UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-39616

Eargo, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**27-3879805**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2665 North First Street, Suite 300	
San Jose, California	**95134**
(Address of principal executive offices)	**(Zip Code)**

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

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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, par value $0.0001 per share	**EAR**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 19, 2022, the registrant had 39,358,558 shares of common stock, par value $0.0001 outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry that involve substantial risks, uncertainties and assumptions. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future financial condition, future operations, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "forecast," "goal," "guidance," "intend," "likely," "may," "objective," "plan," "ongoing," "positioned," "possible," "potential," "predict," "project," "seek," "shall," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the impact on our business of the civil settlement agreement with the U.S. government that resolved the investigation by the U.S. Department of Justice (the "DOJ") related to insurance reimbursement claims submitted to various federal employee health plans under the Federal Employee Health Benefits ("FEHB") program, and the extent to which we may be able to validate and establish processes to support the submission of claims for reimbursement to health plans under the FEHB program in the future, if at all, and our ability to obtain, maintain or increase insurance coverage for our hearing aids in the future;
- the timing or results of claims audits and medical records reviews by third-party payors;
- the expense, timing and outcome of the purported securities class action litigation alleging that certain of our disclosures about our business, operations and prospects, including reimbursements from third-party payors, violated the federal securities laws and the purported derivative action alleging that our directors breached their fiduciary duties by failing to implement and maintain an effective system of internal controls;
- our ability to continue to maintain the listing of our securities on The Nasdaq Stock Market LLC ("Nasdaq"), including our ability to execute a plan to regain compliance with the Nasdaq requirements regarding the timely filing of periodic financial reports with the Securities and Exchange Commission (the "SEC");
- estimates of our future revenue and expenses, including the extent of any losses we incur from hearing aids delivered to customers where we have not submitted an insurance claim and may not receive payment;
- estimates of our future capital needs and our 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;
- our expectations with regard to changes in the regulatory landscape for hearing aid devices, including the anticipated implementation of a pending over-the-counter ("OTC") hearing aid regulatory framework and potential Medicare coverage for certain hearing aids, as well as any potential actions insurance providers may take following any regulatory changes;
- our ability to attract and retain customers;
- our expectations concerning additional orders by existing customers;
- our expectations regarding the potential market size and size of the potential consumer populations for our products and any future products, including our ability to obtain, maintain or increase insurance coverage of and reimbursement of insurance claims for Eargo hearing aids, which is substantially dependent on, among other things, the outcomes of our efforts to validate and establish processes to support the submission of claims for reimbursement from various federal health plans, any third-party payor audits and pending regulations;
- our ability to release new hearing aids and the anticipated features of any such hearing aids and our ability to transition our existing customers to new hearing aids, including when older models are discontinued;
- developments and projections relating to our competitors and our industry, including competing products;
- our ability to maintain our competitive technological advantages against new entrants in our industry;
- the pricing of our hearing aids;
- our expectations regarding the availability, supply, cost and inflationary pressures related to the component parts of our hearing aids;
- our expectations regarding the ability to make certain claims related to the performance of our hearing aids relative to competitive products;
- our commercialization and marketing capabilities and expectations;

- our relationships with, and the capabilities of, our component manufacturers, suppliers and freight carriers;
- the implementation of our business model and strategic plans for our business, products and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our products, including the projected terms of patent protection;
- our ability to effectively manage our business in light of the civil settlement agreement with the U.S. government, third-party payor claims audits and medical records reviews, purported securities class action and derivative litigations, and pending regulations;
- our ability to retain existing talent and attract new, highly skilled talent;
- our estimates regarding the COVID-19 pandemic, including but not limited to, its duration and its impact on our business and results of operations; and
- our future financial performance.

We have based these forward-looking statements largely on our current expectations, estimates, forecasts and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled “Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. 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.

Item 1. Financial Statements.

Eargo, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except share and per share amounts)

	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 89,232	$ 110,500
Accounts receivable, net	12,253	12,547
Inventories	5,787	5,712
Prepaid expenses and other current assets	9,528	10,873
Total current assets	116,800	139,632
Operating lease right-of-use assets	6,794	7,165
Property and equipment, net	8,998	9,551
Intangible assets, net	1,526	1,681
Goodwill	873	873
Other assets	544	1,209
Total assets	$ 135,535	$ 160,111
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,029	$ 9,053
Accrued expenses	9,086	9,235
Sales returns reserve	13,686	13,827
Settlement liability	34,429	34,372
Long-term debt, current portion	5,000	3,333
Other current liabilities	2,070	1,813
Lease liability, current portion	805	750
Total current liabilities	77,105	72,383
Lease liability, noncurrent portion	6,501	6,640
Long-term debt, noncurrent portion	10,363	11,924
Total liabilities	93,969	90,947
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.0001 par value per share; 5,000,000 shares authorized as of March 31, 2022 and December 31, 2021, respectively; zero shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	—	—
Common stock; $0.0001 par value; 110,000,000 shares authorized as of March 31, 2022 and December 31, 2021, respectively; 39,344,518 and 39,307,093 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	4	4
Additional paid-in capital	429,019	425,972
Accumulated deficit	(387,457)	(356,812)
Total stockholders' equity	41,566	69,164
Total liabilities and stockholders' equity	$ 135,535	$ 160,111

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Eargo, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	Three months ended March 31,	
	2022	**2021**
Revenue, net	$ 9,176	$ 22,048
Cost of revenue	5,491	6,297
Gross profit	3,685	15,751
Operating expenses:		
Research and development	5,847	4,778
Sales and marketing	13,290	16,855
General and administrative	14,934	7,487
Total operating expenses	34,071	29,120
Loss from operations	(30,386)	(13,369)
Other income (expense), net:		
Interest income	5	11
Interest expense	(264)	(263)
Total other income (expense), net	(259)	(252)
Loss before income taxes	(30,645)	(13,621)
Income tax provision	—	—
Net loss and comprehensive loss	$ (30,645)	$ (13,621)
Net loss attributable to common stockholders, basic and diluted	$ (30,645)	$ (13,621)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.78)	$ (0.36)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	39,323,386	38,283,360

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Eargo, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands, except share amounts)

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance December 31, 2021	39,307,093	$ 4	$ 425,972	$ (356,812)	$ 69,164
Stock-based compensation	—	—	3,024	—	3,024
Exercise of stock options	37,425	—	92	—	92
Restricted stock units cash settlement	—	—	(69)	—	(69)
Net loss and comprehensive loss	—	—	—	(30,645)	(30,645)
Balance March 31, 2022	39,344,518	$ 4	$ 429,019	$ (387,457)	$ 41,566

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance December 31, 2020	38,246,601	$ 4	$ 392,965	$ (199,058)	$ 193,911
Stock-based compensation	—	—	5,449	—	5,449
Exercise of stock options	51,467	—	118	—	118
Net loss and comprehensive loss	—	—	—	(13,621)	(13,621)
Balance March 31, 2021	38,298,068	$ 4	$ 398,532	$ (212,679)	$ 185,857

Eargo, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Three months ended March 31,	
	2022	**2021**
Operating activities:		
Net loss	$ (30,645)	$ (13,621)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,419	735
Stock-based compensation	2,985	5,131
Non-cash interest expense and amortization of debt discount	105	103
Non-cash operating lease expense	371	295
Bad debt expense	174	62
Loss on disposal of property and equipment	28	—
Changes in operating assets and liabilities:		
Accounts receivable	120	(1,608)
Inventories	(75)	276
Prepaid expenses and other current assets	1,345	565
Other assets	665	(24)
Accounts payable	2,962	715
Accrued expenses	107	(1,598)
Sales returns reserve	(141)	(1,387)
Settlement liability	57	—
Other current and noncurrent liabilities	257	1,364
Operating lease liabilities	(84)	(317)
Net cash used in operating activities	(20,350)	(9,309)
Investing activities:		
Purchases of property and equipment	(685)	(296)
Capitalized software development costs	(257)	(1,074)
Net cash used in investing activities	(942)	(1,370)
Financing activities:		
Proceeds from stock options exercised	93	118
Restricted stock units settled in cash	(69)	-
Net cash provided by financing activities	24	118
Net decrease in cash and cash equivalents	(21,268)	(10,561)
Cash and cash equivalents at beginning of period	110,500	212,185
Cash and cash equivalents at end of period	$ 89,232	$ 201,624
Non-cash operating activities:		
Lease liability obtained in exchange for right-of-use asset	$ —	$ 434
Non-cash investing and financing activities:		
Property and equipment and capitalized software costs in accounts payable and accrued liabilities	$ 116	$ 330
Stock-based compensation included in capitalized software costs	$ 39	$ 318
Convertible preferred stock issuance costs included in accounts payable	$ 600	$ 600

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

1. Description of business and other matters

Eargo, Inc. (the "Company") is a medical device company dedicated to improving the quality of life of people with hearing loss. The Company's innovative product and go-to-market approach address the major challenges of traditional hearing aid adoption, including social stigma, accessibility and cost.

DOJ investigation and settlement and claims audits

On September 21, 2021, the Company was informed that it was the target of a criminal investigation by the U.S. Department of Justice (the "DOJ") related to insurance reimbursement claims the Company submitted on behalf of its customers covered by various federal employee health plans under the Federal Employee Health Benefits ("FEHB") program, which is administered by the Office of Personnel Management (the "OPM"). The investigation also pertained to Eargo's role in customer reimbursement claim submissions to federal employee health plans (collectively, the "DOJ investigation"). Additionally, the Company's historically largest third-party payor, one of the carriers contracted with the OPM under the FEHB program ("largest third-party payor"), conducted an audit of insurance reimbursement claims ("claims") submitted by the Company (the "Primary Audit"), which included a review of medical records. The Company was informed by the third-party payor conducting the Primary Audit that the DOJ was the principal contact related to the subject matter of the Primary Audit. On January 4, 2022, the DOJ confirmed to the Company that the investigation had been referred to the Civil Division of the DOJ and the U.S. Attorney's Office for the Northern District of Texas and the criminal investigation was no longer active.

On April 29, 2022, the Company entered into a civil settlement agreement with the U.S. government that resolved the DOJ investigation related to the Company's role in customer reimbursement claim submissions to various federal employee health plans under the FEHB program. The settlement agreement provided for the Company's payment of approximately $34.4 million to the U.S. government and resolved allegations that the Company submitted or caused the submission of claims for payment to the FEHB program using unsupported hearing loss-related diagnostic codes.

From the time the Company learned of the DOJ investigation and until December 8, 2021, the Company continued to process orders for customers with potential insurance benefits (including FEHB program members) but suspended all claims submission activities and has offered affected customers (*i.e.*, customers using insurance benefits as a method of direct payment for transactions prior to December 8, 2021) the option to return their hearing aids or purchase their hearing aids without the use of their insurance benefits in case their claim is denied or ultimately not submitted by the Company to their insurance plan for payment (the "extended right of return").

Beginning on December 8, 2021, the Company made the decision to stop accepting insurance benefits as a method of direct payment and it is uncertain when, if ever, the Company will resume accepting insurance benefits as a method of direct payment. While the Company intends to work with the government and third-party payors at the appropriate time with the objective of validating and establishing processes to support any future claims that it may submit for reimbursement, the Company may not be able to arrive at acceptable processes or submit any future claims.

Total life-to-date payments the Company has received through March 31, 2022 from the government in relation to claims submitted under the FEHB program, net of any product returns and associated refunds, were approximately $44 million, which is unchanged from December 31, 2021. As discussed further in Note 5, based on the settlement agreement with the U.S. government, the Company has recorded a settlement liability of $34.4 million as of March 31, 2022 and December 31, 2021. The settlement amount was treated as consideration payable to a customer and was recorded as a reduction of revenue in the third quarter of 2021. On May 2, 2022, the Company paid the settlement amount.

The Company determined that customer transactions using insurance benefits as a method of direct payment occurring subsequent to learning of the DOJ investigation on September 21, 2021 did not meet the criteria for revenue recognition under Accounting Standards Codification ("ASC") 606. As such, the Company did not recognize revenue for shipments to customers with potential insurance benefits, substantially all of whom were covered under the FEHB program, subsequent to that date.

The Company estimated that a majority of customers with unsubmitted claims will choose to return the hearing aid system if their insurance provider denies their claim or the claim is ultimately not submitted by the Company for payment, resulting in an increase in expected product returns from such transactions that occurred prior to September 21, 2021 that was recorded during the year ended December 31, 2021. Of the $13.7 million sales returns reserve recorded as of March 31, 2022, $11.3 million relates to unsubmitted claims that are included in accounts receivable, net. Returns associated with unsubmitted claims will reduce the sales returns reserve, with a corresponding reduction in the related accounts receivable at the time the product is returned.

Further, the Company also estimated that, in addition to the customers who choose to return their hearing aid systems, a significant number of customers whose claims are denied by insurance providers or not submitted by the Company for payment may not pay for or return the hearing aid system, resulting in bad debt expense that was recorded during the year ended December 31, 2021.

Notwithstanding the settlement, the Company remains subject to prepayment review of claims by its largest third-party payor before any insurance payments are made. The Company does not intend to submit any claims through the FEHB program until it is able to establish processes with applicable third-party payors to support the submission of these claims, and the Company may be unable to do so.

Liquidity and going concern

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. The Company has incurred losses and negative cash flows from operations since its inception and management expects to incur additional substantial losses in the foreseeable future. As of March 31, 2022, the Company had cash and cash equivalents of $89.2 million and an accumulated deficit of $387.5 million.

The Company believes that without any future financing, its current resources are insufficient to satisfy its obligations as they become due within one year after the date that the financial statements are issued. The negative cash flows and current lack of financial resources of the Company raise substantial doubt as to the Company's ability to continue as a going concern.

The Company's future operating requirements will be substantial and it will need to raise significant additional resources to fund its operations through equity or debt financing, or some variation thereof. The Company is currently exploring fundraising opportunities to meet these capital requirements. If the Company is unable to raise additional funding to meet its operational needs, it will be forced to limit or cease its operations.

The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainty.

