



Axonics® Announces Partial Decision on Inter Partes Review Proceedings

September 13, 2021

IRVINE, Calif.--(BUSINESS WIRE)--Sep. 13, 2021-- Axonics, Inc. (Nasdaq: AXNX), a global medical technology company that is developing and commercializing novel products for the treatment of bladder and bowel dysfunction, today announced that the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office has issued final written decisions on three of the six Medtronic patents that Axonics is contesting.

In March 2020, Axonics filed petitions with the PTAB requesting *inter partes review* (IPR) to contest the validity of patents Medtronic has alleged to be infringed by Axonics. In September 2020, the PTAB granted Axonics' request and instituted a review of the following six Medtronic patents: Nos. 7,774,069; 8,626,314; 8,036,756; 8,457,758; 8,738,148; and 9,821,112.

Today, the PTAB issued its decision with respect to Patent Nos. 7,774,069 (the "069 Patent"); 8,626,314 (the "314 Patent"), and 8,036,756 (the "756 Patent"). Decisions are still pending on the remaining three patents.

The PTAB agreed with Axonics on four of the five claims Axonics is contesting in the '069 Patent, holding that those four claims are invalid and unpatentable. In addition, the PTAB upheld the nearly expired claims in the '756 Patent and the '314 Patent. The '756 Patent expires on November 9, 2021, and the '314 Patent expires on February 18, 2022.

Axonics plans to appeal the PTAB's decisions on the claims it declined to invalidate to the Director of the Patent & Trademark Office and to the U.S. Court of Appeals for the Federal Circuit. The PTAB's decision only relates to the issue of invalidity or patentability of the Medtronic patents and does not mean that Axonics infringes any of the patents.

"We are quite pleased with the PTAB's decision to invalidate four of the five key claims of the '069 Patent, which reflects the merit of the compelling arguments we presented and represents a significant victory for Axonics," said Raymond W. Cohen, chief executive officer of Axonics. "We respectfully disagree with the PTAB's decision on the claims it declined to invalidate, and we intend to appeal. It's also important to understand that the PTAB rulings are not related to the notion of infringement – they are simply addressing whether or not the claims in these patents are valid as a starting point. We are confident that we will ultimately prevail on all of the patent claims Medtronic has asserted against us."

About Axonics

Based in Irvine, Calif., Axonics is a global medical technology company that is developing and commercializing novel products for patients with bladder and bowel dysfunction. The company's rechargeable sacral neuromodulation (SNM) system provides patients suffering from overactive bladder and/or fecal incontinence with long-lived, easy to use, safe, clinically effective therapy. In addition, Axonics' best-in-class urethral bulking agent, Bulkamid®, provides women suffering from stress urinary incontinence (SUI) with safe and durable symptom relief.

Overactive bladder affects an estimated 87 million adults in the U.S. and Europe, with an additional 40 million adults estimated to suffer from fecal incontinence. SUI affects an estimated 20 million women in the U.S. alone. Axonics' clinically proven products are offered at hundreds of medical centers across the U.S. and abroad. Reimbursement coverage is well established in the U.S. and is a covered service in most European countries. For more information, visit www.axonics.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.

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