



VIA EDGAR AND FEDEX

May 22, 2020

Kevin Kuhar, Accounting Branch Chief - Office of Life Sciences  
Lynn Dicker, Staff Accountant  
United States Securities and Exchange Commission  
Division of Corporate Finance  
100 "F" Street, N.E.  
Washington, D.C. 20549

Re: Axogen, Inc.  
Form 10-K For the Fiscal Year Ended December 31, 2019  
Filed February 24, 2020  
File No. 001-36046

Ladies and Gentlemen:

This letter is in response to the comment letter of the staff (the "Staff") of the United States Securities and Exchange Commission (the "Commission") dated April 27, 2020 (the "Comment Letter"), concerning the Annual Report on Form 10-K for the fiscal year ended December 31, 2019 of Axogen, Inc. (the "Company" or "Axogen"), from the Staff regarding the above-referenced filing. For your convenience, the text of each comment contained in the Comment Letter is included below in bold, with the Company's response to the comment set forth immediately thereafter.

Form 10-K For the Fiscal Year Ended December 31, 2019

Item 7. Management's Discussion and Analysis

Comparison of the Years Ended December 31, 2019 and 2018, page 71

- 1. Please expand your results of operations discussion in future filings to quantify the impact of each factor identified, including offsetting, as causing changes in results between periods. For example, we note that your changes in revenue are attributable to a number of factors, including increases in unit volume, net impacts of price increases and changes in product mix. Please quantify the impact of each factor attributing to the increase, here, and throughout your discussion, in accordance with Item 303(a)(3)(iii) of Regulation S-K and Section III.D of SEC Release No. 33-6835.**

**Response:** We acknowledge the Staff's comment and will evaluate and revise our disclosure in future filings to include the quantitative measures of the key factors impacting any changes in revenue including changes in unit volume, and the net impact of price increases and product mix. We will include these expanded disclosures beginning with the Company's Form 10-Q for the quarterly period ended June 30, 2020, as we are collecting the additional information required to make these disclosures. Additionally, we will revise our disclosure in the future to quantify the impact of each factor in Item 7 and throughout our discussion.

---

- 2. We note the increase in your research and development expenses and that you have multiple products in varying stages of development and clinical testing. Please revise future filings to provide more detail for your research and development expenses for each period presented, including but not limited to by product candidate as well as by the nature of the expenses. To the extent that you do not track expenses by product candidate, please disclose as such.**

**Response:** We acknowledge the Staff's comment. In our Form 10-Q for the three-month period ended March 30, 2020 we expanded our disclosure to include the percentage of research and development spent on product development versus development and execution of clinical studies, and how the mix of this spend has changed over the past year. We believe this additional information, when taken in context with our other disclosures, provides investors with useful information regarding the focus and intent of our research and development expenses. Below is the additional disclosure as provided in Form 10-Q for the three-month period ended March 30, 2020.

Research and development expenses increased 11.5% to \$4,614 for the three months ended March 31, 2020, as compared to \$4,139 for the three months ended March 31, 2019. Research and development costs include Axogen's product development and research related thereto ("Development") and clinical efforts ("Clinical") focused on its BLA for the Avance® Nerve Graft and clinical trials. Development represented approximately 50% of total research and development expense in the three months ended March 31, 2020 as compared to 55% in the prior year period. Clinical represented approximately 50% of research and development expense in the three months ended March 31, 2020 as compared to 45% in the prior year period. The increase in clinical in the first quarter was primarily due to increased personnel costs due to higher headcount to support additional clinical trial activities. Although our clinical trial activities decreased towards the end of the quarter due to the inability to access patients as a result of COVID-19, our total investment in clinical trials, such as RECON, increased over the prior year period. As a percentage of total revenues, research and development expenses were 19.0% for the three months ended March 31, 2020 as compared to 17.8% for the three months ended March 31, 2019.