While the extent to which the Company is able to validate and establish processes to support the submission of claims for reimbursement to health plans, including those under the FEHB program, if at all, in the future, and the future impacts of the anticipated implementation of a pending over-the-counter ("OTC") hearing aid regulatory framework (which may lead insurance providers to take actions limiting the Company's ability to access insurance coverage and may also generally result in additional compliance or other regulatory requirements for the Company) is difficult to assess or predict at this time, since the announcement of the DOJ investigation, there has been and may continue to be a significant reduction in shipments, revenue and gross margin, which could negatively impact the Company's liquidity and working capital, including by impacting its ability to increase its existing credit facility or access any additional capital.

2. Summary of significant accounting policies

Basis of presentation and principles of consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with GAAP and applicable rules and regulations of the SEC regarding interim financial reporting of Eargo, Inc. and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated.

These unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, include all adjustments of a normal recurring nature necessary to present fairly the Company's consolidated financial position, results of operations and cash flows. The unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on May 13, 2022.

Use of estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates, assumptions, and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the unaudited condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions made in the accompanying unaudited condensed consolidated financial statements include, but are not limited to, the sales returns reserve, the present value of lease liabilities, the fair value of equity securities, the fair value of financial instruments, the allowance for credit losses, the net realizable value of inventory, the fair value of

assets acquired in a business combination, the useful lives of long-lived assets, accrued product warranty reserve, legal and other contingencies, certain other accruals and recoverability of the Company's net deferred tax assets and the related valuation allowance. Management periodically evaluates its estimates, which are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates.

Significant accounting policies

There have been no significant changes to the accounting policies during the three months ended March 31, 2022, as compared to the significant accounting policies described in Note 2 of the Notes to Consolidated Financial Statements in the Company's audited consolidated financial statements included in the Annual Report on Form 10-K.

Concentration of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of demand deposit accounts, money market accounts and accounts receivable, including credit card receivables. The Company maintains its cash and cash equivalents, which may, at times, exceed federally insured limits, with financial institutions of high credit standing. As of March 31, 2022, the Company has not experienced any losses on its deposit accounts and money market accounts. As of March 31, 2022, the Company does not believe there is significant financial risk from nonperformance by the issuers of the Company's deposit accounts and money market accounts.

Approximately 95% and 93% of the Company's gross accounts receivable as of March 31, 2022 and December 31, 2021, respectively, were for customers with insurance benefits, substantially all of whom were covered under the FEHB program. Furthermore, approximately 92% and 90% of the Company's gross accounts receivable as of March 31, 2022 and December 31, 2021, respectively, were related to shipments of Eargo hearing aids to customers insured under a single insurance plan whose claims are processed through the Company's largest third-party payor, which conducted the Primary Audit. The increase in gross accounts receivable as of March 31, 2022 was primarily due to the Primary Audit, during which certain claims with a service date after March 1, 2021, have not yet and may never be submitted for reimbursement. We remain subject to a prepayment review of claims by the payor who conducted the Primary Audit.

Please see caption "DOJ investigation and settlement and claims audits" in Note 1 for more information regarding the DOJ investigation and claims audits.

Revenue recognition

The Company's revenue is generated from the sale of products (hearing aid systems and related accessories) and services (extended warranties). These products and services are primarily sold directly to customers through the Eargo website and the Company's sales representatives.

Under ASC 606, revenue is recognized when promised goods or services are transferred to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services by following a five step process: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Identify the contract with a customer. The Company generally considers completion of an Eargo sales order (which requires customer acceptance of the Company's click-through terms and conditions for website sales and authorization of payment through credit card or another form of payment for sales made over the phone) as a customer contract provided that collection is considered probable. For payments that are not made upfront by credit card, the Company assesses insurance eligibility or customer creditworthiness based on credit checks, payment history, and/or other circumstances. For orders involving insurance payors, the Company validates customer eligibility and potential reimbursement amounts prior to shipping the product. If the criteria to establish a contract with a customer is not met, revenue is not recognized in accordance with ASC 606.

Identify the performance obligations in the contract. Product performance obligations include hearing aid systems and related accessories and service performance obligations include extended warranty coverage. The Company also offers customers a one-time replacement of certain components of the hearing aid system for a fee (i.e., "loss and damage policy"), which represents an option with material right. However, as the historical redemption rate under the policy has been low, the option is not accounted for as a separate performance obligation. The Company does not assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer.

The Company has elected to treat shipping and handling activities performed after a customer obtains control of products as a fulfillment activity.

Determine the transaction price and allocation to performance obligations. The transaction price in the Company's customer contracts consists of both fixed and variable consideration. Fixed consideration includes amounts to be contractually billed to the customer while variable consideration includes the 45-day right of return that applies to all products and the extended right of return offered for certain shipments involving insurance payors prior to December 8, 2021 (at which time the Company ceased accepting insurance benefits as a method of direct payment). Please see caption "DOJ investigation and settlement and claims audits" in Note 1 for more information regarding the extended right of return. To estimate product returns, the Company analyzes various factors, including historical return levels, current economic trends, and insurance coverage. Based on this information, the Company reserves a percentage of product sale revenue and accounts for the estimated impact as a reduction in the transaction price. Consideration paid or payable to a customer that is not for a distinct good or service is accounted for as a reduction of the transaction price and recorded as a reduction in revenue in the period it becomes payable.

Allocate the transaction price to the performance obligations in the contract. For contracts that contain multiple performance obligations, the Company allocates the transaction price to the performance obligations on a relative standalone selling price basis. Standalone selling prices are based on multiple factors including, but not limited to, historical discounting trends for products and services, gross margin objectives, internal costs, competitor pricing strategies, and industry technology lifecycles.

Recognize revenue when or as the Company satisfies a performance obligation. Revenue for products (hearing aid systems and related accessories) is recognized at a point in time, which is generally upon shipment provided all other revenue recognition criteria have been met.

Contract costs

The Company applies the practical expedient to recognize the incremental costs of obtaining a contract as expense when incurred if the amortization period would be one year or less. These incremental costs include processing fees paid to third-party financing vendors, who provide the Company's customers with the option to finance their purchases. If a customer elects to utilize this service, the Company receives a non-recourse upfront payment for the product sold, less processing fee withheld by the financing vendor. These processing fees are recognized in cost of revenue in the condensed consolidated statements of operations and comprehensive loss as incurred.

Recently adopted accounting pronouncements

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify the accounting for income taxes. This standard removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing standards to improve consistent application. The Company adopted this standard in the fiscal year beginning January 1, 2022. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40),* which is intended to simplify the accounting for convertible debt instruments and convertible preferred stock. This standard removes the existing guidance in ASC 470-20 that requires companies to account for cash conversion features and beneficial conversion features in equity separately from the host convertible debt or preferred stock. The Company adopted this standard in the fiscal year beginning January 1, 2022. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

3. Fair value measurements

There were no financial assets and liabilities outstanding that were remeasured at fair value on a recurring basis as of March 31, 2022 or December 31, 2021.

The carrying amounts reflected in the condensed consolidated balance sheets for cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to their short-term nature. The fair value of the Company's outstanding term loan is estimated using the net present value of the payments, discounted at an interest rate that is consistent with a market interest rate. The fair value of the outstanding term loan approximates the carrying amount as the term loan bears a floating rate that approximates the market interest rate.

4. Balance sheet components

Inventories

Inventories consist primarily of raw materials related to component parts and finished goods. The following is a summary of the Company's inventories by category:

	March 31, 2022	December 31, 2021
	(in thousands)	
Raw materials	$ 1,525	$ 1,905
Finished goods	4,262	3,807
Total inventories	$ 5,787	$ 5,712

Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

	March 31, 2022	December 31, 2021
	(in thousands)	
Advanced payroll deposits	$ 3,599	$ 3,889
Prepaid insurance fees	2,217	2,945
Prepaid marketing costs	2,221	1,948
Prepaid software subscription	1,080	1,468
Other	411	623
Total prepaid expenses and other current assets	$ 9,528	$ 10,873

Property and equipment, net

Property and equipment, net, consists of the following:

	March 31, 2022	December 31, 2021
	(in thousands)	
Capitalized software	$ 11,579	$ 11,569
Tools and lab equipment	4,806	4,712
Furniture and fixtures	906	906
Leasehold improvements	876	861
Computer and equipment	456	401
	18,623	18,449
Less accumulated depreciation and amortization	(9,625)	(8,898)
Total property and equipment, net	$ 8,998	$ 9,551

Depreciation and amortization expense for the three months ended March 31, 2022 and 2021 amounted to $1.3 million and $0.7 million, respectively, which includes amortization of capitalized software costs of $1.0 million and $0.2 million, respectively.

Intangible assets, net

Intangible assets, net consist of the following:

	March 31, 2022		
	Gross carrying value	Accumulated amortization	Net carrying value
		(in thousands)	
Developed technologies	$ 1,700	$ 319	$ 1,381
Other	290	145	145
Total intangible assets, net	$ 1,990	$ 464	$ 1,526

	December 31, 2021		
	Gross carrying value	Accumulated amortization	Net carrying value
	(in thousands)		
Developed technologies	$ 1,700	$ 212	$ 1,488
Other	290	97	193
Total intangible assets, net	$ 1,990	$ 309	$ 1,681

Amortization expense was $0.2 million for the three months ended March 31, 2022.

The following table summarizes estimated future amortization expense of finite-lived intangible assets, net as of March 31, 2022:

	Amount
	(in thousands)
Remainder of 2022	$ 463
2023	425
2024	425
2025	213
Total	$ 1,526

Accrued expenses

Accrued expenses consist of the following:

	March 31, 2022	December 31, 2021
	(in thousands)	
Accrued compensation	$ 4,428	$ 4,845
Accrued warranty reserve	4,240	4,014
Refunds due to customers	418	376
Total accrued expenses	$ 9,086	$ 9,235

Sales returns reserve

The sales returns reserve consists of the following activity:

	Three months ended March 31,	
	2022	2021
	(in thousands)	
Sales returns reserve, beginning balance	$ 13,827	$ 4,326
Reduction of revenue	4,584	6,304
Utilization of sales returns reserve	(4,725)	(7,691)
Sales returns reserve, ending balance	$ 13,686	$ 2,939

Of the $13.7 million sales returns reserve recorded as of March 31, 2022, $11.3 million relates to unsubmitted claims from shipments prior to September 22, 2021 (at which time the Company suspended all claims submissions activities) that are included in accounts

receivable, net. Returns associated with unsubmitted claims will reduce the sales returns reserve, with a corresponding reduction in the related accounts receivable at the time the product is returned.

Allowance for credit losses

The allowance for credit losses consists of the following activity:

	Three months ended March 31,	
	2022	2021
	(in thousands)	
Allowance for credit losses, beginning balance	$ 4,838	$ 1,868
Charged to expense	174	62
Accounts written off, net of recoveries	(292)	(298)
Allowance for credit losses, ending balance	$ 4,720	$ 1,632

Accrued warranty reserve

The accrued warranty reserve consists of the following activity:

	Three months ended March 31,	
	2022	2021
	(in thousands)	
Accrued warranty reserve, beginning balance	$ 4,014	$ 2,390
Charged to cost of revenue	958	950
Utilization of accrued warranty reserve	(732)	(353)
Accrued warranty reserve, ending balance	$ 4,240	$ 2,987

5. Commitments and contingencies

Operating leases

In September 2021, the Company entered into a lease agreement, as amended, for office and laboratory space located in San Jose, California. The lease commenced in September 2021 and has a 93-month term with two 60-month renewal options, which are not reasonably certain of being exercised. The Company also leases office space in Nashville, Tennessee, with a lease term that expires in March 2023. Variable lease payments are primarily comprised of common area maintenance.

The ROU asset and corresponding lease liability for the Company's operating leases were estimated using a weighted-average incremental borrowing rate of 7.7%. The weighted-average remaining lease term is 7.06 years.

For the three months ended March 31, 2022, the Company incurred $0.5 million of operating lease costs. Variable lease payments for operating expenses and costs related to short-term leases were immaterial for the three months ended March 31, 2022 and March 31, 2021.

As of March 31, 2022, undiscounted future minimum lease payments due under the non-cancelable operating leases are as follows:

	Operating leases
	(in thousands)
Remainder of 2022	$ 1,103
2023	1,114
2024	1,081
2025	1,331
2026	1,372
Thereafter	3,607
Total minimum future lease payments	9,608
Present value adjustment for minimum lease commitments	(2,302)
Total lease liability	$ 7,306

Legal and other contingencies

The Company is involved in legal proceedings in the ordinary course of its business and may become involved in additional legal proceedings. Other than those listed below, the Company does not believe that any lawsuits or claims currently pending against it, individually or in the aggregate, are material or will have a material adverse effect on its financial condition, results of operations or cash flows. The Company may enter into settlement discussions, and may enter into settlement agreements, if it believes settlement is in the best interest of the Company and its shareholders. Unless stated otherwise, the matters discussed below, if decided adversely or settled by the Company, individually or in the aggregate, may result in a liability material to the Company's financial condition, results of operations or cash flows.

The Company is also subject to review from federal and state taxing authorities in order to validate the amounts of income, sales and/or use taxes which have been claimed and remitted. The Company has estimated exposure and established reserves for its estimated sales tax audit liability.

In the normal course of business, the Company may agree to indemnify third parties with whom it enters into contractual relationships, including customers, lessors, and parties to other transactions with the Company, with respect to certain matters. The Company has agreed, under certain conditions, to hold these third parties harmless against specified losses, such as those arising from a breach of representations or covenants, other third-party claims that the Company's products, when used for their intended purposes, infringe the intellectual property rights of such other third parties, or other claims made against certain parties. It is not possible to determine the maximum potential amount of liability under these indemnification obligations due to the Company's limited history of prior indemnification claims and the unique facts and circumstances that are likely to be involved in any particular claim.

