition, page F-8

22. We note from your disclosure that you earn fees from storage of products. Please explain to us the situations in which you store products for your customers and tell us how you recognize the related revenue for those products.

Response:

In response to the Staff's comment, the Company proposes to remove storage from the note on revenue recognition. Prior to the 2011 fiscal year, the Company had a distribution partner for which there were certain storage arrangements. Subsequent to that time, the Company has not had any such arrangements and does not intend to enter into any similar arrangement in the future.

23. We note the disclosure on page 42 that AxoGuard is manufactured by Cook Biotech and that you entered into an agreement to distribute these products worldwide. Please revise to separately describe your revenue recognition policy for products that you do not manufacture but are sold under distribution agreements.

Response:

The Company's revenue recognition policy is the same for product that the Company manufactures and that is obtained from Cook Biotech. The Company purchases AxoGuard product from Cook takes title and places in inventory until sold. In response to the Staff's comment, the Company proposes to amend and restate the following sentence in Note 3, Revenue Recognition on page F-8 to clarify:

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.

Inventories, page F-9

24. We note your reference to an inventory reserve. Please confirm that the inventory write-down to the lower-of-cost-or-market creates a new cost basis for the related items and that those items cannot be subsequently written up based on changes in underlying facts and circumstances.

Response:

The Company confirms that the Company's inventory write-down to the lower-of-cost-or-market creates a new cost basis for the related items and that those items cannot be subsequently written up based on changes in underlying facts and circumstances.

Note 7. Long-Term Debt/ Note Payable, page F-14

25. We see that you entered into an agreement with PDL BioPharma in October 2012 which you refer to as the Revenue Interest Purchase Agreement. Please respond to the following:

- **Describe the terms of the agreement and clarify how you determined that the sale of the right to receive future royalties on your net revenues should be classified as long-term debt/notes payable. Please also clarify the repayment terms on this arrangement and explain the reason for entering into the arrangement.**

Response:

On March 12, 2013, the Company filed a confidential treatment request for certain portions of its agreement with PDL BioPharma. The disclosures set forth herein, in the Registration Statement and in the Company's other public filings are consistent with that confidential treatment request. The Company believes that all material terms of the agreement have been disclosed.

In October of 2012, in exchange for $20.8 million, the Company assigned a portion of its future revenues to PDL BioPharma. The Company will pay the greater of high single digit royalty rate of future revenues or a pre-determined fixed amount each quarter from the closing date through the termination date, which is 8 years from the closing date. The agreement contains a put option whereby the purchaser may terminate the agreement on the 4 year anniversary of the closing date. The put price is equal to an amount that would generate a specified rate of return for PDL. The agreement also contains a call option after 4 years whereby the Company may terminate the agreement. The call option price would be equal to an amount that would generate a specified rate of return for PDL.

The arrangement was entered into because the Company could not obtain similar financing under a traditional credit agreement with a lender and cost of capital for an equity transaction was viewed as prohibitive at that time.

ASC 470-10-25 addresses the accounting as debt:

Sales of Future Revenues or Various Other Measures of Income

An entity receives cash from an investor and agrees to pay to the investor for a defined period a specified percentage or amount of the revenue or of a measure of income (for example, gross margin, operating income, or pretax income) of a particular product line, business segment, trademark, patent, or contractual right. It is assumed that immediate income recognition is not appropriate due to the facts and circumstances. The payment to the investor and the future revenue or income on which the payment is based may be denominated in a foreign currency.

While the classification of the proceeds from the investor as debt or deferred income depends on the specific facts and circumstances of the transaction, the presence of any one of the following factors independently creates a rebuttable presumption that classification of the proceeds as debt is appropriate:

a. The transaction does not purport to be a sale (that is, the form of the transaction is debt).

b. The entity has significant continuing involvement in the generation of the cash flows due the investor (for example, active involvement in the generation of the operating revenues of a product line, subsidiary, or business segment).

c. The transaction is cancelable by either the entity or the investor through payment of a lump sum or other transfer of assets by the entity.

d. The investor's rate of return is implicitly or explicitly limited by the terms of the transaction.

e. Variations in the entity's revenue or income underlying the transaction have only a trifling impact on the investor's rate of return.

f. The investor has any recourse to the entity relating to the payments due the investor.

The Company considered all of the criteria and noted that criteria (b) is clearly met because the Company continues to operate the business, thereby having continuing involvement in the generation of the cash flows. As a result of the rebuttable presumption guidance discussed above for debt classification was deemed appropriate.

- **We note that you record interest using your best estimate of the effective interest rate and that you are currently using the specified internal rate of return of the put option. Clarify why you are using the internal rate of return of the put option and how the rate was determined. Please also disclose the effective interest rate used each period.**

Response:

The Company will pay the greater of a high single digit royalty rate of future revenues or a pre-determined fixed amount each quarter. Based on the Company's current future revenue projections, the "greater of" calculation results in paying the minimum quarterly amounts after October 14, 2013 rather than high single digit royalty rate of revenues each quarter through the termination date. Using an amortization model based on the loan amount of $20.8 million and the minimum

quarterly repayments, the implicit rate was estimated to be in the high teens. Because PDL has the ability to terminate the arrangement after four years at a slightly higher rate of return, there is currently a presumption that PDL will exercise this option. As a result, the incremental interest is being recorded as additional interest expense and a corresponding increase to the note.

