



Eargo Supports Over-the-Counter Hearing Aid Final Ruling

August 17, 2022

Company Applauds FDA for Increased Access, Innovation

SAN JOSE, Calif., Aug. 17, 2022 (GLOBE NEWSWIRE) -- [Eargo, Inc.](https://www.eargo.com) (Nasdaq: EAR) ("Eargo" or the "Company"), a medical device company on a mission to improve hearing health, announced its support of the new regulatory category of over-the-counter ("OTC") hearing aids, as finalized by the Food and Drug Administration (the "FDA") Wednesday, August 17, 2022.

Christian Gormsen, President and Chief Executive Officer, said, "This ruling directly aligns with Eargo's mission. By making hearing aids more accessible and affordable while maintaining safety standards, the industry will now finally be driven by consumer demand for superior products."

Mr. Gormsen continued, "Based on our initial review of the final rule, we believe Eargos can continue to be sold under existing regulations as well as classified as OTC hearing aids, subject to compliance with labelling and other requirements of the final rule. For example, we believe Eargo hearing aids currently on the market are within the FDA's output and insertion depth limit requirements. We also believe the FDA's removal of certain selling restrictions for OTC hearing aids will allow Eargo to expand the way we serve customers by making the addition of full retail and physical locations in a simplified and scalable way, which will allow Eargo to more broadly meet customers' hearing health needs. We plan on adding partnered physical locations to our online experience in 2022 and 2023. With that said, we will need to expend time and resources evaluating the final rule and ensuring that our devices and processes come into compliance with the new requirements."

Mr. Gormsen concluded, "This industry milestone will drive greater innovation and provide the types of consumer-friendly hearing care experiences the industry needs. The hearing aid industry has traditionally been stagnant and slow to adapt to consumers' evolving needs. Stigma is the biggest hindrance to people's decision to wear hearing devices—Eargo launched its first product six years ago to overcome stigma with its virtually invisible hearing aids. Our differentiated product and consumer-first approach, which includes lifetime remote customer care, empower people to take control of their own hearing wellness. Eargo wholeheartedly supports the FDA's decision to take this monumental step forward to promote accessibility, and we look forward to the positive changes this will have on the future of hearing health."

The new ruling, which is expected to go into effect October 2022, stands to increase product access for the estimated 45 million American adults who experience some degree of hearing loss. Only one in four individuals who would benefit from wearing a hearing device has worn one. The regulatory category of OTC hearing aids aims to make hearing care devices more affordable and attractive to consumers while upholding reasonable standards of safety and efficacy.

The final rule will become effective 60 days after its publication in the Federal Register. Based on the current regulatory classification of Eargo hearing aids as Class I or Class II exempt air conduction hearing aids, we believe Eargo will have 240 days after the date of publication in the Federal Register to achieve compliance with new or revised requirements, including labelling requirements. If, however, any of our current devices require 510(k) clearance in order to come into compliance with the final rule, we would need to obtain clearance for such devices by the effective date of the final rule.

About Eargo

Eargo is a medical device company on a mission to improve hearing health. Our innovative product and go-to-market approach address the major challenges of traditional hearing aid adoption, including social stigma, accessibility and cost. We believe our Eargo hearing aids are the first virtually invisible, rechargeable, completely-in-canal, FDA-regulated, Class I or Class II exempt devices indicated to compensate for mild to moderate hearing loss. Our differentiated, consumer-first approach empowers consumers to take control of their hearing. Consumers can purchase Eargo hearing aids online or over the phone and get personalized and convenient consultation and support from hearing professionals via phone, text, email or video chat. Eargo hearing aids are offered to consumers at approximately half the cost of competing hearing aids purchased through traditional channels in the United States.

Eargo's sixth generation device, Eargo 6, is an FDA Class II exempt hearing device featuring Sound Adjust technology that automatically optimizes the soundscape as the user moves between environments. <http://eargo.com>

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact contained in this press release are forward-looking statements, including statements regarding the future effects of the FDA's rule for OTC hearing aids, the Company's ability to add full retail and physical locations in a simplified and scalable manner, and the impact of the FDA final rule and the Company's assessment, ability and timing for compliance with the new requirements. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks, uncertainties and assumptions related to: completion of the rights offering; the extent to which the Company may be able to validate processes to support the submission of claims for reimbursement from the FEHB program or other insurance programs in the future, if at all, and the Company's ability to maintain or increase insurance coverage of Eargo hearing aids; the timing or results of ongoing claims audits and medical records reviews by third-party payors; the extent of losses from hearing aids delivered to customers from September 21, 2021 until December 8, 2021; the impact of third-party payor audits and the regulatory landscape for hearing aid devices on the Company's business and results of operations; the Company's expectations concerning additional orders by existing customers; the Company's expectations regarding the potential market size and size of the potential consumer populations for its products and any future products, including the increase insurance coverage of Eargo hearing aids; the Company's ability to release new hearing aids and the anticipated features of any such hearing aids; developments and projections relating to the Company's competitors and its industry, including competing products; the Company's ability to maintain its competitive technological advantages against new entrants in its industry; the pricing of the Company's hearing aids; the Company's expectations regarding the ability to make certain

claims related to the performance of its hearing aids relative to competitive products; the Company's expectations with regard to changes in the regulatory landscape for hearing aid devices, including the implementation of the OTC hearing aid regulatory framework and the Company's assessment, ability and timing for compliance with the new requirements; and the Company's estimates regarding the COVID-19 pandemic, including, but not limited to, its duration and its impact on the Company's business and results of operations. These and other risks are described in greater detail under the section titled "Risk Factors" contained in the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other filings with the U.S. Securities and Exchange Commission. Any forward-looking statements in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, are based on current expectations, forecasts and assumptions, and speak only as of the date of this press release. Except as required by law, the Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor Contact

Nick Laudico

Senior Vice President of Corporate Strategy and Investor Relations

ir@eargo.com