



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

June 10, 2013

Via E-mail

Karen Zederej  
Chief Executive Officer  
Axogen, Inc.  
13859 Progress Boulevard, Suite 100  
Alachua, Florida 32615

**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. Zederej:

We have reviewed your filings and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

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.

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

Risk Factors, page 6

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

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.

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.

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.

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.

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.

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.

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.

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

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.

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.

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.
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.
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.

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.

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.

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.
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.

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.

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.
  - 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.
  - 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.

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

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.

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.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Act of 1933 and all applicable Securities Act rules require. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event you request acceleration of the effective date of the pending registration statement please provide a written statement from the company acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please refer to Rules 460 and 461 regarding requests for acceleration. We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under

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Axogen, Inc.  
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the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Julie Sherman at (202) 551-3640 or Brian Cascio at (202) 551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Sally Brammell at (202) 551-3779 or me at (202) 551-3528 with any other questions.

Sincerely,

/s/ Amanda Ravitz

Amanda Ravitz  
Assistant Director

cc (via e-mail): Emilio Ragosa, Esq.