DOJ Investigation and Settlement. On September 21, 2021, the Company was informed that it was the target of a criminal investigation by the DOJ related to insurance reimbursement claims the Company submitted on behalf of its customers covered by various federal employee health plans under the FEHB program. The investigation also pertained to the Company's role in customer reimbursement claim submissions to federal employee health plans. Additionally, the Company was the subject of an ongoing claims audit by an insurance company that is the Company's largest third-party payor and was informed by such insurance company that the DOJ was the principal contact related to the subject matter of the audit. In addition to such audit, the Company has been subject to a number of other audits of insurance reimbursement claims submitted to additional third-party payors. One of these claims audits does not relate to claims submitted under the FEHB program. On January 4, 2022, the DOJ confirmed to the Company that the investigation had been referred to the Civil Division of the DOJ and the U.S. Attorney's Office for the Northern District of Texas and the criminal investigation was no longer active.

On April 29, 2022, the Company entered into a civil settlement agreement with the U.S. government that resolved the DOJ investigation, including allegations that the Company violated the False Claims Act by knowingly submitting or causing the submission of false claims for payment under the FEHB program during the period from February 1, 2021 through September 22, 2021. The settlement agreement provided for the payment by the Company of approximately $34.4 million to the U.S. government and resolved allegations that the Company submitted or caused the submission of claims for payment to the FEHB program using unsupported hearing loss-related diagnostic codes. As of March 31, 2022 and December 31, 2021, the Company recorded a $34.4 million settlement liability in the condensed consolidated balance sheets in connection with the settlement. The settlement amount was treated as consideration payable to a customer and was recorded as a reduction in revenue in the third quarter of 2021. On May 2, 2022, the Company paid the settlement amount.

The settlement of the investigation may not resolve all of the audits of insurance reimbursement claims by additional third-party payors, and additionally the Company remains subject to a prepayment review of claims by the payor who conducted the Primary Audit. The Company will need to work with applicable third-party payors to establish processes to demonstrate medical necessity and support any future claims that it may submit for reimbursement, and there are no guarantees that the Company will be able to arrive at any such acceptable processes or submit any future claims. The Company does not intend to submit any claims through the FEHB program until it is able to align with such payors on and establish processes for supporting the submission of these claims.

Securities Class Action. *Fazio v. Eargo, Inc., Christian Gormsen, & Adam Laponis.*, No. 21-cv-07848 (N.D. Cal. Oct. 6, 2021); *Chung v. Eargo, Inc., Christian Gormsen, & Adam Laponis.*, No. 21-cv-08597 (N.D. Cal. Nov. 4, 2021); *IBEW Local 353 Pension Plan v. Eargo, Inc., Christian Gormsen, Adam Laponis, Josh Makower, Juliet Bakker, Peter Tuxen Bisgaard, Doug Hughes, Geoff Pardo, Nina Richardson, A. Brooke Seawell, David Wu, J.P. Morgan Securities LLC, BofA Securities, Inc., Wells Fargo Securities, LLC, & William Blair & Company, L.L.C.*, No. 21-cv-08747 (N.D. Cal. Nov. 10, 2021). On October 6, 2021, putative shareholder Joseph Fazio filed a purported securities class action against the Company and certain of its officers (the "Fazio action"). Plaintiff alleges that certain of the Company's disclosures about its business, operations, and prospects, including reimbursements from third-party payors, violated federal securities laws. Fazio voluntarily dismissed his complaint on December 6, 2021. On November 4, 2021, putative shareholder Alden Chung filed a substantially similar purported class action lawsuit (the "Chung action"). On November 10, 2021, putative shareholder IBEW Local 353 Pension Plan filed a similar purported class action, and also asserted claims under the

federal securities laws against current and former members of the Company's Board of Directors (the "Board of Directors") and the underwriters of the Company's October 15, 2020 initial public offering of common stock (the "IBEW action"). These class actions, which seek damages and other relief, were filed in the U.S. District Court for the Northern District of California. The Fazio and Chung actions were brought purportedly on behalf of a class of investors who purchased or otherwise acquired Eargo securities between February 25, 2021 and September 22, 2021. The IBEW Local 353 action was brought purportedly on behalf of a class of investors who purchased or otherwise acquired: (i) Eargo shares in or traceable to the Company's October 15, 2020 initial public offering of common stock; and/or (ii) shares of Eargo common stock between October 15, 2020 and September 22, 2021. On January 5, 2022, the court consolidated the foregoing class actions (as consolidated, the "Securities Class Action") under the caption *In re Eargo, Inc. Securities Litigation*, No. 21-cv-08597-CRB, and appointed IBEW Local 353 Pension Plan and Xiaobin Cai as Lead Plaintiffs and Bernstein Litowitz Berger & Grossmann LLP and Block & Leviton LLP as Lead Counsel. Lead Plaintiffs filed a consolidated amended complaint, which purports to extend the class period through March 2, 2022, on May 20, 2022. Defendants intend to file a motion to dismiss.

The Company intends to vigorously defend the Securities Class Action and cannot reasonably estimate any loss or range of loss that may arise from the litigation. Accordingly, the Company can provide no assurance as to the scope and outcome of this matter and no assurance as to whether its business, financial position, results of operations, or cash flows will not be materially adversely affected.

Derivative Action. *Wolfson v. Christian Gormsen, Joshua Makower, Douglas J. Hughes, Nina Louise Richardson, Katie J. Bayne, Peter Tuxen Bisgaard, A. Brooke Seawell, David Wu, and Eargo, Inc.*, No. 21-cv-09342 (N.D. Cal. Dec. 3, 2021). On December 3, 2021, putative shareholder Barbara Wolfson filed a derivative complaint purportedly on Eargo's behalf against members of the Board of Directors and the Company as nominal defendant (the "Derivative Action"). Plaintiff asserts, among other things, that the defendants breached their fiduciary duties by allegedly failing to implement and maintain an effective system of internal controls related to the Company's financial reporting, public disclosures and compliance with laws, rules and regulations governing the business. Plaintiff purports to assert derivative claims on the Company's behalf for alleged violations of Section 14(a) of the Securities Exchange Act of 1934, as amended, breach of fiduciary duty, waste of corporate assets, and aiding and abetting. On March 1, 2022, the court entered the parties' stipulation staying the Derivative Action until the anticipated motion to dismiss in the Securities Class Action is decided.

The defendants intend to vigorously defend the Derivative Action and cannot reasonably estimate any loss or range of loss that may arise from the litigation. Accordingly, the Company can provide no assurance as to the scope and outcome of this matter and no assurance as to whether its business, financial position, results of operations, or cash flows will not be materially adversely affected.

6. Debt obligations

2018 Loan Agreement

In June 2018, the Company entered into a Loan and Security Agreement (the "2018 Loan Agreement") with Silicon Valley Bank, as amended in January 2019, May 2020 and September 2020 (the "Third Amendment"). The Company's existing subsidiaries are, and any additional future domestic subsidiaries of the Company are required to be, co-borrowers jointly and severally liable under the 2018 Loan Agreement.

The Company borrowed $15.0 million under the Third Amendment in September 2020 and used $10.2 million of the proceeds to repay the existing term loan. The term loan under the Third Amendment matures in September 2024 with interest-only monthly payments until July 2022. The term loan accrues interest at a per annum rate equal to the Wall Street Journal prime rate plus 1.0% (4.50% as of March 31, 2022) and includes a final payment fee equal to 6.25% of the original aggregate principal amount. In connection with the execution of the Third Amendment, the Company issued Silicon Valley Bank a warrant to purchase 53,487 shares of Series E convertible preferred stock. The estimated fair value of the warrants at issuance was recorded as a discount on the loan and is amortized to interest expense over the term of the agreement using the effective interest method.

Borrowings under the Third Amendment are collateralized by substantially all the assets of the Company, excluding intellectual property (but including rights to payment and proceeds thereof). The Third Amendment contains customary affirmative and restrictive covenants, including with respect to the Company's ability to enter into fundamental transactions, incur additional indebtedness, grant liens, pay any dividend or make any distributions to its holders, make investments, merge or consolidate with any other person or engage in transactions with the Company's affiliates, but do not include any financial covenants. The Company was in compliance with all of the covenants as of March 31, 2022.

As of March 31, 2022, outstanding principal on the term loan and accrual for the final payment fee amounted to $15.5 million. During the three months ended March 31, 2022 and 2021, the Company recognized interest expense related to the term loans of $0.3 million and $0.3 million, respectively, which is inclusive of amortization of debt discount. The effective interest rate was 7.25% as of March 31, 2022.

7. Stock-based compensation

Total stock-based compensation is as follows:

	Three months ended March 31,	
	2022	2021
	(in thousands)	
Cost of revenue	$ 22	$ 186
Research and development	985	1,067
Sales and marketing	637	1,856
General and administrative	1,341	2,022
Total stock-based compensation	$ 2,985	$ 5,131

Stock-based compensation costs capitalized as part of capitalized software costs was less than $0.1 million and $0.3 million during the three months ended March 31, 2022 and March 31, 2021, respectively.

Equity incentive plans

As of March 31, 2022, 5,060,304 shares of common stock are issuable upon the exercise of outstanding awards under the 2010 Equity Incentive Plan. As of March 31, 2022, the Company had reserved 8,964,966 shares of common stock for issuance under the 2020 Equity Incentive Plan (the "2020 Plan"), of which 6,612,353 are available for issuance in connection with grants of future awards.

As a result of the uncertainty created by the DOJ investigation and the ongoing claims audits, the Company suspended its practice of granting equity awards to new hires, except for new restricted stock units ("RSU") grants that the Company has the option to settle in cash at the time of vesting, suspended its ESPP and deferred the settlement of outstanding RSUs, each effective as of November 9, 2021. All equity awards that are currently outstanding continue to vest in accordance with their existing vesting schedules.

Stock options

Stock option activity for the three months ended March 31, 2022 is set forth below:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual term	Aggregate intrinsic value
			(in years)	(in thousands)
Balance December 31, 2021	5,406,815	$ 4.87	7.88	$ 12,860
Grants	—	—		
Exercises	(37,425)	2.49		
Cancelled/forfeited	(15,291)	17.44		
Balance March 31, 2022	5,354,099	$ 4.85	7.65	$ 13,601
Vested and exercisable at March 31, 2022	2,653,892	$ 3.43	7.08	$ 7,626

There were no options granted during the three months ended March 31, 2022. The weighted-average grant-date fair value of options granted during the three months ended March 31, 2021 was $29.13 per share.

The aggregate intrinsic values of options outstanding and vested and exercisable were calculated as the difference between the exercise price of the options and the fair value of the Company's common stock.

As of March 31, 2022, total unrecognized stock-based compensation related to outstanding unvested stock options was $11.6 million, which the Company expects to recognize over a remaining weighted-average period of approximately 2.2 years.

Restricted stock units

RSUs granted under the 2020 Plan are share awards that generally entitle the holder to receive freely tradable shares of the Company's common stock upon vesting. However, the Company has deferred the settlement of outstanding RSUs effective November 9, 2021. The RSUs cannot be transferred and the awards are subject to forfeiture if the holder's service to the Company terminates prior to the release of the vesting restrictions.

RSU activity for the three months ended March 31, 2022 is set forth below:

	Number of shares	Weighted average grant date fair value per share
Balance December 31, 2021	348,451	$ 43.19
RSUs granted	1,641,480	5.18
RSUs vested	(18,551)	49.65
RSUs forfeited	(11,208)	42.48
Balance March 31, 2022	1,960,172	$ 11.30

As of March 31, 2022, total unrecognized stock-based compensation related to unvested RSUs was $20.8 million, which the Company expects to recognize over a remaining weighted-average period of approximately 3.7 years. As of December 31, 2021, there were 17,310 RSUs that had vested but not settled, which settled for $0.1 million in cash during the three months ended March 31, 2022. As of March 31, 2022, there were 18,551 RSUs that had vested but not settled.

Performance-based restricted stock units

In June 2021, the Company granted 80,000 RSUs with performance-based vesting conditions that primarily related to the achievement of certain minimum sales of Eargo hearing aid systems and that must be met by December 31, 2022 for the awards to vest. The vesting conditions were deemed probable as of March 31, 2022. The grant date fair value of the awards was $3.0 million. None of these awards have vested or were forfeited as of March 31, 2022.

Employee stock purchase plan

As of March 31, 2022, the Company reserved 1,502,310 shares of common stock for issuance under the ESPP, of which 1,327,567 are available for future issuance. The ESPP provides for consecutive, overlapping 24-month offering periods, which are generally divided into four purchase periods of approximately six months. The offering periods are scheduled to start on the first trading day on or after May 16 and November 16 of each year. Contributions under the ESPP are generally limited to a maximum of 15% of an employee's eligible compensation.

Each offering period consists of four six-month purchase periods. On each purchase date, which falls on the last date of each purchase period, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock at the start of the offering period or (2) the fair market value of the common stock on the purchase date.

The ESPP was suspended on November 9, 2021, and there were no offering periods in effect during the three months ended March 31, 2022.

8. Net loss per share attributable to common stockholders

The following outstanding potentially dilutive common stock equivalents have been excluded from the computation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	Three months ended March 31,	
	2022	2021
Common stock options issued and outstanding	5,354,099	6,319,155
Restricted stock units	2,040,172	253,300
Shares issuable pursuant to ESPP	—	176,867
Total	7,394,271	6,749,322

9. Subsequent events

Settlement of DOJ investigation

On April 29, 2022, the Company entered into a civil settlement agreement with the U.S. government that resolved the DOJ investigation related to the Company's role in customer reimbursement claim submissions to various federal employee health plans under the FEHB program. On May 2, 2022, the Company paid the settlement amount of $34.4 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q, and for a full understanding of Eargo's results of operations and financial condition, in conjunction with the consolidated financial statements and notes for the fiscal year ended December 31, 2021 contained in the Company's Form 10-K filed on May 13, 2022. The following discussion and analysis of our financial condition and results of operations contains forward-looking statements about us and our industry that involve substantial risks, uncertainties and assumptions. All statements other than statements of historical facts contained in this item, including statements regarding factors affecting our business, trends and uncertainties, are forward-looking statements. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by these forward-looking statements. You should carefully read the "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

Overview

We are a medical device company dedicated to improving the quality of life of people with hearing loss. We developed the Eargo solution to create a hearing aid that consumers actually want to use. 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 ever virtually invisible, rechargeable, completely-in-canal, United States Food and Drug Administration ("FDA") regulated, exempt Class I or Class II devices indicated to compensate for mild to moderate hearing loss. Our rapid pace of innovation is enabled by our deep industry and technical expertise across mechanical engineering, product design, audio processing, clinical and hearing science, consumer electronics and embedded software design, and is supported by our strategic intellectual property portfolio.

