



K&L GATES LLP
1 PARK PLAZA
TWELFTH FLOOR
IRVINE, CA 92614
T 949.253.0900 F 949.253.0902
klgates.com

October 5, 2018

VIA EDGAR

U.S. Securities and Exchange Commission
Division of Corporation Finance
100 F. Street, N.E.
Washington, D.C. 20549

Attn: Tim Buchmiller
Geoff Kruczek

**Re: Axonics Modulation Technologies, Inc.
Draft Registration Statement on Form S-1
Submitted August 28, 2018
CIK No. 0001603756**

Ladies and Gentlemen,

Axonics Modulation Technologies, Inc., a Delaware corporation (the “**Company**”), hereby provides the following information in response to the comments received from the staff (the “**Staff**”) of the U.S. Securities and Exchange Commission (the “**Commission**”) in its letter to the Company dated September 24, 2018 (the “**Comment Letter**”). The Company’s responses are preceded by a reproduction of the corresponding Staff comments in italics as set forth in the Comment Letter.

In addition, if the Staff would like hard copies of the Registration Statement on Form S-1 (the “**Registration Statement**”) as filed with the Commission on the date hereof, marked against the Draft Registration Statement as confidentially submitted to the Commission on August 28, 2018, please so advise and we would be happy to provide such copies. All page number references contained in the Company’s responses below correspond to the page numbers in the Registration Statement.

[Draft Registration Statement on Form S-1 submitted August 28, 2018](#)

[Overview, page 1](#)

1. *We note the disclosure regarding your estimates of the addressable SNM market. Please tell us how the data you included accounts for less frequent procedures to be performed, given the battery life of your product compared to the battery life of your competition. Also tell us how such data accounts for SNM being a third-line therapy, per your disclosure, and 70% advancement from trial stimulation referenced on page 121.*

Company Response: The disclosure on page 1 of the Registration Statement states that the global market for sacral neuromodulation (“SNM”) therapy in 2017 was \$605 million. The Company respectfully notes that this data is only for SNM therapy and not for all therapies that treat patients with overactive bladder, fecal incontinence and urinary retention. Currently, there is only one approved product for SNM therapy and therefore the historical market data is reflective of the estimated revenue for that product in 2017. Additionally, the growth rate for the SNM market that the Company discloses on page 6 of the Registration Statement is based on historical data.

The Company does not disclose anticipated specific future market size in the Registration Statement. The Company believes that the potential impact of its r-SNM System on the size of the SNM market is a complex analysis with many variables. Although the r-SNM System is expected to have a longer battery life than the current product offering, replacement procedures are estimated to constitute only 25% of the annual SNM procedure volume, which equates to approximately 15% of the revenue for the SNM market. In addition, the Company believes that through patient and physician outreach efforts, more patients in the future could elect to undergo SNM therapy, which would increase the size of the SNM market.

2. *We note the disclosure regarding continued positive results from your ARTISAN-SNM pivotal study. Please expand to disclose that such study is not being conducted in accordance with FDA recommendations, as referenced in your disclosure beginning on page 15. Also, since that study has not been completed, please tell us why it is not too preliminary to characterize any results from that study to date as positive.*

Company Response: The Company acknowledges the Staff's comment and has revised the disclosure on pages 1 and 2 of the Registration Statement accordingly.

Anti-takeover provisions in our certificate of incorporation, page 71

3. *Please revise to present the last paragraph as a separate, appropriately captioned risk factor.*

Company Response: The Company acknowledges the Staff's comment and has revised the disclosure on page 77 of the Registration Statement accordingly.

Use of Proceeds, page 76

4. *Please revise to specify the technological enhancements and research and development activities you intend to fund with the proceeds of this offering.*

Company Response: The Company acknowledges the Staff's comment and has revised the disclosure on page 81 of the Registration Statement accordingly.

Dilution, page 81

5. *Please revise to clarify how the numbers and percentages in the table on page 82 would change assuming the exercise of all outstanding options and warrants.*

Company Response: The Company acknowledges the Staff's comment and has revised the disclosure on pages 88 and 89 of the Registration Statement accordingly.