Note 3. Summary of Significant Accounting Policies Revenue Recognition, page 91

- 3. We note your disclosure that you do not provide disaggregated revenue because of the similarity of products and arrangements. Please explain to us in greater detail your consideration of ASC 606-10-50-5 and 55-89 through 55-91 in determining that disaggregation of revenue is not required. In particular, describe what types of sales information is reviewed by management to assess operating performance and the similarity of your individual product gross margins impacting cash flows. As an example, we note that you cite changes in product mix as a factor in increasing revenue for the year. We also note in your recent earnings call that you identified Avance contributes over half your revenue and growth and you also describe differences between the direct and indirect sales channels. Lastly, tell us how you considered the disclosure requirements of ASC 280-10-50-40.**

**Response:** Axogen's surgical solution product portfolio provides surgeons off-the-shelf products for a wide variety of peripheral nerve damage or transection. The Company's proprietary products and technologies are designed to be an integrated solution to overcome fundamental challenges in peripheral nerve repair. Axogen's Avance® Nerve Graft is the alternative to autografts and other off-the-shelf peripheral nerve repair products for nerve gaps of various lengths. The Axoguard® Nerve Connector is a coaptation aid for transected peripheral nerves. Axoguard® Nerve Protector is a protective wrap for peripheral nerves damaged by compression, or where the surgeon wants to protect and isolate the peripheral nerve during the healing process after surgery. Avive® Soft Tissue Membrane provides a resorbable covering to keep tissue structures apart while providing the beneficial properties of a placental membrane. Axoguard® Nerve Cap is a uniquely designed nerve termination device which provides a protective environment for the nerve end.

Axogen's portfolio of products are marketed and sold to the same types of customers, generally, hospitals, surgical facilities where they are used by surgeons in the treatment of patients with peripheral nerve damage and transections. The contracts that Axogen enters into with these customers typically include the full portfolio of products, not just a single product line, and the contractual terms are the same across all product types. Axogen's distribution model includes both a direct sales force and independent sales agencies, who cover accounts on our behalf. We utilize the same direct and independent sales agencies to sell all of our nerve repair products, not just a single portfolio product. Additionally, customers typically make purchases of the different product types at the same time as the products are complementary in the treatment of peripheral nerve damage or transection. Our marketing, sales, and educational promotion efforts span the full portfolio of products and are designed to show the benefit of the integration of all products in our portfolio. Our marketing and sales strategy is aligned with the way our customers view our products, that is, a portfolio of products that treat the same focused specialty.

Since Axogen's products are marketed, sold, and managed as an integrated peripheral nerve repair solution, there is significant inherent product integration and we view ourselves as having a single product category. Therefore, management believes the nature, amount, timing, and uncertainty of revenue and cash flows from our products are similar and affected equally by economic factors. Axogen's information systems provide management with product sales and margin information; however, this information is not generally used internally or externally to evaluate Axogen's operating or financial performance as there are no separate economic factors to evaluate or forecast from given the integrated nature of the products which will depend on the severity of the nerve reconstruction needs and could include either of or a combination of the products.

As we assessed and considered ASC 606-10-50-5 and 55-89 through 55-91, we concluded that disaggregation of revenue is not required under the standard, nor would it be useful to financial statement users. As noted above, there is not a difference in the nature, amount, timing, and uncertainty of revenue and cash flows with any individual product primarily because our products are sold to the same type of customers, under the same contractual terms, all for the treatment peripheral nerve damage. Our reference to changes in product mix changes referred to higher pricing in larger units within product categories versus mix changes between categories. Axogen doesn't disclose detailed financial information about our products externally because it isn't used to evaluate our operating performance.

Finally, Axogen considered the disclosure requirements of ASC 280-10-50-40. As noted above, our products are sufficiently similar in that they are sold to the same type of customers, under the same contractual terms, and all to treat peripheral nerve damage. Management does not allocate resources differently for each of the products in its portfolio, nor does it monitor the operating result of each product. As such, management believes that disaggregation by product would not be beneficial to the users of the financial statements.