We market and sell our hearing aids direct to consumers with a personalized, consumer-centric approach. Our commercial organization consists of a talented marketing team with deep experience in consumer-focused brand and performance marketing, a team of inside sales consultants, and a dedicated customer support team that includes audiologists and hearing professionals. We generate revenue from orders processed primarily through our website and over the phone by our sales consultants.

We believe that our differentiated hearing aids and consumer-oriented approach have fueled the rapid adoption of our hearing aids and high customer satisfaction, as evidenced by over 97 thousand Eargo hearing aid systems sold, net of returns, as of March 31, 2022.

For the three months ended March 31, 2022, we generated net revenue of $9.2 million, a decrease of $12.9 million from the three months ended March 31, 2021. The revenue decline was primarily due to a decrease in the volume of Eargo hearing aid systems shipped that was primarily due to our selling our products on a "cash-pay" basis only during the three months ended March 31, 2022 as compared to our having accepted both cash pay and insurance as a method of direct payment during the three months ended March 31, 2021. We previously accepted insurance as a method of direct payment, but suspended all claims submission activities on September 22, 2021 when we learned of the investigation by the DOJ related to our role in customer reimbursement claim submissions to various federal employee health plans under the FEHB program, as discussed in more detail below under "—DOJ investigation and settlement and claims audits." We have sold our products on a "cash-pay" basis only since December 8, 2021. To date, all our revenue has been generated from customers in the United States.

Our net losses were $30.6 million and $13.6 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of $387.5 million. We expect to continue to incur losses for the foreseeable future.

DOJ investigation and settlement and claims audits

As previously disclosed, on September 21, 2021, we were informed that we were the target of a criminal investigation by the DOJ related to insurance reimbursement claims we submitted on behalf of our customers covered by various federal employee health plans under the Federal Employee Health Benefits ("FEHB") program, which is administered by the Office of Personnel Management ("OPM"). The investigation also pertained to our role in customer reimbursement claim submissions to federal employee health plans (collectively, the "DOJ investigation"). Also as previously disclosed, our historically largest third-party payor, one of the carriers contracted with the OPM under the FEHB program ("largest third-party payor"), conducted an audit of insurance reimbursement claims ("claims") submitted by us (the "Primary Audit"), which included a review of medical records. We were informed by the third-party payor conducting the Primary Audit that the DOJ was the principal contact related to the subject matter of the Primary Audit. In addition to the Primary Audit, we have been subject to a number of other audits of insurance reimbursement claims submitted to additional third-party payors (collectively with the Primary Audit, the "claims audits"). One of these claims audits does not relate to claims submitted under the FEHB program. On January 4, 2022, the DOJ confirmed to us that the investigation had been referred to the Civil Division of the DOJ and the U.S. Attorney's Office for the Northern District of Texas and the criminal investigation was no longer active.

On April 29, 2022, we entered into a civil settlement agreement with the U.S. government that resolved the previously disclosed DOJ investigation related to our role in customer reimbursement claim submissions to various federal employee health plans under the FEHB program. We cooperated fully with the DOJ investigation. We deny the allegations in the settlement agreement, and the settlement is not an admission of liability by us. The allegations did not pertain to the quality or performance of our product. The settlement agreement provided for our payment of approximately $34.4 million to the U.S. government and resolved allegations that we submitted or caused the submission of claims for payment to the FEHB program using unsupported hearing loss-related diagnostic codes. On May 2, 2022, the Company paid the settlement amount.

The settlement with the U.S. government may not resolve all of the audits of insurance reimbursement claims by the various third-party payors, and additionally we remain subject to a prepayment review of claims by the payor who conducted the Primary Audit.

From the time we learned of the DOJ investigation and until December 8, 2021, we continued to process orders for customers with potential insurance benefits (including FEHB program members) but suspended all claims submission activities and offered affected customers (*i.e.*, customers using insurance benefits as a method of direct payment for transactions prior to December 8, 2021) the option to return their hearing aids or purchase their hearing aids without the use of their insurance benefits in case their claim is denied or ultimately not submitted by us to their insurance plan for payment (the "extended right of return").

Beginning on December 8, 2021, we made the decision to stop accepting insurance benefits as a method of direct payment and it is uncertain when, if ever, we will resume accepting insurance benefits as a method of direct payment. While we intend to work with the government and third-party payors at the appropriate time with the objective of validating and establishing processes to support any future claims that we may submit for reimbursement, we may not be able to arrive at acceptable processes or submit any future claims.

Total life-to-date payments we have received through March 31, 2022 from the government in relation to claims submitted under the FEHB program, net of any product returns and associated refunds, were approximately $44 million, which is unchanged from December 31, 2021. As discussed further in Note 5 to the Unaudited Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q, based on the settlement agreement with the U.S. government, we recorded a settlement liability of $34.4 million in the condensed consolidated balance sheets as of March 31, 2022 and December 31, 2021. The settlement amount was recorded as a reduction of revenue in the third quarter of 2021.

We determined that customer transactions using insurance benefits as a method of direct payment occurring subsequent to learning of the DOJ investigation on September 21, 2021 did not meet the criteria for revenue recognition under ASC 606. As such, we did not recognize revenue for shipments to customers with potential insurance benefits, substantially all of whom were covered under the FEHB program, subsequent to that date.

We estimated that a majority of customers with unsubmitted claims will choose to return the hearing aid system if their insurance provider denies their claim or the claim is ultimately not submitted by us for payment, resulting in an increase in expected product returns from such transactions that occurred prior to September 21, 2021 that was recorded during the year ended December 31, 2021. Of the $13.7 million sales returns reserve recorded as of March 31, 2022, $11.3 million relates to unsubmitted claims that are included in accounts receivable, net. Returns associated with unsubmitted claims will reduce the sales returns reserve, with a corresponding reduction in the related accounts receivable at the time the product is returned.

Further, we also estimated that, in addition to the customers who choose to return their hearing aid systems, a significant number of customers whose claims are denied by insurance providers or not submitted by us for payment may not pay for or return the hearing aid system, resulting in bad debt expense that was recorded during the year ended December 31, 2021.

Notwithstanding the settlement, we remain subject to prepayment review of claims by our largest third-party payor before any insurance payments are made. We do not intend to submit any claims through the FEHB program until we are able to establish processes with applicable third-party payors to support the submission of these claims, and we may be unable to do so. While we intend to work as quickly as possible toward establishing processes with applicable third-party payors to support the submission of claims, we cannot provide any assurance as to the timing or costs associated with establishing such processes, if we can do so at all, or the impact that such processes may have on our business and results of operations. Further, the pending over-the-counter ("OTC") hearing aid regulatory framework, if finalized as currently proposed, may lead such payors to take additional actions further limiting our ability to access insurance coverage, which may have a material adverse effect on our financial condition, results of operations or cash flows.

In addition, based on our correspondence to date with the OPM and the largest third-party payor, we expect that any such processes will require additional testing by a licensed healthcare provider to establish medical necessity, with supporting clinical documentation. Because our current operating structure does not permit us to perform diagnostic tests, we are evaluating alternatives for testing, including but not limited to accepting clinical documentation and prescriptions from third-party healthcare professionals, contracting with third parties or existing networks, and/or establishing a management services organization. We cannot provide any assurance as to the timing or costs associated with these alternatives, whether we will be successful in implementing them, or the impact that such changes may have on our business and operations.

On January 5, 2022, the U.S. District Court for the Northern District of California consolidated three purported securities class actions brought against the Company (the "Securities Class Action"). While the lead plaintiffs have not yet filed a consolidated amended complaint, the complaints of the individual lawsuits filed prior to the consolidation generally alleged that certain of the Company's disclosures about its business, operations and prospects, including reimbursements from third-party payors, violated federal securities laws. On December 3, 2021, a putative stockholder filed a derivative complaint purportedly on the Company's behalf against members of the Company's Board of Directors and the Company as nominal defendant (the "Derivative Action"), alleging (among other things) that the defendants breached their fiduciary duties by allegedly failing to implement and maintain an effective system of internal controls related to the Company's financial reporting, public disclosures, and compliance with laws, rules, and regulations governing the business. See Note 5 of the Notes to Unaudited Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q for more information.

As a result of the uncertainty created by the DOJ investigation and the claims audits, we took certain actions including, but not limited to:

- We suspended our practice of granting equity awards, except for new restricted stock unit grants that we have the option to settle in cash at the time of vesting, suspended our 2020 Employee Stock Purchase Plan ("ESPP") and deferred the settlement of outstanding restricted stock units ("RSUs"), in each case effective as of November 9, 2021 (collectively, the "employee equity actions").
- Our Board of Directors suspended the non-employee director compensation program with respect to the option awards that would otherwise have been awarded to non-employee directors automatically on the date of our annual meeting of stockholders held on November 9, 2021.
- On December 7, 2021, we announced a plan to reduce our employee workforce to streamline our organization in response to declines in customer orders since we announced the investigation of the Company by the DOJ. We substantially completed the employee workforce reduction during the fourth quarter of 2021, resulting in a reduction of approximately 27% of our employee workforce, or approximately 90 people.

Factors affecting our business

We believe that our future performance will depend on many factors, including those described below and in the section titled "Risk Factors" included elsewhere in this Quarterly Report on Form 10-Q.

Efficient acquisition of new customers

We have spent significant amounts on sales and marketing designed to build a strong brand, achieve broad awareness of our Eargo system, acquire new customers and convert sales leads. Since our public disclosure of the DOJ investigation on September 22, 2021 and our related decision to stop accepting insurance benefits as a method of direct payment, we have experienced and may continue to experience a material decline in gross systems shipped.

Beginning on December 8, 2021, as a result of the DOJ investigation and claims audits (as further described in "—DOJ investigation and settlement and claims audits") we do not currently accept insurance as a direct method of payment, and all sales from such date are considered by us to be "cash-pay," which includes upfront payment, credit card, third-party financing, and distributor payment. We have refocused our sales and marketing efforts and related spend to prioritize conversion of cash-pay consumer leads into satisfied customers. While we intend to work with the government and third-party payors at the appropriate time with the objective of validating and establishing the process to support any future claims that we may submit for reimbursement, we may not be able to arrive at an acceptable process or submit any future claims. The shift to a model that excludes insurance as a direct method of payment will likely result in a sustained increased cost of customer acquisition and require significant sales and marketing investments, based on the historically lower conversion rate for cash-pay customers as compared to customers with potential insurance benefits. Further, the exclusion of insurance as a direct payment method may also necessitate identifying commercial partnerships, omni-channel, including retail, or other opportunities, as well as the potential implementation of cost-savings measures, in order to drive cost-efficient cash-pay customer acquisition and offset the significantly higher return rates as well as the related negative impact on revenue and gross margin historically applicable to cash-pay customers

Changes to the regulatory landscape

Hearing aids are considered medical devices subject to regulation by the FDA. We currently market our products pursuant to the FDA regulatory framework for air-conduction hearing aids, which are classified as Class I or Class II devices exempt from premarket review procedures. In addition, while applicable FDA regulations establish certain "conditions for sale" of all hearing aids, including that prospective hearing aid users must have a medical evaluation by a licensed physician within the six months prior to hearing aid dispensation or sign a waiver of medical evaluation, the FDA has stated that it does not intend to enforce these medical evaluation and

waiver requirements prior to the dispensing of Class I air-conduction and Class II wireless air-conduction hearing aids to individuals 18 years of age and older. Accordingly, while we are required to comply with other FDA requirements, including specific hearing aid labeling requirements and provision of a User Instructional Brochure, our products have not been reviewed by the FDA and are not dispensed by licensed physicians.

The regulatory landscape for hearing aid devices has been subject to recent changes that may alter or increase our requirements for regulatory compliance. The FDA Reauthorization Act of 2017 ("FDARA") set forth a process to create a new category of OTC hearing aids that are intended to be available without supervision, prescription, or other order, involvement or intervention of a licensed practitioner. The language in FDARA is not self-implementing, and on October 20, 2021, the FDA published the Proposed Rule to establish new regulatory categories for OTC and prescription hearing aids.

The Proposed Rule also includes revised requirements for labeling, conditions for sale, performance standards and other provisions applicable to either OTC or prescription hearing aids, or both. Under the Proposed Rule, devices that require 510(k) clearance to come into compliance with the new requirements would need to be cleared by the effective date of the Final Rule to continue marketing. For all other currently marketed devices, the proposed compliance date is 180 days after the effective date of the Final Rule (240 days after the publication of the Final Rule).

We market the Eargo system devices as Class I air-conduction hearing aids or Class II wireless air-conduction hearing aids, both of which are exempt from 510(k) premarket review. Our hearing aids may be marketed under the current FDA framework during the FDA's rulemaking proceeding. However, we cannot know to what extent the Final Rule may differ from the Proposed Rule. Once the FDA issues a Final Rule, 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 in order to market our products in line with our primary direct-to-consumer business and omni-channel models in the future. It is possible that a finalized regulatory framework for OTC hearing aids may lead to additional commercial partnership, omni-channel, including retail, or other opportunities, although there are no assurances that it will do so. The Final Rule and the responses thereto by leading insurance providers could also materially impact our efforts to resume submitting claims for customers with potential insurance benefits or have other unforeseen impacts on our business and results of operations.

Please see the Risk Factor titled, "Changes in the regulatory landscape for hearing aid devices could render our direct-to-consumer business model contrary to applicable regulatory requirements, and we may be required to seek additional clearance or approval for our products" for more information.