Comparison of the Six Months Ended June 30, 2018 and 2017, page 91

6. *Disclose why you did not generate revenue from sales of your r-SNM System as part of the evaluation agreement with the hospital in Canada during the six months ended June 30, 2018.*

Company Response: The Company acknowledges the Staff's comment and has revised the disclosure on page 99 of the Registration Statement to clarify that, in 2017, the Company sold several of its r-SNM Systems as part of a one-time evaluation agreement (the "**Evaluation Agreement**") with a single hospital in Canada, at a discounted price, so that the hospital could evaluate the Company's r-SNM System. The Company has no continuing or accruing obligations under the Evaluation Agreement and therefore did not generate revenue in 2018 under such agreement.

Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations, page 91

7. *We note that the sale of your r-SNM System in 2018 generated \$12,000 in revenue while the sale of your system in 2017 generated \$128,000 in revenue. Please revise to explain the difference in revenue and gross profit for the two systems sold. In addition, revise your disclosure to describe the evaluation agreement referenced for the 2017 sale.*

Company Response: The Company acknowledges the Staff's comment and advises the Staff that the sale of several of the Company's r-SNM Systems in 2017 pursuant to the Evaluation Agreement represented a one-time transaction whereby the Company agreed to sell its r-SNM Systems at discounted prices in order for the hospital in Canada to evaluate the Company's r-SNM System. In 2018, the Company sold only one r-SNM System to a single customer in the United Kingdom. The Company has revised the disclosure on page 99 of the Registration Statement accordingly. The Company further respectfully advises the Staff that the Evaluation Agreement is immaterial to the Company and included only the terms pursuant to which the purchase of the r-SNM Systems was made. As a result, the Company has not revised its disclosure to describe the Evaluation Agreement in further detail.

Liquidity and Capital Resources, page 94

8. *Given your regulatory approvals in other markets, disclose whether you will expend capital resources pursuing sales in those markets.*

Company Response: The Company acknowledges the Staff's comment and has revised the disclosure on page 100 of the Registration Statement accordingly.

Indebtedness, page 96

9. *Please revise to clarify whether this offering will satisfy the condition regarding gross proceeds from the sale of your equity securities.*

Company Response: The Company acknowledges the Staff's comment and has revised the disclosure on page 103 of the Registration Statement accordingly.

Contractual Obligations, page 98

10. *We note the disclosure that the information in the table reflects your obligations as of December 31, 2017. Please revise to clarify any material changes to such information since that date. We note, for example, disclosure regarding the new lease and loan agreement with Silicon Valley Bank.*

Company Response: The Company acknowledges the Staff's comment and has revised the disclosure on pages 104 and 105 of the Registration Statement accordingly.

ARTISAN-SNM Study, page 128

11. *We note your disclosure regarding the FDA reiterating its previously expressed recommendations that you make modifications to your ARTISAN-SNM pivotal study. Please clarify which FDA recommendations you have or have not incorporated into your study and briefly indicate why you have chosen to incorporate only certain of those recommendations into your study. We also note your disclosure that if you intend to modify the study design to address any of the FDA's considerations that you have not already addressed, you will be required to obtain FDA approval of an IDE supplement before implementing the changes, which could result in significant delays. Please clarify in your "Use of Proceeds" disclosure if your existing funds would be sufficient for you to complete any modified or delayed trials.*

Company Response: The Company acknowledges the Staff's comment and has revised the disclosure on pages 138-139 of the Registration Statement accordingly. In addition, the Company respectfully advises the Staff that the Company has sufficient funds available to complete any modified or delayed trials and therefore has not modified the Use of Proceeds disclosure.

Intellectual Property, page 134

12. *Please discuss the application of Section 6.1(b) and (c) of Exhibit 10.1 to the intellectual property you disclose that you own.*

Company Response: The Company acknowledges the Staff's comment and has revised the disclosure on pages 146 and 147 of the Registration Statement accordingly.

13. *Refer to the first paragraph on page 136. Please revise to clarify AMF's rights to use the intellectual property you own, as referenced in the carryover paragraph here.*

Company Response: The Company acknowledges the Staff's comment and has revised the disclosure on pages 146-147 of the Registration Statement accordingly.

Investors' Rights Agreement, page 173

14. *Please revise to clarify the duration of the obligations discussed in the last paragraph of this section.*

Company Response: The Company acknowledges the Staff's comment and has revised the disclosure on page 186 of the Registration Statement accordingly. The Company respectfully advises the Staff that the Company intends to enter into an amendment to the Fourth Amended and Restated Investors' Rights Agreement, dated March 29, 2018, by and among the Company and the investors signatory thereto, with the requisite parties thereto (the "**Amendment**"), prior to the completion of the offering pursuant to which the Registration Statement relates (the "**Offering**"), to provide for the termination of such obligations in connection with the closing of the Offering. The Company has a reasonable basis to believe the requisite parties will enter into the Amendment.