- **We note your disclosure that PDL is to receive royalty payments based on a high single digit royalty rate of your net revenues, subject to certain agreed upon minimum payment requirements. Please tell us how the royalty rate was determined. Please also clarify how these royalty payments are recorded.**

Response:

The minimum quarterly payments were established between the two parties in order to achieve an effective interest rate commensurate with the level of risk assumed by PDL.

The royalty rate, in the event actual revenues are higher than projected, was agreed-upon by both parties to provide additional potential increased value to PDL as contingent interest.

Each quarterly payment is treated as a re-payment of principal if applicable, plus interest. The reduction in principal is calculated using the implicit rate discussed above.

- **Clarify your accounting treatment for this agreement and cite the relevant accounting literature upon which you based your accounting. Please explain how you determined the amounts recorded in your financial statements related to this arrangement, including your accounting for the Put and Call Option.**

Response:

When the $20.8 million was received, it was recorded as long-term debt. Due to low quarterly payment amounts in the early years of the arrangement, none of the payments in 2013 represent principal, therefore there is no current portion of long-term debt. At the time of minimum quarterly payments, a portion will be recorded as a reduction of principal, using the implicit rate noted above. Also as noted above, additional interest is being recorded and a corresponding increase to the note reflected.

The Company considered whether or not the put and call options required separate accounting.

Per ASC 815-15-25-1:

An embedded derivative shall be separated from the host contract and accounted for as a derivative instrument pursuant to Subtopic 815-10 if and only if all of the following criteria are met:

a. The economic characteristics and risks of the embedded derivative are not clearly and closely related to the economic characteristics and risks of the host

b. The hybrid instrument is not remeasured at fair value under otherwise applicable generally accepted accounting principles (GAAP) with changes in fair value reported in earnings as they occur.

c. A separate instrument with the same terms as the embedded derivative would, pursuant to Section 815-10-15, be a derivative instrument subject to the requirements of this Subtopic.

We focused on criteria (a) above, whether or not the potential embedded derivative is clearly and closely related to the debt host.

ASC 815-15-25-40 discusses put and call options on debt instruments.

Provided the call (put) options also are considered to be clearly and closely related to the debt host contract under paragraph 815-15-25-26, call (put) options that can accelerate the repayment of principal on a debt instrument are considered to be clearly and closely related to a debt instrument that requires principal repayments unless both of the following conditions exist:

a. The debt involves a substantial premium or discount (which is common with zero-coupon bonds).

b. The call (put) option is only contingently exercisable.

In the literature above, neither criteria (a) nor (b) are true, and therefore the put and call options are clearly and closely related to the debt host and under ASC 815-15-25-1 does not need to be bifurcated and accounted for separately.

- **Clarify how you considered the Guarantee and Collateral Agreement in determining your accounting for the Revenue Interest Purchase Agreement.**

Response:

The guarantee and collateral agreement provided a security interest to PDL in all accounts of the AxoGen, Inc. and AxoGen Corporation. AxoGen Corporation is a wholly owned subsidiary of AxoGen, Inc. Therefore, the guarantee is a subsidiary's guarantee of a parent's debt.

ASC 460-10-25-1(h) provides a scope exception from the recognition requirements for a subsidiary's guarantee of a parent's debt to a third party. The recognition exception reads:

A subsidiary's guarantee of the debt owed to a third party by either its parent or another subsidiary of that parent.

Therefore, there was no separate accounting associated with the guarantee.

Item 15. Recent Sales of Unregistered Securities, page II-2

26. Please disclose the company's relationship to the investors in the Regulation D private placement.

Response:

In response to the Staff's comment, the Company proposes to add the following disclosure regarding its relationship to the investors in the private placement to page II-2 of Amendment No. 1:

This offering was completed in conjunction with the Merger. Purchasers of Company securities were certain shareholders of AC prior to the Merger and included AC's Chief Executive Officer and certain members of its Board of Directors.

Exhibits, page II-3

26. Please include Exhibit 10.4.3, the third amendment to your Amended and Restated Nerve Tissue Processing Agreement with LifeNet Health in your exhibit list.

Response:

In response to the Staff's comment, the Company proposes to add the following to the exhibit table:

**10.4.3	Third Amendment dated March 12, 2012 to Amended and Restated Nerve Tissue Processing Agreement, dated as of February 27, 2008, by and between AxoGen Corporation and LifeNet Health (Incorporated by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2012)

The Company believes that the above responses will be acceptable to the Staff. Please contact the undersigned at (609) 919-6633 if you have any questions regarding the foregoing.

Sincerely,

/s/ Emilio Ragosa

cc: Karen Zaderej
Gregory G. Freitag
Fahd M.T. Riaz