Omni-channel marketing and distribution activities through commercial partnerships

Eargo's self-administered hearing screens are intended to be part of our 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. We also have a select number of commercial partnerships to, among other things, facilitate the retail experience, and we intend to continue to pursue additional opportunities for in-person customer engagement. We believe that if the Proposed Rule by the FDA regarding an OTC regulation of hearing aids is finalized in substantially the same form as proposed, the Final Rule will facilitate negotiation and execution of additional retail opportunities in the future.

Third-party payors

A significant portion of our revenue has historically been dependent on payments from third-party payors; for example, in the year ended December 31, 2021, 44% of total gross systems shipped were to customers with potential insurance coverage. Historically, we submitted claims on behalf of our customers to a concentrated number of third-party payors under certain benefit plans, and substantially all such claims related to the FEHB program.

As described in Note 2 of the Notes to Unaudited Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q, approximately 95% and 93% of our gross accounts receivable as of March 31, 2022 and December 31, 2021, respectively, were for customers with potential insurance benefits, substantially all of whom were covered under the FEHB program. Furthermore, approximately 92% and 90% of our gross accounts receivable as of March 31, 2022 and December 31, 2021, respectively, were related to shipments of Eargo hearing aids to customers insured under a single insurance plan whose claims are processed through our largest third-party payor, which conducted the Primary Audit. We remain subject to a prepayment review of claims by the payor who conducted the Primary Audit. In addition to the Primary Audit, we are currently subject to a number of other ongoing audits of insurance reimbursement claims. One of these claims audits does not relate to claims submitted under the FEHB program. During the claims audits, the third-party payors (including our largest third-party payor) conducting such claims audits have generally suspended payments for, and in some cases denied, claims we submitted on behalf of customers, other than one third-party payor that has continued to process claims for payment throughout its ongoing audit.

We recorded a sales returns reserve of $13.7 million and $13.8 million as of March 31, 2022 and December 31, 2021, respectively, largely related to our estimate that a majority of customers with unsubmitted claims will choose to return the hearing aid system if

their insurance provider denies their claim or the claim is ultimately not submitted by us for payment. We recorded an allowance for credit losses of $4.7 million and $4.8 million as of March 31, 2022 and December 31, 2021, respectively, primarily related to insurance claims receivable due from third-party payors and end-users as we estimate that, in addition to the customers who choose to return their hearing aid systems, a significant number of customers with an extended right of return and claims that have not yet and may never be submitted by us for payment may not pay for or return the hearing aid system.

While we intend to work with third-party payors at the appropriate time with the objective of validating and establishing processes to support any future claims that we may submit for reimbursement, we may not be able to arrive at acceptable processes or submit any future claims. For example, we do not currently conduct in-person hearing tests, as they run counter to our primary direct-to-consumer business and omni-channel models. Based on our correspondence to date with the OPM and the largest third-party payor, we expect that any such processes to support claims for reimbursement will require additional testing by a licensed healthcare provider to establish medical necessity, with supporting clinical documentation. Because our current operating structure does not permit us to perform diagnostic tests, we are evaluating alternatives for testing, including but not limited to accepting clinical documentation and prescriptions from third-party healthcare professionals, contracting with third parties or existing networks, and/or establishing a management services organization. We cannot provide any assurance as to the timing or costs associated with these alternatives, whether we will be successful in implementing them, or the impact that such changes may have on our business and operations. In addition, it is possible that such testing would be required to be conducted in-person, representing a significant change from our past processes and customer experience that may adversely impact the attractiveness of our offerings to customers, and we may not be able to efficiently or effectively integrate such tests into our operating model. In light of the DOJ investigations, claims audits and pending OTC hearing aids regulatory framework, we may need to make significant changes to our business and operating model, including a potential long-term shift to a model that excludes insurance as a direct method of payment, which would likely result in a sustained increased cost of customer acquisition and require identification of commercial partnership, omni-channel, including retail, or other opportunities, to drive cost efficient acquisition of cash-pay customers.

See "—DOJ investigation and settlement and claims audits" for more information. Please see the Risk Factors titled, "We are subject to risks from legal proceedings, investigations, and inquiries, including a number of recent legal proceedings and investigations, which have had and could continue to have a material adverse effect on our reputation, business, financial condition, cash flows and results of operations, and could result in additional claims and material liabilities," and "We face considerable uncertainty in our business prospects, as a significant portion of our revenue has historically been dependent upon reimbursement from third-party payors participating in the FEHB program but we have operated on a "cash pay" only basis since December 8, 2021. Following the civil settlement with the U.S. government on April 29, 2022, we may be unsuccessful in validating and establishing processes to support the submission of claims for reimbursement from third-party payors participating in the FEHB program in the future. As a result, we have faced a significant reduction in revenue and any failure to establish processes to support reimbursement from third-party payors in the future may significantly and adversely impact our business and growth prospects and our ability to sell our products."

Sales returns rate

Our return policy generally allows our customers to return hearing aids for any reason within the first 45 days of delivery for a full refund, subject to a handling fee in certain states, and can be extended under certain circumstances, including the extended right of return offered for shipments involving insurance payors. Historically, the most commonly cited reason for returning our hearing aids is unsatisfactory fit, which we believe is a byproduct of our direct-to-consumer model and online distribution that results in nearly all of our customers ordering our product without trying it first. In addition to unsatisfactory fit, the next most cited reason for returns is that our hearing aids do not provide sufficient audio amplification.

We report revenue net of expected returns, which is an estimate informed in part by historical return rates. As such, our returns rate impacts our reported net revenue and gross profit or loss. Sales returns rates, as defined under "—Key business metrics," were 32% for the year ended December 31, 2021 and 34% for the three months ended March 31, 2022.

New product introductions

Our technical capabilities and commitment to innovation have allowed us to deliver product enhancements on a rapid development timeline and support a compelling new product roadmap that we believe will continue to differentiate our competitive position over the next several years. With the full commercial launch of the Eargo 5 in July 2021 and the launch of Eargo 6 in January 2022, we have now launched six generations of our hearing aids since 2017, with each iteration having increased functionality and improved sound quality, amplification, noise reduction, physical fit, comfort, water resistance and ease-of-use, as well as reduced costs of goods and better connectivity. We are focused on continuing to launch new versions of the Eargo hearing aid devices that further improve these attributes. We believe that the continued introduction of new products is critical to maintaining existing customers, attracting new customers, achieving market acceptance of our products and maintaining or increasing our competitive position in the market.

We expect to continue refining and improving Eargo hearing aids, and we have the intention of an approximate annual cadence of new product launches. To this end, we are working on the development of a cost-conscious offering as well as the next Eargo hearing aid

model with improved functionality. Accordingly, we expect to continue to invest in research and development to support new product introductions. In connection with our product innovation and iteration, we also need to successfully manage our product transitions to avoid delays in customer purchases, excess or obsolete inventory and increased returns as customers wait for our new products to become available. Our development priorities are focused, in part, on expanding refurbishment capability for returned hearing aids. Our refurbishment capabilities include full refurbishment, conversion, and components, and allow us to refurbish and resell or reuse certain returned devices.

Recruitment and retention of personnel

Our success depends in part upon our continued ability to recruit, retain and motivate high-quality employees, including management, administrative, our clinical and scientific personnel and our direct sales force (among others), and competition for qualified personnel can be intense due to the limited number of individuals possessing the requisite training, skill and experience we require. As a result of uncertainty created by the DOJ investigation and the claims audits, we suspended our practice of granting equity awards (except for new restricted stock unit grants that we have the option to settle in cash at the time of vesting), suspended our employee stock purchase plan and deferred the settlement of outstanding restricted stock units, in each case effective as of November 9, 2021. In addition, on December 7, 2021, we announced a plan to reduce our employee workforce to streamline our organization in response to declines in customer orders since we announced the DOJ investigation. We substantially completed the employee workforce reduction during the fourth quarter of 2021, resulting in a reduction of approximately 27% of our employee workforce, or approximately 90 people. Both the suspension of equity awards and reduction in workforce, in addition to any negative perceptions of employment with us as a result of the DOJ investigation, the settlement with the U.S. government, and the claims audits, could continue to adversely affect employee morale and have a material adverse impact on our ability to recruit, retain and motivate the high-quality employees critical to our operations, which in turn could have a material adverse effect on our business, results of operations and financial condition.

COVID-19 pandemic

We believe the COVID-19 pandemic has accelerated the pace of consumer awareness of our vertically integrated telecare model and has facilitated customer adoption of the same. Shelter-in-place restrictions and increased reluctance of consumers to conduct in-person activities, particularly among older individuals that comprise a majority of the population needing hearing aids has resulted in increased knowledge of our business and sales. We cannot be sure this trend will continue.

Although we believe the COVID-19 pandemic has largely resulted in favorable trends for our business, we have experienced business disruptions, particularly at our California headquarters, where a majority of our employees have been working remotely (which we permitted as an accommodation to our employees despite the fact that we were never required to close our facilities because we were deemed to have an essential workforce under the relevant California COVID-19 measures). Moreover, travel restrictions, factory closures and disruptions in global supply chains have resulted in industry-wide component supply shortages (such as in semiconductors), and we may not be able to obtain adequate inventory on a timely basis or at all. To date, increases in component pricing have occurred but have not had a material impact on supply continuity or gross margin. We have taken steps to monitor our supply chain and actions to address limited supply and increasing lead times, including outreach to critical suppliers and spot market purchases. While we have not been impacted by any disruptions to our supply chain that have impacted our ability to service customers or access to necessary raw materials and component parts for the manufacture of our products to date, disruptions have occurred across a number of industries and we cannot provide any assurance that future disruptions will not emerge as a result of the ongoing supply chain issues, inflation, the COVID-19 pandemic or other extrinsic factors. Future disruptions in our supply chain, including the sourcing of certain components and raw materials, such as semiconductor and memory chips, as well as increased logistics costs, could impact our sales and gross margins.

Key business metrics

To analyze our business performance, determine financial forecasts and help develop long-term strategic plans, we review the following key business metrics, each of which is an important measure that represents the state of our business:

- *Gross systems shipped.* We define our gross systems shipped as the number of hearing aid systems shipped during the period. However, we have not recorded revenue and related sales returns reserve for approximately 670 shipments of Eargo hearing aid systems to customers with potential insurance benefits during the three months ended September 30, 2021 but subsequent to learning of the DOJ investigation, and approximately 1,560 of such shipments during the three months ended December 31, 2021. Since our public disclosure of the DOJ investigation on September 22, 2021 and our related decision to stop accepting insurance benefits as a method of direct payment, we have experienced and may continue to experience a material decline in gross systems shipped. Continued negative publicity, including in relation to the DOJ investigation, the claims audits, and other legal proceedings could further harm our reputation and lead to a further decline in gross systems shipped. See "—DOJ investigation and settlement and claims audits" and "—Factors affecting our business."

- *Sales returns rates.* Sales returns rates are determined by management at the end of each reporting period to estimate the percentage of products for which we have recorded revenue during that period that are expected to be returned. This determination is informed in part by historical actual return rates. Sales returns rates do not represent actual returns during a period as customers may return the product for a period of time that can extend beyond the period end, which can result in a hearing aid being returned after the period in which the revenue from its sale was recognized. If actual returns differ from the sales returns rate determined at period end or new factors arise, indicating a rate of return that is different from the original estimated sales returns rate, revenue is adjusted in subsequent periods to reflect the actual returns made. Such an adjustment to revenue is not included in the sales returns rates disclosed in the table below.

The following table details the number of gross systems shipped and sales returns rates for the periods presented below:

	Three months ended				
	March 31, 2021	June 30, 2021	September 30, 2021	December 31, 2021	March 31, 2022
Gross systems shipped	11,704	12,548	13,117	7,767	5,773
Sales returns rate	23.2%	24.1%	46.4%	34.0%	33.9%

We believe these key business metrics provide useful information to help investors understand and evaluate our business performance. Gross systems shipped is a key measure of sales volume, which drives potential revenue, while sales returns rates are an indicator of expected reductions to revenue and an indicator of change in customer mix and factors affecting the returns rates by customer type. However, as discussed elsewhere in this report, our sales volume, sales returns rate and revenue during the current period were not consistent with the prior periods as a result of the DOJ investigation and settlement and claims audits. See "—DOJ investigation and settlement and claims audits."

Due to the historically higher return rate for cash-pay customers as compared to insurance customers, we expect that revenue, gross profit and gross margin may remain depressed as compared to prior periods for so long as we are unable to accept insurance benefits as a direct method of payment.

Components of our results of operations

See the discussion under "—DOJ investigation and settlement and claims audits," which describes a variety of circumstances currently affecting our business and results of operations, and which require that we continually evaluate and adapt our business model and expenditures as new information becomes available.

Revenue, net

We generate revenue from the sale of Eargo hearing aid systems, accessories and, to a lesser extent, sales of extended warranties, with the majority of our revenue coming from sales of our Eargo hearing aid systems. Following the launch of Eargo 6 in January 2022, we currently offer four versions of our hearing aid systems, the Eargo Max, the Eargo Neo HiFi, the Eargo 5, and the Eargo 6, each at different price points, and we periodically offer discounts and promotions, including holiday promotions. For product sales, control is transferred upon shipment to the customer. We report revenue net of expected returns, which is an estimate informed in part by historical return rates.

Since learning of the DOJ investigation, we have suspended all insurance claims submissions and, beginning on December 8, 2021, do not currently accept insurance as a direct method of payment. Instead, we are currently focused on "cash-pay" customers, which includes upfront payment, credit card, third-party financing and distributor payment. Historically, cash-pay customers have had significantly higher return rates than customers with potential insurance benefits, and therefore the current shift to cash-pay only sales may adversely impact revenue, net.

Cost of revenue and gross margin

Cost of revenue consists of expenses associated with the cost of finished goods, freight, personnel costs, consumables, product warranty costs, transaction fees, reserves for excess and obsolete inventory, depreciation and amortization, and related overhead.

