



Eargo Celebrates 1-Year Anniversary of FDA's Over-the-Counter (OTC) Hearing Aid Regulations, Driving a New Era of Accessibility and Innovation

November 1, 2023

SAN JOSE, Calif., Nov. 01, 2023 (GLOBE NEWSWIRE) -- Eargo, Inc. (Nasdaq: EAR) ("Eargo") celebrates the one-year anniversary of the creation of an over-the-counter (OTC) hearing aid category in the US. This important advancement by the US Food & Drug Administration (FDA), following a bipartisan mandate from Congress, was meant to reduce costs, increase competition, improve access, and drive innovation in the hearing aid category, resulting in more widespread adoption of hearing technology. This firmly aligns with Eargo's founding mission.

The FDA [has noted](#) that the use of hearing aids has been associated with health benefits, improved social participation, and a better quality of life. The revised regulations were intended to encourage more widespread adoption of hearing aids. Eargo is proud to have actively supported the FDA's rulemaking in establishing this nascent category, though Eargo believes much remains to realize its true intent.

OTC hearing aids are improving accessibility and adoption

Eargo recently surveyed its customers who purchased an OTC self-fitting hearing aid available in the brand's portfolio of offerings in the year since the regulations have been in effect. Nearly 900 Eargo customers responded. Survey highlights affirm the spirit of the FDA's objectives of accessibility, affordability, competition, innovation, and effectiveness are being met through direct-to-consumer delivery models like Eargo's.

- Approximately 70% of survey respondents were new to hearing aids when they purchased a device from Eargo.
- Of those survey respondents, the average time from when individuals recognized they had hearing loss to getting their first hearing aid was approximately 4 years. This is much shorter than a 2019 study estimate of 8.9 years.¹
- Eargo's hearing aids are virtually invisible when worn and rechargeable without custom earmolds, which we believe is unique among hearing aids. Only half of the survey respondents were still certain they would get a hearing aid if only visible options were available. The new OTC regulations allow us to more broadly market and sell a hearing aid that encourages people not to let their condition go untreated.
- Approximately 77% of Eargo users surveyed indicated that buying devices directly online is more affordable or about the same cost as buying in person.
- Approximately 75% of Eargo survey respondents who had previously worn a traditional hearing aid indicated that Eargo's performance was equal to or better than their traditional hearing aid.

The next frontier in access: insurance plan support for OTC hearing aids

Eargo believes that realizing the intent of the OTC mandate requires further efforts to enable access to hearing aids for adults with hearing loss, such as third-party payment assistance via insurance plan hearing aid benefits. Ahead of the 2024 plan year, Eargo is heartened to see some progressive health plans providing coverage for OTC hearing aids and hopes this is indicative of a trend in coverage for future benefit years.

Leaders like UnitedHealthcare are adding benefits for OTC hearing aids across its Medicare Advantage plans and other lines of business. This offers to improve access to OTC hearing aids for the tens of millions of Americans covered by such plans.

To date, most plans have made no changes to the hearing aid benefits offered, and a handful of plans exclude coverage of OTC hearing aids.

By covering hearing aids—including FDA-cleared self-fitting OTC hearing aids—in high-risk populations without significant administrative hurdles, third-party payors could improve the health of their members while reducing costs of downstream comorbidities that are associated with untreated hearing loss.

As Eargo marks the one-year anniversary of the FDA's launch of the OTC hearing aid category, the company remains focused on providing a discreet and supported experience to counteract the stigma associated with hearing loss, empowering individuals to take control of their hearing wellness journey on their own terms. Eargo's commitment to accessibility and innovation envisions a future where hearing care is transformative and accessible to all Americans who need it.

About Eargo

Eargo is a medical device company on a mission to improve hearing health. Our innovative products 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 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 online, at retail locations 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 seventh generation device, Eargo 7, is an FDA 510(k) cleared, self-fitting over-the-counter hearing aid featuring Sound Adjust+ with Comfort and Clarity Modes, which focuses on noise reduction and adapting to the user's environment and needs. Eargo 7 is available for purchase at <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, but not limited to, statements regarding the differentiation of Eargo products and Eargo's ability to support its customers; Eargo's ability to address the objectives of the OTC hearing aid category and expand access to hearing care; Eargo's strategy and innovation priorities; and the availability of future health plan coverage for Eargo products. 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: Eargo's expectations regarding its omni-channel business, including partnerships with retailers, resellers and other distributors (whether brick and mortar or online); the extent to which Eargo may be able to validate and establish processes to support the submission of claims for reimbursement from third-party payors or to otherwise establish relationships with health plans, benefits managers, and managed care providers, and its ability to maintain or increase insurance coverage of Eargo hearing aids; the timing or results of ongoing claims audits by third-party payors; estimates of Eargo's future capital needs and ability to raise capital on favorable terms, if at all, including the timing of future capital requirements and the terms or timing of any future financings; the effects, timing and costs of Eargo's cost reduction plans; the impact of the regulatory landscape for hearing aid devices on Eargo's business and results of operations; Eargo's expectations concerning additional orders by existing customers; Eargo's expectations regarding the potential market size and size of the potential consumer populations for its products and any future products, including insurance coverage of Eargo hearing aids; Eargo's ability to release new hearing aids and the anticipated features of any such hearing aids; the performance, differentiation and attractiveness to consumers of Eargo's products; developments and projections relating to Eargo's competitors and industry, including competing products; Eargo's ability to maintain its competitive technological advantages against new entrants in the industry; the pricing of Eargo's hearing aids; Eargo's expectations regarding the ability to make certain claims related to the performance of Eargo hearing aids relative to competitive products; Eargo's expectations with regard to changes in the regulatory landscape for hearing aid devices and related opportunities, including the implementation and effects of the new over-the-counter hearing aid regulatory framework; and Eargo's expectations regarding macroeconomic conditions, including but not limited to the impact of COVID-19, inflationary trends, uncertainty or volatility in the market (including recent and potential disruption in the banking system and financial markets and geopolitical events (such as the conflict in Ukraine and tensions across the Taiwan Strait)) on Eargo's business and results of operations. These and other risks are described in greater detail in the sections titled "Risk Factors" contained in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and in our other filings with the 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, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor Contact

Adam Laponis
Chief Financial Officer
ir@eargo.com

¹ Simpson AN, Matthews LJ, Cassarly C, Dubno JR. Time from hearing-aid candidacy to hearing-aid adoption: a longitudinal cohort study. *Ear hear.* 2019; 40(3):468-476. doi:10.1097/AUD.0000000000000641.