



Axonics® Provides Additional Update on Inter Partes Review Proceedings

September 22, 2021

IRVINE, Calif.--(BUSINESS WIRE)--Sep. 22, 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 additional 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 six Medtronic patents. On September 13, 2021, the PTAB issued its [decision](#) with respect to Patent Nos. 7,774,069; 8,626,314, and 8,036,756. Today, the PTAB issued its decision on the three remaining Medtronic patents Axonics is contesting: Patent Nos. 9,821,112 ('112 patent), 8,457,758 ('758 patent); and 8,738,148 ('148 patent).

Either party may appeal the IPR decisions to the Director of the Patent & Trademark Office and to the U.S. Court of Appeals for the Federal Circuit.

Axonics expects the stay on legal proceedings in the U.S. District Court in the Central District of California to continue until the appeals process is complete.

"First and foremost, it is important to understand that the PTAB rulings as to whether the claims in the Medtronic patents are valid or not do not mean that anyone has 'won' anything. When one party suggests that another party is infringing, the other party often asks the PTAB to determine if the claims in the patents are actually valid. This is what Axonics has done and for Medtronic to claim 'victory' is purely posturing. The fact that the PTAB decided to invalidate several claims in Medtronic's '112 patent is a net positive for Axonics. Moreover, we believe the PTAB's narrow construction of the claims in the '758 patent and '148 patent strengthens our non-infringement argument. Axonics remains confident that it does not infringe any Medtronic patents – valid or invalid – and that we will ultimately prevail on the patent claims asserted against us," said Raymond W. Cohen, chief executive officer of Axonics.

Cohen continued, "Since our founding, Axonics has been an innovation-driven company keenly focused on developing best-in-class incontinence solutions for the benefit of patients. Our management team and external patent counsel carefully studied and navigated the SNM intellectual property landscape before we began developing our SNM product. We then invested tens of millions of dollars and thousands of hours in R&D to create a strong portfolio of our own intellectual property. As stated before, we believe Medtronic's claims are without merit and are simply designed to stifle competition, limit patient and physician choice and protect the incumbent's monopoly in sacral neuromodulation. Medtronic took advantage of its monopoly and chose not to innovate for over 20 years. Axonics took a different path and, in effect, created a renaissance in SNM therapy by introducing significant enhancements such as a long-lived rechargeable implantable neurostimulator and making SNM devices MRI compatible for the first time. We refuse to be intimidated by Medtronic and are confident that Axonics will ultimately prevail on all of the patent claims Medtronic has asserted against us. In the meantime, we remain focused on fulfilling our mission of changing the lives of patients suffering from bladder and bowel dysfunction."

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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