Our gross margin has been and will continue to be affected by a variety of factors, including sales volumes, product mix, channel mix, pricing strategies, sales returns rates, costs of finished goods, product warranty claim rates and refurbishment strategies, and our ability to service insurance customers in the future and any potential actions insurance providers may take following the anticipated implementation of a pending OTC hearing aid regulatory framework that may limit our ability to access insurance coverage (which OTC framework may also generally result in additional compliance or other regulatory requirements for Eargo).

We expect our gross margin to remain depressed for so long as we are unable to accept insurance benefits as a direct method of payment unless we can successfully target and convert new customers with a similarly low rate of return.

Research and development expenses

Research and development ("R&D") expenses, consist primarily of engineering and product development costs to develop and support our products, regulatory expenses, non-recurring engineering and other costs associated with products and technologies that are in development, as well as related overhead costs. These expenses include personnel-related costs, including salaries and stock-based compensation, supplies, consulting fees, prototyping, testing, materials, travel expenses, depreciation and allocated facility overhead costs. Additionally, R&D expenses include internal and external costs associated with our regulatory compliance and quality assurance functions, and related overhead costs. The uncertainty regarding the anticipated implementation of a pending OTC hearing aid regulatory framework will require that we evaluate our R&D expenses as new information becomes available.

Sales and marketing expenses

Our sales and marketing expenses are the largest component of our operating expenses and consist primarily of personnel-related costs, including salaries and stock-based compensation, direct and channel marketing, advertising and promotional expenses, consulting fees, public relations costs and allocated facility overhead costs. Sales and marketing personnel include our inside sales consultants, hearing professionals, marketing professionals and related support personnel. We expect our sales and marketing expenses to fluctuate over time as a percentage of revenue. In response to the factors discussed in "—DOJ investigation and settlement and claims audits," we have reduced sales and marketing resources that were previously focused on insurance customers to prioritize the conversion of cash-pay consumers into satisfied customers, including as part of the reduction in force announced on December 8, 2021.

General and administrative expenses

Our general and administrative expenses consist primarily of compensation for executive, finance, legal, information technology and administrative personnel, including stock-based compensation. Other significant expenses include professional fees for legal and accounting services, consulting fees, recruiting fees, information technology costs, corporate insurance, bad debt expense, general corporate expenses and allocated facility overhead costs.

Excluding the costs associated with the DOJ investigation, we expect our general and administrative expenses will increase in absolute dollars in future periods as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, and those of the Nasdaq Stock Market, additional insurance costs, investor relations activities and other administrative and professional services, as well as professional service and legal fees and expenses related to shareholder litigation that has been filed and that may be filed in the future.

Interest income

Interest income consists of interest earned on cash and cash equivalents.

Interest expense

Interest expense consists of interest related to borrowings under our debt obligations.

Income tax provision

We use the asset and liability method to account for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. Due to our historical operating performance and our recorded cumulative net losses in prior fiscal periods, our net deferred tax assets have been fully offset by a valuation allowance.

Financial statement effects of uncertain tax positions are recognized when it is more-likely-than-not, based on the technical merits of the position, that it will be sustained upon examination. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax.

Results of operations

Comparison of the three months ended March 31, 2022 and 2021

(dollars in thousands)	Three months ended March 31, 2022	2021	Change Amount	%
Revenue, net	$ 9,176	$ 22,048	$ (12,872)	(58.4)%
Cost of revenue	5,491	6,297	(806)	(12.8)
Gross profit	3,685	15,751	(12,066)	(76.6)
Operating expenses:				
Research and development	5,847	4,778	1,069	22.4
Sales and marketing	13,290	16,855	(3,565)	(21.2)
General and administrative	14,934	7,487	7,447	99.5
Total operating expenses	34,071	29,120	4,951	17.0
Loss from operations	(30,386)	(13,369)	(17,017)	127.3
Other income (expense), net:				
Interest income	5	11	(6)	(54.5)
Interest expense	(264)	(263)	(1)	0.4
Total other income (expense), net	(259)	(252)	(7)	2.8
Loss before income taxes	(30,645)	(13,621)	(17,024)	125.0
Income tax provision	—	—	—	—
Net loss and comprehensive loss	$ (30,645)	$ (13,621)	$ (17,024)	125%

* *Not meaningful*

Revenue, net

(dollars in thousands)	Three months ended March 31, 2022	2021	Change Amount	%
Revenue, net	$ 9,176	$ 22,048	$ (12,872)	(58.4)%

Revenue decreased by $12.9 million, or 58.4%, from $22.0 million during the three months ended March 31, 2021, to $9.2 million during the three months ended March 31, 2022, primarily due to a decrease in the volume of Eargo hearing aid systems shipped from 11,704 gross systems shipped during the three months ended March 31, 2021 to 5,773 during the three months ended March 31, 2022 as we no longer accepted insurance as a method of direct payment as of December 8, 2021. The decrease in revenue was also attributable to an increase in sales returns rate as we operated on a cash-pay basis only during the three months ended March 31, 2022, whereas we accepted both cash pay and insurance as a direct method of payment in the comparable period. We have experienced a historically higher return rate for cash-pay customers as compared to insurance customers.

Cost of revenue, gross profit, and gross margin

(dollars in thousands)	Three months ended March 31, 2022	2021	Change Amount	%
Cost of revenue	$ 5,491	$ 6,297	$ (806)	(12.8)%
Gross profit	3,685	15,751	(12,066)	(76.6)%
Gross margin	40.2%	71.4%		

Cost of revenue decreased by $0.8 million, or 12.8%, from $6.3 million during the three months ended March 31, 2021 to $5.5 million during the three months ended March 31, 2022. The change was primarily due to the decrease in the volume of Eargo hearing aid systems shipped.

Gross margin decreased to 40.2% during the three months ended March 31, 2022, compared to 71.4% during the three months ended March 31, 2021. The change in gross margin percentage was primarily due to an increase in sales returns rates, an increase in cost of goods per product sold due to a change in product mix, and an increase in amortization of capitalized software costs subsequent to the launch of Eargo 5 in July 2021 and Eargo 6 in January 2022.

Research and development (R&D)

(dollars in thousands)	Three months ended March 31, 2022	2021	Change Amount	%
Research and development	$ 5,847	$ 4,778	$ 1,069	22.4%

R&D expenses increased by $1.1 million, or 22.4%, from $4.8 million during the three months ended March 31, 2021 to $5.8 million during the three months ended March 31, 2022. The change was primarily due to a net increase of $0.8 million in personnel and personnel-related costs due in part to a decrease in the amount of internal use software development costs being capitalized subsequent to the launch of Eargo 5 in July 2021 and Eargo 6 in January 2022.

Sales and marketing

(dollars in thousands)	Three months ended March 31, 2022	2021	Change Amount	%
Sales and marketing	$ 13,290	$ 16,855	$ (3,565)	(21.2)%

Sales and marketing expenses decreased by $3.6 million, or 21.2%, from $16.9 million during the three months ended March 31, 2021 to $13.3 million during the three months ended March 31, 2022. The change was primarily due to decreases in direct marketing, advertising and promotional expenses of $1.8 million due to a reduction in media following our decision to stop accepting insurance benefits as a method of direct payment on December 8, 2021 and decreases in personnel and personnel-related costs of $1.8 million, which includes a $1.2 million decrease in stock-based compensation.

General and administrative

(dollars in thousands)	Three months ended March 31, 2022	2021	Change Amount	%
General and administrative	$ 14,934	$ 7,487	$ 7,447	99.5%

General and administrative expenses increased by $7.4 million, or 99.5%, from $7.5 million during the three months ended March 31, 2021 to $14.9 million during the three months ended March 31, 2022. This change was primarily due to an increase in general corporate costs of $7.3 million, which includes a $6.7 million increase in legal and other professional fees as a result of the DOJ investigation.

Liquidity and capital resources

Sources of liquidity and operating capital requirements

Since our inception, we have incurred net losses and negative cash flows from operations. We have funded our operations primarily from the net proceeds received from the sale of our equity securities, indebtedness and revenue from the sale of our products.

As of March 31, 2022, we had $15.0 million in principal outstanding under the 2018 Loan, which matures in September 2024 with interest-only payments until July 2022. Interest on the 2018 Loan accrues at a per annum rate equal to the Wall Street Journal prime rate plus 1.0%, or 4.50% as of March 31, 2022.

As of March 31, 2022, we had cash and cash equivalents of $89.2 million, which are available to fund operations, and an accumulated deficit of $387.5 million.

We expect to incur additional substantial losses in the foreseeable future. We believe that without any future financing, our current resources are insufficient to satisfy our obligations as they become due within one year after the date that the financial statements are issued. Our negative cash flows and current lack of financial resources raise substantial doubt as to our ability to continue as a going concern.

We anticipate our future operating requirements will be substantial and that we will need to raise significant additional resources to fund our operations through equity or debt financing, or some combination thereof. We are currently exploring fundraising opportunities to meet these capital requirements. If we are unable to raise additional funding to meet our operational needs, we will be forced to limit or cease our operations.

In addition to our current capital needs, we regularly consider fundraising opportunities and may decide, from time to time, to raise capital based on various factors, including market conditions and our plans of operation. We may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings. Additional capital may not be available to us on acceptable terms on a timely basis, or at all. If adequate funds are not available, or if the terms of potential funding sources are unfavorable, our business and our ability to develop our technology and our products would be harmed. Furthermore, any new equity or convertible debt securities we issue may result in the dilution of our stockholders, and any debt financing may include covenants that restrict our business.

Our longer term future capital requirements and ability to raise additional capital will depend on many forward-looking factors and are not limited to the following:

- investor confidence in our ability to continue as a going concern;
- the timing, receipt and amount of sales from our current and future products;
- the costs involved in resolving the third-party claims audits and potential recoupment of previous claims paid, as well as other legal proceedings (including the shareholder class action and derivative suits discussed in Note 5 to the Unaudited Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q), and their duration and impact on our business generally (particularly with respect to our ability in future periods to accept insurance as a direct method of payment);
- the availability of insurance coverage for our hearing aid devices, and any costs associated with reimbursement and compliance, including the anticipated implementation of a pending OTC regulatory framework (which may lead insurance providers to take actions limiting our ability to access insurance coverage and may also generally result in additional compliance or other regulatory requirements for us), and any resulting changes to our business model, including a potential long-term shift to a model that excludes insurance benefits as a method of direct payment to Eargo, which would likely result in a sustained increased cost of customer acquisition;
- the cost and timing of expanding our sales, marketing and distribution capabilities and our continued success in reducing our customer acquisition costs;
- any expenses, as well as the impact to our business and operating model, as a result of changes in the regulatory landscape for hearing aid devices;
- the cost of manufacturing, either ourselves or through third-party manufacturers, our products;
- the terms, timing and success of any other licensing, partnership, omni-channel, including retail, or other arrangements that we may establish;
- any product liability or other lawsuits related to our current or future products;
- the expenses needed to attract, hire and retain skilled personnel;
- the extent of our spending to support research and development activities and the expansion of our product offerings;
- the costs associated with being a public company;
- the duration and severity of the COVID-19 pandemic and its impact on our business and financial markets generally;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the extent to which we acquire or invest in businesses.

Our liquidity is subject to various risks, including the risks identified in the section titled “Risk Factors” in Item 1A of Part II. While the extent to which we are able to validate and establish processes to support the submission of claims for reimbursement to health plans, including those under the FEHB program, if at all, in the future, and the future impacts of the anticipated implementation of a pending OTC hearing aid regulatory framework (which may lead insurance providers to take actions limiting our ability to access insurance coverage and may also generally result in additional compliance or other regulatory requirements for Eargo) are difficult to assess or predict at this time, since the announcement of the DOJ investigation and our related decision to stop accepting insurance benefits as a method of direct payment, there has been and may continue to be a significant reduction in shipments, revenue and gross margin which could in the future negatively impact our liquidity and working capital, including by impacting our ability to access any additional capital.

Contractual obligations and commitments

There have been no changes to our contractual obligations and commitments included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, except for the following:

The Wall Street Journal prime rate increased from 3.25% from 3.50% in March 2022, resulting in an increase in the interest rate on our 2018 Loan from 4.25% to 4.50% per annum. This increase will result in an additional $24,000 in payments during 2022 and $27,000 in payments thereafter as compared to the amounts previously reported.

Cash flows

The following table summarizes our cash flows for the periods indicated:

	Three months ended March 31,	
(in thousands)	2022	2021
Net cash used in operating activities	$ (20,350)	$ (9,309)
Net cash used in investing activities	(942)	(1,370)
Net cash provided by financing activities	24	118
Net decrease in cash	$ (21,268)	$ (10,561)

Operating activities

During the three months ended March 31, 2022, cash used in operating activities was $20.4 million, attributable to a net loss of $30.6 million, partially offset by a net change in our net operating assets and liabilities of $5.2 million and non-cash charges of $5.1 million. Non-cash charges primarily consisted of $3.0 million in stock-based compensation, $1.4 million in depreciation and amortization expense and $0.4 million in non-cash operating lease expense. The change in our net operating assets and liabilities was primarily due to a $3.0 million increase in accounts payable, $1.3 million decrease in prepaid expenses and other current assets, $0.7 million decrease in other assets and $0.3 million increase in other current and noncurrent liabilities.

During the three months ended March 31, 2021, cash used in operating activities was $9.3 million, attributable to a net loss of $13.6 million and a net change in our net operating assets and liabilities of $2.0 million, partially offset by non-cash charges of $6.3 million. Non-cash charges primarily consisted of $5.1 million in stock-based compensation and $0.7 million in depreciation and amortization expense. The change in our net operating assets and liabilities was primarily due to a $1.6 million decrease in accrued expense, a $1.6 million increase in account receivable and a $1.4 million decrease in sales return reserve. These changes were partially offset by a $1.4 million increase in other current and noncurrent liabilities, $0.7 million increase in account payable and $0.6 million decrease in prepaid expenses and other current assets.

Investing activities

During the three months ended March 31, 2022, cash used in investing activities was $0.9 million, which consisted of $0.7 million related to the purchase of property and equipment and approximately $0.3 million in capitalized costs related to the development of internal use software.

