
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 5, 2019

Axonics Modulation Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38721
(Commission File Number)

45-4744083
(I.R.S. Employer
Identification No.)

26 Technology Drive
Irvine, California 92618
(Address of principal executive offices) (Zip Code)

(949) 396-6322
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Exchange Act:

<u>Title of class</u>	<u>Trading symbol</u>	<u>Name of exchange on which registered</u>
Common stock, par value \$0.0001 per share	AXNX	Nasdaq Global Select Market

Item 8.01. Other Events.

On November 5, 2019, Axonics Modulation Technologies, Inc. (the “Company”) issued a press release announcing that it received notice that Medtronic, Inc., Medtronic Puerto Rico Operations Co., Medtronic Logistics LLC and its U.S. operating company Medtronic USA, Inc. (collectively, “Medtronic”) filed a lawsuit against the Company in the United States District Court for the Central District of California. The lawsuit asserts that the Company’s rechargeable sacral neuromodulation system infringes Medtronic’s U.S. Patent Nos. 8,036,756, 8,626,314, 9,463,324, and 9,821,112. The lawsuit requests customary remedies for patent infringement. The Company intends to vigorously defend itself against Medtronic’s claims. The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of Axonics Modulation Technologies, Inc., dated November 5, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AXONICS MODULATION TECHNOLOGIES, INC.

Dated: November 5, 2019

By:

/s/ Raymond W. Cohen

Raymond W. Cohen

Chief Executive Officer

Axonics® Responds to Patent Action by Medtronic

Believes Claims are Without Merit and an Attempt to Suppress Innovation and Competition

IRVINE, Calif. – November 5, 2019 – Axonics Modulation Technologies, Inc. (NASDAQ:AXNX), a medical technology company that has developed and is commercializing sacral neuromodulation (“SNM”) devices, today announced that it received notice on Monday, November 4, that Medtronic, Inc, Medtronic Puerto Rico Operations Co., Medtronic Logistics LLC and its U.S. operating company Medtronic USA, Inc. (“Medtronic”) filed a lawsuit against Axonics in the United States District Court for the Central District of California. The lawsuit asserts that the Axonics r-SNM® System infringes Medtronic’s U.S. Patent Nos. 8,036,756, 8,626,314, 9,463,324, and 9,821,112. The lawsuit requests the typical remedies for patent infringement, including damages and an injunction.

Axonics has invested substantial time and resources in understanding the competitive landscape over the years since its inception in October 2013 and has been careful to respect the intellectual property rights of others in the design of its products, including the rights of Medtronic. Axonics is prepared to act quickly and defend itself aggressively and has already begun working with legal counsel. Beyond this, the need to protect the confidentiality of attorney communications limits what the Company can say about the specific allegations at this time.

“Axonics believes that this lawsuit is the kind of response that is all too predictable from Medtronic signaling that it is lacking the wherewithal to compete fairly. It is ironic that the largest medical device company in the world, with over a 20-year long monopoly in the SNM market, failed to introduce any meaningful innovation for the sake of patients or their physician customers. Instead, they have chosen to employ legal tactics to engage in clear anticompetitive behavior and yet another attempt to change the dialogue with physicians and U.S. institutional investors,” said Axonics CEO Raymond W. Cohen.

Cohen continued, “We believe in competition. Our team is neither naive, nor inexperienced and we refuse to be intimidated. We have developed our own considerable IP estate relating to our technology platform. It should be obvious, to even the most casual observer, that this is an attempt to use legal tactics to slow down competition, and deny patients and physicians the innovative new technology that they desire. The bottom line is that a large number of Medtronic’s customers want to work with Axonics and offer their patients our long-lived, fuss free, full-body MRI-capable SNM system, and we will continue to work vigorously to accomplish our objective of becoming the market leader in SNM.”

About Axonics Modulation Technologies, Inc. and Sacral Neuromodulation

Axonics, based in Irvine, Calif., has developed and is commercializing novel implantable SNM devices for patients with urinary and bowel dysfunction. The Axonics r-SNM System is the first rechargeable SNM system approved for sale in the United States, Europe, Canada and Australia. These conditions are caused by a miscommunication between the bladder and the brain and significantly impacts quality of life. Overactive bladder affects an estimated 87 million adults in the U.S. and Europe. Another estimated 40 million adults are reported to suffer from fecal incontinence/accidental bowel leakage. SNM therapy has been employed to reduce symptoms and restore pelvic floor function for the past two decades. Reimbursement coverage is well established in the U.S. and Europe. The Axonics r-SNM System is also the first SNM system to gain full-body MRI conditional labeling. For more information, visit the Company’s website at www.axonicsmodulation.com.

Forward-Looking Statements

Statements made in this press release that relate to future plans, events, prospects or performance are forward-looking statements as defined under the Private Securities Litigation Reform Act of 1995. Words such as “planned,” “expects,” “believes,” “anticipates,” “designed,” and similar words are intended to identify forward-looking statements. While these forward-looking statements are based on the current expectations and beliefs of management, such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual

results to differ materially from the expectations expressed in this press release, including the risks and uncertainties disclosed in Axonics filings with the Securities and Exchange Commission, all of which are available online at www.sec.gov. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, Axonics undertakes no obligation to update or revise any forward-looking statements to reflect new information, changed circumstances or unanticipated events.

Axonics' Contact

Axonics Modulation Technologies, Inc.
Dan Dearen, +1-949-396-6320
President & Chief Financial Officer
ir@axonics.com

Investor & Media Contact

W2Opure
Matt Clawson, +1-949-370-8500
mclawson@w2ogroup.com