Share Exchange Agreement, page 174

15. *We note that you consolidate Axonics Europe, S.A.S. since you exercise control over that entity. Please explain to us your basis for consolidation since, as indicated on page 174, the majority of Axonics Europe's shares are held by other entities. In addition, explain how you will account for the Share Exchange Agreement. Refer to the requirements of ASC 810.*

Company Response: The Company acknowledges the Staff’s comment and has revised the related statements and disclosures. The Company does not own a majority of the shares of Axonics Europe, S.A.S. (“**Axonics Europe**”). However, the Company exercises control over and shares a management team with Axonics Europe. Further, the interests held by the other investors in Axonics Europe can be converted at any time into a fixed number of shares of the Company’s preferred stock. Due to this conversion right, the investors’ interests are considered to be protected from any losses of Axonics Europe. Therefore, the Company is considered to be responsible for absorbing the losses of Axonics Europe, and as such, has a variable interest in Axonics Europe. Axonics Europe has no equity at risk and is therefore considered a variable interest entity since it is dependent on the Company to finance its activities. The investors in Axonics Europe have entered into an agreement with the Company acknowledging that their investment is not intended to give them voting control over Axonics Europe and they have agreed to vote as directed by the Company’s board of directors. Therefore, the Company is the primary beneficiary of Axonics Europe and consolidates this entity. Due to the rights of the respective parties under the Fourth Amended and Restated Share Exchange Agreement, dated June 30, 2017, by and among the Company, BioDiscovery 4 FCPR, and Coöperatieve Gilde Healthcare IV U.A. (the “**Share Exchange Agreement**”), the noncontrolling interest in Axonics Europe is reflected in Mezzanine Equity. The expenses and net loss from Axonics Europe are reported in the consolidated financial results of the Company and the Company absorbs all the losses of this entity. All shares of Axonics Europe subject to the Share Exchange Agreement will automatically exchange and convert into the Company’s common stock upon completion of the Offering.

16. *Please revise to clarify the purpose of the arrangement described in this section, including why a portion of the proceeds fund a subsidiary in France.*

Company Response: The Company respectfully notes to the Staff that the disclosure on page 187 of the Registration Statements states that the French corporation was established to accommodate a requirement from one of the Company’s investors. However, the Company has added additional disclosure on page 187 to clarify that those proceeds were generally subsequently distributed to the Company.

Principal Stockholders, page 177

17. *Please tell us why note 4 identifies a different manager of BioDiscovery than Exhibit 10.29.*

Company Response: The Company respectfully advises the Staff that in April 2018, Edmond de Rothschild Investment Partners completed a management buyout and assumed the business name of “Andera Partners”. Exhibit 10.29 filed with the Registration Statement was entered into before such name change took effect.

18. *Please revise to identify the natural persons who have or share voting and/or dispositive powers with respect to the shares held by Noble Prestige Holdings. Please also revise to clarify whether the other managing member of Longitude Venture Partners mentioned in note 9 shares voting and/or dispositive power with Ms. Tammenoms Bakker.*

Company Response: The Company acknowledges the Staff’s comment and has revised the disclosure on page 192 of the Registration Statement accordingly.

General

19. *We note your graphics indicate your product is “the future of sacral neuromodulation.” Please revise to highlight that you do not yet have regulatory approval in the United States to market and sell your product.*

Company Response: The Company acknowledges the Staff’s comment and has revised the inside front cover page of the Registration Statement to set forth a different phrase altogether.

If you have any questions or comments concerning these responses, please do not hesitate to call me at (949) 623-3519 or e-mail me at michael.hedge@klgates.com.

Sincerely,

/s/ Michael A. Hedge

Michael A. Hedge
K&L Gates LLP

cc:

Michael Fay, U.S. Securities and Exchange Commission
Brian Cascio, U.S. Securities and Exchange Commission
Raymond W. Cohen, Axonics Modulation Technologies, Inc.
Michael V. Williamson, Axonics Modulation Technologies, Inc.
Jason C. Dreibelbis, K&L Gates LLP
Alexa M. Ekman, K&L Gates LLP
Iilir Mujalovic, Shearman & Sterling LLP