

**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): January 4, 2023

EARGO, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-39616
(Commission File Number)

27-3879804
(IRS Employer Identification No.)

2665 North First Street, Suite 300
San Jose, California
(Address of principal executive offices)

95134
(Zip Code)

Registrant's telephone number, including area code: (650) 351-7700

Not Applicable
(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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock, \$0.0001 par value per share	EAR	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company 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.

Item 7.01. Regulation FD Disclosure.

On January 4, 2023, Eargo, Inc. (“Eargo” or the “Company”) issued a press release announcing the launch of its new, seventh generation product, Eargo 7, at CES 2023. Eargo also announced that it had received U.S. Food and Drug Administration (“FDA”) 510(k) clearance for Eargo 5 and Eargo 6 as self-fitting hearing aids. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in this Item 7.01, including the exhibit hereto, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On December 22, 2022, Eargo received FDA 510(k) clearance for Eargo 5 and 6 as self-fitting hearing aids. Eargo is launching Eargo 7 as its third over-the-counter, self-fitting device. The Eargo self-fitting hearing aids are intended to amplify and transmit sound to the ear and compensate for perceived mild to moderate hearing impairment in individuals 18 years of age or older. They are adjusted by the user to meet the user’s hearing needs. No pre-programming or hearing test is necessary. The products are intended to be used without the assistance of a hearing care professional. As previously disclosed, the Company plans to market its devices as over-the-counter (“OTC”) hearing aids and intends to comply with all applicable OTC regulatory requirements as of the compliance date for currently marketed devices on April 14, 2023, or sooner. In addition, the Company may seek to market certain devices as prescription hearing aids, which would require compliance with separate physical and electronic labeling requirements under the FDA’s OTC final rule.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact contained in this Current Report are forward-looking statements, including statements regarding the intended use of Eargo products and the Company’s marketing plans and compliance with applicable OTC regulatory 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: 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 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 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 Current Report 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 Current Report. 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
No.	
99.1	Press Release dated January 4, 2023.
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

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.

Date: January 4, 2023

EARGO, INC.

By: /s/Adam Laponis

Adam Laponis

Chief Financial Officer

**HEARING WELLNESS PIONEER EARGO LAUNCHES
EARGO 7, ITS MOST REVOLUTIONARY DEVICE YET, AT CES**

- **EARGO 7 OFFERS CLARITY MODE, CREATING ITS MOST NATURAL HEARING EXPERIENCE FOR THOSE WITH MILD TO MODERATE HEARING LOSS**
- **NEW OTC DEVICE TO BE AVAILABLE IN-STORE THROUGH PARTNERSHIP WITH VICTRA, ONE OF AMERICA'S LARGEST WIRELESS RETAILERS**
- **EARGO 5 AND 6 HAVE RECEIVED FDA 510(K) CLEARANCE AS SELF-FITTING HEARING AIDS; EARGO 7 WILL LAUNCH AS EARGO'S THIRD OVER-THE-COUNTER, SELF-FITTING DEVICE**
- **EARGO'S RECENT PARTNERSHIP WITH NATIONS BENEFITS CONTINUES TO ADVANCE ITS MISSION TO INCREASE ACCESS TO BETTER HEARING**

LAS VEGAS, Jan. 04, 2023 (GLOBE NEWSWIRE) -- Eargo, Inc. (Nasdaq: EAR), a medical device company on a mission to improve the quality of life of people with hearing loss, today launched the Eargo 7, its seventh generation device, at CES. As Eargo's premiere device to be sold as an over-the-counter (OTC) self-fitting hearing aid, Eargo 7 introduces Sound Adjust+ with Clarity Mode, which aims to help address consumers' core need to hear more clearly in noisy environments and provide those with hearing loss Eargo's most natural hearing experience yet.

Eargo 7 advances Eargo's commitment to disrupting the hearing aid industry through groundbreaking service and product innovation. Key features include:

- **New! Sound Adjust+:** Eargo 7's Sound Adjust+ feature provides more sophisticated sound processing in loud environments. It analyzes the soundscape, then automatically chooses whether to emphasize speech or reduce noise for comfort, making Eargo 7 optimal in noisy environments.
- **Improved Performance in Noise:** Eargo's fast-acting noise reduction limits loud background noise, enabling improved hearing in noisy environments such as restaurants, work settings and the outdoors.
- **Water-resistant:** Eargo 7 has been tested to a water-resistance rating of IPX7, meaning water resistance of up to 30 minutes at a water depth of up to one meter. This gives users the confidence to wear the device while exercising and/or in rainy weather.
- **Rechargeable:** Eargo hearing aids use fully customized and rechargeable batteries that provide the highest energy density in the smallest space. Eargo 7 is fully charged within six hours for up to 16 hours of continuous power.

Eargo 7 comes at a critical moment. Nearly 45 million adults in the United States suffer from hearing loss, but only approximately 25% have ever used a hearing aid—and hearing loss is only on the rise. The World Health Organization released a new standard for safe listening at venues and events in 2022, noting that millions of young adults may be at risk of hearing loss due to the “unsafe use of personal audio devices and exposure to damaging sound levels at venues such as nightclubs, bars, concerts and sporting events.” The result is a heightened sense of urgency to promote hearing wellness and find innovative ways to assist those with hearing loss.

On December 22, 2022, Eargo received FDA 510(k) clearance for Eargo 5 and 6 as self-fitting hearing aids. Eargo is launching Eargo 7 as its third over-the-counter, self-fitting device.

Christian Gormsen, CEO and President of Eargo commented, “On the heels of our recently announced partnerships with Victra Wireless stores and NationsBenefits, we could not be more thrilled to now launch the Eargo 7 as our most advanced device to be sold over the counter, further advancing our mission to make hearing wellness more widely accessible.”

Gormsen continued, “Eargo 7 is truly designed for consumers. We are not creating another product to take advantage of a moment; we are innovating on our passion to ensure each generation of the Eargo leverages the latest technology and offers the best user experience possible. Eargo 7 combines the high tech and high touch of high-end devices at a more affordable price point relative to competing hearing aids purchased through traditional channels, without ever compromising quality or user experience like other low-priced entrants to the OTC market. Eargo 7 is a high-quality product uniquely designed for the OTC era.”

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. To learn more, please visit <https://www.eargo.com/>.

Forward-Looking Statements

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