During the three months ended March 31, 2021, cash used in investing activities was $1.4 million, which consisted of $1.1 million in capitalized costs related to the development of internal use software and $0.3 million related to the purchase of property and equipment.

Financing activities

During the three months ended March 31, 2022, cash provided by financing activities consisted of $93,000 in proceeds from the exercise of stock options, partially offset by $69,000 in cash paid to settle restricted stock units.

During the three months ended March 31, 2021, cash provided by financing activities was $0.1 million from the exercise of stock options.

Critical accounting estimates

Management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and assumptions regarding the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

There have been no significant changes in our critical accounting estimates as compared to the critical accounting estimates disclosed in the section titled "Management's Discussion and Analysis of Financial Condition and Operations" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Recent accounting pronouncements

See Note 2 of the Notes to Unaudited Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q for more information about recent accounting pronouncements, the timing of their adoption, and our assessment.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest rate risk

Our cash and cash equivalents as of March 31, 2022 and December 31, 2021 consisted of $89.2 million and $110.5 million, respectively, in bank deposits and money market funds. Such interest-earning instruments carry a degree of interest rate risk. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents.

As of March 31, 2022 and December 31, 2021, we had $15.0 million in variable rate debt outstanding. The 2018 Loan matures in September 2024 and has interest-only payments until July 2022. The 2018 Loan accrues interest at a floating per annum rate equal to the Wall Street Journal prime rate plus 1.0% with a floor of 0.0% (4.50% as of March 31, 2022). A hypothetical increase or decrease of 100 basis points in the aforementioned prime rate would not have a material impact on our financial position or results of operations.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file under the Exchange Act of 1934, as amended, with the U.S. Securities and Exchange Commission ("SEC"), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer, principal financial officer, and principal accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

As of March 31, 2022, our management, with the participation and supervision of our principal executive officer, our principal financial officer, and our principal accounting officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive, principal financial, and principal accounting officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures.

Based on this evaluation, our principal executive officer, our principal financial officer, and our principal accounting officer concluded that solely as a result of the material weaknesses in our internal control over financial reporting and entity level controls described below, our disclosure controls and procedures were not effective as of March 31, 2022 to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer, our principal financial officer, and our principal accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

Remediation efforts on previously reported material weaknesses

In connection with the preparation of our financial statements in connection with our IPO and through the current reporting period, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of

deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

The material weakness identified in connection with our IPO related to a lack of qualified supervisory accounting resources, including those necessary to account for and disclose certain complex transactions and for which we lacked the technical expertise to identify, analyze and appropriately record those transactions. We have implemented and are in the process of implementing additional measures designed to improve our internal control over financial reporting to remediate this material weakness, including the hiring of additional qualified supervisory resources, the engagement of additional technical accounting consulting resources and plans to hire additional finance department employees.

In addition, in connection with the preparation of our financial statements for the financial reporting periods ended September 30, 2021 and December 31, 2021, we identified a material weakness related to a lack of sufficient qualified healthcare industry compliance and risk management resources, including those necessary to provide appropriate oversight, monitor compliance, and to identify and mitigate risks with respect to the financial reporting and disclosures of our operations. We intend to enhance our compliance and risk management processes with respect to our operations in the healthcare industry to remediate this material weakness, including the hiring of additional qualified personnel, and the engagement of additional specialized consulting resources.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. While we believe that our efforts have improved our internal control over financial reporting, remediation of the material weaknesses will require further validation and testing of the design and operating effectiveness of internal controls over a sustained period of financial reporting cycles, and we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses.

Changes in internal control over financial reporting

Other than the changes intended to remediate the previously reported material weakness noted above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We discuss certain legal proceedings in Part I of this Quarterly Report on Form 10-Q in Note 5, "Commitments and contingencies" under the caption "Legal and other contingencies," which is incorporated herein by reference. We refer you to that discussion for important information concerning those legal proceedings, including the alleged factual basis for such actions and, where known, the relief sought, as well as the name of the lawsuit, the court in which the lawsuit is pending, and the date on which the complaint commencing the lawsuit was filed.

In addition, we may in the ordinary course of business face various claims brought by third parties, and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights as well as claims relating to employment matters and the safety or efficacy of our products. Any of these claims could subject us to costly litigation, and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our business, financial condition and results of operations. Additionally, any such claims, whether or not successful, could damage our reputation and business.

Item 1A. Risk Factors.

Risk factor summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC, before making investment decisions regarding our common stock.

- We face considerable uncertainty in our business prospects, as a significant portion of our revenue has historically been dependent upon reimbursement from third-party payors participating in the FEHB program but we have operated on a "cash pay" only basis since December 8, 2021. Following the civil settlement with the U.S. government on April 29, 2022, we may be unsuccessful in validating and establishing processes to support the submission of claims for reimbursement from third-party payors participating in the FEHB program in the future. As a result, we have faced a significant reduction in revenue and any failure to establish processes to support reimbursement from third-party payors in the future may significantly and adversely impact our business and growth prospects and our ability to sell our products.
- Our negative cash flows and current lack of financial resources raise substantial doubt as to our ability to continue as a going concern. If we are unable to raise additional funding to meet our operational needs, we will be forced to limit or cease our operations and/or liquidate our assets.
- Potential opportunities for growth in our business outside of the FEHB program, such as the anticipated implementation of the pending OTC hearing aid regulatory framework and any potential Medicare, or other insurance, coverage for certain hearing aids, may not materialize and, as such, our business and growth prospects and our ability to sell our products may be materially and adversely impacted.
- We are subject to risks from legal proceedings, investigations and inquiries, including a number of recent legal proceedings and investigations, which have had and could continue to have a material adverse effect on our reputation, business, financial condition, cash flows and results of operations, and could result in additional claims and material liabilities.
- We have a limited operating history and have grown significantly in a short period of time. If we are unable to manage our business and anticipated growth effectively, our business and growth prospects could be materially and adversely affected.
- If we fail to attract and retain senior management and key technology personnel, our business may be materially and adversely affected.
- We have a history of net losses, and expect to incur additional substantial losses in the foreseeable future.
- Changes in the regulatory landscape for hearing aid devices could render our direct-to-consumer business model contrary to applicable regulatory requirements, and we may be required to seek additional clearance or approval for our products.

- If we cannot innovate at the pace of our hearing aid manufacturing competitors, we may not be able to develop or exploit new technologies in time to remain competitive.
- We are deploying a new business model in an effort to disrupt a relatively mature industry. In order to successfully challenge incumbent business models and become profitable, we will need to continue to refine our product and strategy.
- We operate in a highly competitive industry, and competitive pressures could have a material adverse effect on our business.
- If we are unable to reduce our return rates or if our return rates continue to increase, our net revenue may continue to decrease, and our business, financial condition and results of operations could be adversely affected.
- We rely on a limited number of manufacturers for the assembly of our hearing aids. If we encounter manufacturing problems or delays, we may be unable to promptly transition to alternative manufacturers and our ability to generate revenue will be limited.
- We rely on the timely supply of high-quality components, parts and finished products, and our business could suffer if suppliers or manufacturers are unable to procure raw materials or other components of an acceptable quality (or at all) or otherwise fail to meet their delivery obligations, raise prices or cease to supply us with components, parts or products or acceptable quality.
- If the quality of our hearing aid products does not meet consumer expectations, or if our products wear out more quickly than expected, then our brand and reputation or our business could be adversely affected.
- There are a variety of hearing aid products and technologies, and consumer confusion about product features and technology could lead consumers to purchase competitive products instead of our products, or to conflate any adverse events or safety issues associated with third-party hearing aid products with our products, which could adversely affect our business, financial condition and results of operations.
- Our success depends in part on our proprietary technology, and if we are unable to obtain, maintain or successfully enforce our intellectual property rights, the commercial value of our products and services will be adversely affected and our competitive position may be harmed.

Risk Factors

Our operating and financial results are subject to various risks and uncertainties. You should carefully consider the risks described below, as well as all of the other information contained in this Quarterly Report on Form 10-Q, including our financial statements and related notes, before investing in our common stock. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business.

Risks relating to our industry and business

We face considerable uncertainty in our business prospects, as a significant portion of our revenue has historically been dependent upon reimbursement from third-party payors participating in the FEHB program but we have operated on a "cash pay" only basis since December 8, 2021. Following the civil settlement with the U.S. government on April 29, 2022, we may be unsuccessful in validating and establishing processes to support the submission of claims for reimbursement from third-party payors participating in the FEHB program in the future. As a result, we have faced a significant reduction in revenue and any failure to establish processes to support reimbursement from third-party payors in the future may significantly and adversely impact our business and growth prospects and our ability to sell our products.

A significant portion of our revenue has historically been dependent on payments from third-party payors; for example, in the quarter ended September 30, 2021, 6,243 out of the 13,117 total gross systems shipped were for customers with potential insurance benefits. However, since December 8, 2021, we have not accepted insurance benefits as a method of direct payment.

Third-party payors periodically conduct pre- and post-payment reviews, including audits of previously submitted claims, and we are currently experiencing and may experience such reviews and audits of claims in the future. Historically, we submitted claims to a concentrated number of third-party payors under certain benefit plans, and substantially all such claims related to the FEHB program. We suspended all claims submission activities on September 22, 2021 when we learned of the investigation by the DOJ related to our role in customer reimbursement claim submissions to various federal employee health plans under the FEHB program.

On April 29, 2022, we entered into a civil settlement agreement with the U.S. government that resolved the DOJ investigation. Pursuant to the settlement agreement, we paid approximately $34.4 million to the U.S. government. We cooperated fully with the DOJ investigation. We deny the allegations in the settlement agreement, and the settlement is not an admission of liability by us. While we will need to work with applicable third-party payors contracted with the OPM under the FEHB program to align on the process and required documentation for potentially submitting claims in the future, we may be unable to validate and establish processes to support the submission of claims for reimbursement to health plans under the FEHB program in the future. For example, we do not currently conduct in-person hearing tests as they run counter to our primary direct-to-consumer business and omni-channel models, and it is possible that in-person testing would be required to support any claims submissions, representing a significant change from our past processes and direct-to-customer business model that may adversely impact the attractiveness of our offerings to customers. In addition, based on our correspondence to date with the OPM and the largest third-party payor, we expect that any such processes to support claims submissions will require additional testing by a licensed healthcare provider to establish medical necessity, with supporting clinical documentation. Because our current operating structure does not permit us to perform diagnostic tests, we are evaluating alternatives for testing, including but not limited to accepting clinical documentation and prescriptions from third-party healthcare professionals, contracting with third parties or existing networks, and/or establishing a management services organization. We cannot provide any assurance as to the timing or costs associated with these alternatives, whether we will be successful in implementing them, or the impact that such changes may have on our business and operations.

While we intend to work as quickly as possible toward establishing processes with the OPM and applicable third-party payors to support the submission of claims, we cannot provide any assurance as to the timing or costs associated with establishing such processes, if we can do so at all, or the impact that such processes may have on our business and results of operations. Further, the pending over-the-counter ("OTC") hearing aid regulatory framework, if finalized as currently proposed, may lead such payors to take additional actions further limiting our ability to access insurance coverage, which may have a material adverse effect on our financial condition, results of operations or cash flows.

Following the settlement with the U.S. government, we remain subject to prepayment review of claims by our largest third-party payor, which accounted for approximately 92% of our gross accounts receivable as of March 31, 2022. Further, with respect to such payor, claims submitted since March 1, 2021 have not been paid and have either been denied or have not yet and may never be submitted for reimbursement by us. Two additional payor audits related to claims submitted for customers with FEHB plans are also in process, although one of the payors has continued to process claims during its audit. Additionally, as of December 2021, we are subject to a new audit that does not relate to claims submitted under the FEHB program.

As a result of the change to a "cash-pay" only business model, we have faced a significant reduction in revenue and reduced growth prospects. If we are unable to establish processes to support reimbursement from third-party payors in the future, our business and growth prospects and our ability to sell our products may be significantly and adversely impacted.

Our negative cash flows and current lack of financial resources raise substantial doubt as to our ability to continue as a going concern. If we are unable to raise additional funding to meet our operational needs, we will be forced to limit or cease our operations and/or liquidate our assets.

We believe that, without any future financing, we will not be able to satisfy our obligations as they become due within one year from the date of filing of this Quarterly Report on Form 10-Q. We anticipate our future capital requirements will be substantial and that we will need to raise significant additional capital to fund our operations through equity or debt financing, or some combination thereof. While we are currently exploring fundraising opportunities to meet these capital requirements, additional capital may not be available to us on acceptable terms on a timely basis, or at all. If we are unable to raise additional funding to meet our operational needs, we will be forced to limit or cease our operations and/or liquidate our assets, in which case it is likely that investors would lose part or all of their investment.

Our expected future capital requirements and ability to raise additional capital will depend on many factors, including but not limited to the following:

- investor confidence in our ability to continue as a going concern;
- the timing, receipt and amount of sales from our current and future products;
- the costs involved in resolving third-party claims audits and recoupment of previous claims paid, as well as other legal proceedings (including the shareholder class action and derivative suits discussed in

Note 5 to the Unaudited Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q), and their duration and impact on our business generally (particularly with respect to our ability in future periods to accept insurance as a direct method of payment);

- the availability of insurance coverage for our hearing aid devices, and any costs associated with reimbursement and compliance, including anticipated implementation of a pending OTC regulatory framework (which may lead insurance providers to take actions limiting our ability to access insurance coverage and may also generally result in additional compliance or other regulatory requirements for us), and any resulting changes to our business model, including a potential long-term shift to a model that excludes insurance benefits as a method of direct payment to Eargo, which would likely result in a sustained increased cost of customer acquisition;
- the cost and timing of expanding our sales, marketing and distribution capabilities;
- any expenses, as well as the impact to our business and operating model, as a result of changes in the regulatory landscape for hearing aid devices;
- the cost of manufacturing, either ourselves or through third-party manufacturers, our products;
- the terms, timing and success of any other licensing, partnership, omni-channel, including retail, or other arrangements that we may establish;
- any product liability or other lawsuits related to our current or future products;
- the expenses needed to attract, hire and retain skilled personnel;
- the extent of our spending to support research and development activities and the expansion of our product offerings;
- the costs associated with being a public company;
- the duration and severity of the COVID-19 pandemic and its impact on our business and financial markets generally;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the extent to which we acquire or invest in businesses.