Item 9A. Controls and Procedures, page 114

4. **We note that within Management’s Annual Report on Internal Control Over Financial Reporting, you state that management evaluated the effectiveness of the design and operation of disclosure controls and procedures and concluded that your disclosure controls and procedures were effective. Please note that Item 308 of Regulation S-K requires a separate evaluation of your internal control over financial reporting. Please amend your filing to provide both the required management’s report on internal control over financial reporting under Item 308 of Regulation S-K and management’s conclusions on the effectiveness of your disclosure controls and procedures as part of your Evaluation of Disclosure Controls and Procedures section under Item 307 of Regulation S-K.**

**Response:** The Company acknowledges the Staff’s comment and has revised the disclosure in Amendment No. 1 to the Form 10-K for fiscal year ended December 31, 2019 (the “Amendment”) to provide both the required Management’s Report on Internal Control Over Financial Reporting in Item 9A, Controls and Procedures, in accordance with Item 308 of Regulation S-K and management’s conclusions on the effectiveness of our disclosure controls and procedures as part of our Evaluation of Disclosure Controls and Procedures section, in accordance with Item 307 of Regulation S-K. Additionally, the Company has refiled the Section 302 and Section 906 officer certifications dated as of the date of the Amendment.

5. **Please tell us your consideration of whether management’s failure to complete and disclose its report on internal control over financial reporting for two successive annual periods impacts its conclusions regarding the effectiveness of your disclosure controls and procedures as of the end of the fiscal year covered by the report and revise your disclosure as appropriate. In particular, please explain to us how you considered the definition of disclosure controls and procedures provided in Rule 13a-15(e), which indicates that effective controls and procedures would ensure that information required to be disclosed by the issuer is recorded, processed, summarized and reported within the time periods specified in the Commission’s rules and forms.**

**Response:** The Company respectfully advises the Staff that it has considered whether management’s failure to complete and disclose its report on internal control over financial reporting impacts the effectiveness of our disclosure controls and procedures conclusion as of December 31, 2018 and December 31, 2019, and has concluded that the Company’s disclosure controls and procedures were designed to provide reasonable assurance of achieving their control objectives as of such dates and that the disclosure controls and procedures were effective at the reasonable assurance level as of such date. While the required reports were omitted from the Company’s Form 10-K for fiscal years ended December 31, 2018 and December 31, 2019, the Company

respectfully advises the Staff that its management had completed the required assessment of internal control over financial reporting at the time of each filing of the Form 10-K and had included certifications with respect to the Company's internal control over financial reporting in the Section 302 officer certifications filed with each filing of the Form 10-K. The Company's management believes such mistakes were due to typographical errors and that no changes to the design of the Company's disclosure controls and procedures are necessary to provide management with reasonable assurance of achieving their control objectives. However, the Company's management has made certain immaterial changes to further strengthen the Company's disclosure controls and procedures for future periods. Below is the proposed disclosure for the Amendment 1 to the Form 10-K for the fiscal year ending December 31, 2019.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

The Company maintains "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, and Board of Directors, as appropriate, to allow timely decisions regarding required disclosure. Our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable assurance of achieving the desired objectives, and we necessarily are required to apply our judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures.

### **Changes in Internal Control Over Financial Reporting**

In the ordinary course of business, we routinely enhance our information systems by either upgrading current systems or implementing new ones. There were no changes in our internal control over financial reporting that occurred during the three months ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. The Company's internal control system is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external

purposes in accordance with accounting principles generally accepted in the United States of America and includes those policies and procedures that:

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

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

Our management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of our internal control over financial reporting as of December 31, 2019. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013). Based on their evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our internal control over financial reporting was effective.

The Company's independent registered public accounting firm, Deloitte & Touche LLP, who audited the consolidated financial statements included in this Annual Report on Form 10-K, has issued an attestation report on the effectiveness of managements internal control over financial reporting as of December 31, 2019. This report states that the internal control over financial reporting was effective and appears on page 81 of this Annual Report on Form 10-K.

Should the Staff have any additional questions or comments after reviewing this letter, the Company would appreciate the opportunity to discuss the comments with the Staff. Please direct any questions about this letter to me at (386) 462-6856.

Sincerely,

/s/ Peter Mariani

Peter Mariani  
Chief Financial Officer

cc: Karen Zaderej  
Gregory Freitag