

**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): October 17, 2022

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered:</u>
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 8.01 Other Events.

Eargo, Inc. (“Eargo” or the “Company”) is providing the following information regarding the final rule published by the United States Food and Drug Administration (“FDA”) on August 17, 2022, which establishes new regulatory categories for over-the-counter (“OTC”) and prescription hearing aids (the “OTC Final Rule”), and the Company’s plans to market its devices as OTC hearing aids in accordance with the OTC Final Rule. The OTC Final Rule includes revised requirements for labelling, conditions of sale, performance standards, design requirements and other provisions under which manufacturers may elect to market hearing aids as either OTC or prescription devices, or both. The OTC Final Rule becomes effective on October 17, 2022, although certain currently marketed devices have until April 14, 2023 to come into compliance with the OTC Final Rule.

OTC hearing aids are intended to be available without supervision, prescription or other order, involvement or intervention of a licensed practitioner. Following the effective date of the OTC Final Rule, customers can not only learn about Eargo hearing aids and obtain general information about their hearing through the Company’s current hearing screeners, they can also purchase or order Eargo hearing aids in retail settings. Eargo’s self-administered hearing screeners are intended to be part of a retail customer experience and are expected to be located in physical retail settings so customers can obtain general information regarding their hearing and see Eargo hearing aids in person. The Company has a select number of commercial partnerships to, among other things, facilitate the retail experience, and intends to continue to pursue additional opportunities for in-person customer engagement.

The Company plans to market its devices as 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, while also potentially selling its products as prescription devices. In June 2022, the Company submitted a 510(k) premarket notification seeking FDA clearance of expanded labelling for Eargo 5 and 6 hearing aids as “self-fitting.” In August 2022, the FDA requested additional data and information in support of the Company’s pending 510(k) submission to market Eargo 5 and 6 as self-fitting hearing aids, including additional clinical study data. While the Company is working to produce this data expediently, if it is unable to obtain 510(k) clearance for Eargo 5 and 6 as self-fitting hearing aids, it may need to remove certain product features and revise current and future marketing plans for these products in order to market them OTC.

Prior to the effective date of the OTC Final Rule, no OTC category of hearing aids existed, and certain carriers excluded from coverage so-called “over-the-counter” hearing aids and enhancement devices (such as personal sound amplification products, or “PSAPs”). Accordingly, the new regulatory category of OTC hearing aids created with the OTC Final Rule may not be covered under certain plans as currently written, until such time as such carriers update their coverage policies to reflect the newly established OTC category under the OTC Final Rule, if ever. In addition, even if health plans update their coverage policies to include the new regulatory category of OTC hearing aids, they nonetheless may require a prescription, evaluation or diagnostic test conducted by a licensed healthcare professional to establish medical necessity. The Company intends to work with such carriers to establish coverage as necessary.

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 future effects of the OTC Final Rule, the Company's ability to add full retail and physical locations or experiences, the impact of the OTC Final Rule and the Company's assessment, ability and timing for compliance with the new requirements, and the Company's intention to work with carriers to establish coverage as necessary. 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 Company's 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 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 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.

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: October 17, 2022

EARGO, INC.

By: /s/ Adam Laponis
Adam Laponis
Chief Financial Officer