If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities. Even if we are able to raise significant additional capital necessary to continue our operations within the next year, if we are unable to obtain additional adequate financing or financing on terms satisfactory to us, when we require it, our ability to continue to pursue our business objectives, develop our technology and products, and respond to business opportunities, challenges, unforeseen circumstances, or developments, including the anticipated implementation of a pending OTC hearing aid regulatory framework, could be significantly limited, and our business, financial condition and results of operations could be materially adversely affected.

Potential opportunities for growth in our business outside of the FEHB program, such as the anticipated implementation of the pending OTC hearing aid regulatory framework and any potential Medicare, or other insurance, coverage for certain hearing aids, may not materialize and, as such, our business and growth prospects and our ability to sell our products may be materially and adversely impacted.

Since December 8, 2021, we have not accepted insurance benefits as a method of direct payment. While we will need to work with applicable third-party payors contracted with the OPM under the FEHB program to align on the process and required documentation for potentially submitting claims in the future, we may be unable to validate and establish processes to support the submission of claims for reimbursement to health plans under the FEHB program in the future. As such, our future growth prospects may be dependent upon other opportunities, such as the pending OTC hearing aid regulatory framework and any potential Medicare or other insurance coverage, if any, for certain hearing aids that we may be able to access.

We intend to focus on both securing third-party reimbursement and increasing coverage and reimbursement for our current products and any future products we may develop. Our long-term ability to service insurance customers may be dependent on any potential actions insurance providers may take following the anticipated implementation of the pending OTC hearing aid regulatory framework that may limit our ability to access insurance coverage. Currently, no OTC category of hearing aids exists, although certain carriers currently exclude from coverage “over-the-counter” hearing aids and enhancement devices (such as personal sound amplification products, or “PSAPs”). Accordingly, if our products are marketed as OTC hearing aids, they may not be covered under certain plans even if medical necessity is otherwise established. We may need to work with individual carriers (including FEHB plans) to establish coverage for OTC hearing aids. In addition, the OTC framework may also generally result in additional compliance or other

regulatory requirements for us. It may also be dependent on any potential Medicare or other insurance coverage, if any, for certain hearing aids (which may not include Eargo hearing aids). We may never achieve sufficient additional third-party reimbursement to meaningfully restore or expand our access to insurance coverage.

We cannot predict whether, under what circumstances, or at what payment levels third-party payors will cover and reimburse our products. If we fail to establish and maintain broad adoption of our products or fail to penetrate the insurance and managed care markets for our products, our ability to generate revenue could be harmed and our prospects and our business could suffer. To the extent we sell our products internationally, market acceptance may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government-sponsored healthcare and private insurance. We may not obtain international coverage and reimbursement approvals in a timely manner, if at all. Our failure to receive such approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought. Please also see the Risk Factor titled, "Changes in the regulatory landscape for hearing aid devices could render our direct-to-consumer business model contrary to applicable regulatory requirements, and we may be required to seek additional clearance or approval for our products."

We are subject to risks from legal proceedings, investigations, and inquiries, including a number of recent legal proceedings and investigations, which have had and could continue to have a material adverse effect on our reputation, business, financial condition, cash flows and results of operations, and could result in additional claims and material liabilities.

We are currently subject to a number of legal proceedings, investigations and inquiries, including: (i) purported securities class action litigation alleging that certain of our disclosures about our business, operations and prospects, including reimbursements from third-party payors, violated federal securities laws; and (ii) purported derivative action alleging the directors breached their fiduciary duties by allegedly failing to implement and maintain an effective system of internal controls related to the Company's financial reporting, public disclosures, and compliance with laws, rules and regulations governing the business. On April 29, 2022, we entered into a civil settlement agreement with the U.S. government that resolved the DOJ investigation and pursuant to which we paid approximately $34.4 million. We remain subject to audit or prepayment review by various third-party payors. In addition, we could face additional legal proceedings, investigations, and inquiries relating to these or similar matters. For more information regarding legal proceedings, see "Item 1. Legal Proceedings."

We are unable to predict how long such legal proceedings, investigations and inquiries will continue, but we have incurred and anticipate that we will continue to incur significant costs in connection with these matters and that these legal proceedings, investigations and inquiries have resulted and will continue to result in substantial distraction of management's time, regardless of the outcome. These legal proceedings, investigations and inquiries may result in damages, fines, penalties, consent orders or other sanctions (including exclusion from government programs and/or a recoupment of previous claims paid) against us and/or certain of our officers or directors, or in changes to our business practices, including the potential long-term shift to a model excluding insurance as a method of payment to Eargo. Furthermore, publicity surrounding these legal proceedings, investigations and inquiries or any enforcement action as a result thereof, even if ultimately resolved favorably for us, coupled with the recent intensified public scrutiny of our Company, could result in additional legal proceedings, investigations and inquiries. As a result, these legal proceedings, investigations and inquiries have had and could continue to have a material adverse effect on our reputation, business, financial condition, cash flows and results of operations.

These legal proceedings, investigations and inquiries, and the uncertainty stemming from them, could also precipitate or heighten the other Risk Factors that we identify in this Item 1A, any of which could materially adversely impact our business. Further, these legal proceedings, investigations and inquiries may also affect our business and financial results in a manner that is not presently known to us or that we currently do not consider to present significant risks to our operations.

Additionally, we may become subject to other legal disputes and regulatory proceedings in connection with our business activities involving, among other things, product liability, product defects, intellectual property infringement and/or alleged violations of applicable laws in various jurisdictions. Although we maintain liability insurance in amounts we believe to be consistent with industry practice, we may not be fully insured against all potential damages that may arise out of any claims to which we may be party in the ordinary course of our business. A negative outcome of these proceedings may prevent us from pursuing certain activities and/or require us to incur additional costs in order to do so and pay damages.

The outcome of pending or potential future legal and arbitration proceedings is difficult to predict with certainty. In the event of a negative outcome of any material legal or arbitration proceeding, whether based on a judgment or a settlement agreement, we could be obligated to make substantial payments, which could have a material adverse effect on our business, financial condition and results of operations. In addition, the costs related to litigation and arbitration proceedings may be significant, and any legal or arbitration proceedings could have a material adverse effect on our business, financial condition and results of operations.

We have a limited operating history and have grown significantly in a short period of time. If we are unable to manage our business and anticipated growth effectively, our business and growth prospects could be materially and adversely affected.

We were organized in 2010 and began selling hearing aids in 2015. In that time, we have grown significantly, increasing the size of our organization and expanding our business. We have expanded, and any growth that we experience in the future will require us to further expand, our sales, clinical, and research and development personnel (including those with software and hardware expertise), our manufacturing operations and our general and administrative infrastructure. As a public company, we need to support increased managerial, operational, financial and other resources. Rapid expansion in personnel could mean that less experienced people develop, market and sell our products, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure.

The challenges we face in managing our business, including our shift to a "cash-pay" only business model, the obstacles to our being able to obtain reimbursement for our products from third-party payors, and the changing regulatory landscape, place significant demands on our management, financial, operational, technological and other resources, and we expect that managing our business will continue to place significant demands on our management and other resources and will require us to continue developing and improving our operational, financial and other internal controls, reporting systems and procedures. In particular, the challenges in managing our business involve a number of areas, including recruiting and retaining sufficient skilled personnel, providing adequate training and supervision to maintain our high-quality product standards and regulatory compliance and preserving our culture and values. We may not be able to address these challenges in a cost-effective manner, or at all. In addition, we completed an employee workforce reduction in the fourth quarter of 2021, which may continue to impact the attraction and retention of employees, as well as employee morale and productivity. We cannot assure you that any increases in scale, related improvements and quality or compliance assurance will be successfully implemented or that appropriate personnel will be available to facilitate the management and growth of our business. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs or an inability to meet demand. If we do not effectively manage our business through the various challenges we face, we may not be able to execute on our business plan, respond to competitive pressures, take advantage of market opportunities, satisfy customer requirements or maintain high-quality product offerings, which could have a material adverse effect on our business, financial condition and results of operations.

If we fail to attract and retain senior management and key technology personnel, our business may be materially and adversely affected.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, administrative and clinical and scientific personnel, including those with software and hardware expertise. We are highly dependent upon our senior management, particularly our President and Chief Executive Officer, as well as our senior technology personnel and other members of our senior management team. The unplanned loss of the services of any of our members of senior management could adversely affect our business until a suitable replacement can be found.

Competition for qualified personnel in the medical device field in general and the audiology field specifically is intense due to the limited number of individuals who possess the training, skills and experience required by our industry. In addition, our success also depends on our ability to attract, recruit, develop and retain skilled managerial, sales, administration, operating and technical personnel. We will continue to review, and where necessary, strengthen our senior management as the needs of the business develop, including through internal promotion and external hires. However, there may be a limited number of persons with the requisite competencies to serve in these positions and we cannot assure you that we would be able to locate or employ such qualified personnel on terms acceptable to us, or at all. Therefore, the unplanned loss of one or more of our key personnel, or our failure to attract and retain additional key personnel, could have a material adverse effect on our business, financial condition and results of operations. Our ability to attract and retain such qualified personnel has been and may continue to be negatively impacted by the DOJ investigation or shareholder litigation, our recent workforce reduction and suspension of certain of our equity compensation practices, and related negative publicity. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

We may experience difficulties in managing our business, and a deterioration in our relationships with our employees could have an adverse impact on our business.

We expect to rely on our managerial, operational, finance and other resources in order to manage our operations and continue our research and development activities. We may expand our international operations, which would subject us to the legal, political, regulatory and social requirements and economic conditions of these jurisdictions, and create a variety of potential operational challenges due to a variety of international factors, including local labor laws and regulations and managing a geographically dispersed workforce. Our management and personnel, systems and facilities currently in place may not be adequate to support our business. Our need to effectively execute our strategy requires that we:

- manage our commercial operations effectively;

- identify, recruit, retain, incentivize and integrate additional employees;
- manage our internal development and operational efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

Maintaining good relationships with our employees is crucial to our operations. As a result, any deterioration of the relationships with our employees could have a material adverse effect on our business, financial condition and results of operations. Our ability to attract and retain qualified personnel, and foster positive employee morale, has been and may continue to be negatively impacted by the DOJ investigation and related negative publicity as well as the suspension of certain of our equity compensation practices. In addition, we completed an employee workforce reduction in the fourth quarter of 2021, which may impact the attraction and retention of employees, as well as employee morale and productivity. Further, many of our key employees receive a total compensation package that includes equity awards. In addition to the aforementioned suspension of certain equity compensation practices, volatility in the stock market, our share price and other factors could diminish the Company's use or the value of the Company's equity awards, putting the Company at a competitive disadvantage.

Additionally, material disruption to our business as a result of strikes, work stoppages or other labor disputes could disrupt our operations, result in a loss of reputation, increased wages and benefits or otherwise have a material adverse effect on our business, financial condition and results of operations.

We have a history of net losses, and we expect to incur additional substantial losses in the foreseeable future.

We have incurred net losses since inception, and we expect to incur additional substantial losses in the foreseeable future. For the years ended December 31, 2021 and 2020, we incurred net losses of $157.8 million and $39.9 million, respectively, and for the three months ended March 31, 2022 and 2021, we incurred net losses of $30.6 million and $13.6 million, respectively. As a result of our ongoing losses, as of March 31, 2022, we had an accumulated deficit of $387.5 million. Since inception, we have spent significant funds on organizational and start-up activities, to recruit key managers and employees, to develop our hearing aids, to develop our manufacturing know-how and customer support resources and for research and development. The net losses we incur may fluctuate significantly from quarter to quarter and have and may continue to increase as a result of the costs involved in resolving the DOJ investigation, including the approximately $34.4 million we paid pursuant to the settlement agreement with the U.S. government, and other corrective actions and recoupment of previous claims paid, as well as other legal proceedings, and their duration and impact on our business generally. They may also fluctuate and increase as a result of the anticipated implementation of a pending OTC hearing aid regulatory framework and any potential Medicare coverage for certain hearing aids, neither of which may ultimately be favorable to us.

Our long-term success is dependent upon our ability to successfully develop, commercialize and market our products, earn revenue, obtain additional capital when needed and, ultimately, to achieve profitable operations. The uncertainty regarding the extent to which we are able to validate and establish processes to support the submission of claims for reimbursement to health plans, including those under the FEHB program, if at all, in the future, the anticipated implementation of a pending OTC hearing aid regulatory framework (which may lead insurance providers to take actions limiting our ability to access insurance coverage and may also generally result in additional compliance or other regulatory requirements for Eargo) and potential Medicare coverage for certain hearing aids (which may not include Eargo hearing aids) will require that we evaluate and consider any changes to our business model as new information becomes available, including a potential long-term shift to a model excluding insurance as a method of payment to Eargo, which would likely result in a sustained increased cost of customer acquisition and a reduction in shipments, revenue, gross margin and higher operating expenses, which could have a material negative impact on our ability to achieve profitability and our growth prospects. We will need to generate significant additional revenue and raise significant additional capital to continue our operations and potentially achieve profitability. It is possible that even if we generate significant additional revenue and raise significant additional capital, we will not achieve profitability or that, even if we do achieve profitability, we may not maintain or increase profitability in the future. Without the benefit of customers with insurance coverage and significant additional capital, the future prospects of the Company and our ability to achieve profitability are uncertain.

Changes in the regulatory landscape for hearing aid devices could render our direct-to-consumer business model contrary to applicable regulatory requirements, and we may be required to seek additional clearance or approval for our products.

Hearing aids are considered medical devices subject to regulation by the FDA. We currently market our products pursuant to the FDA regulatory framework for air-conduction hearing aids, which are classified as Class I or Class II devices exempt from premarket review procedures. In addition, while applicable FDA regulations establish certain "conditions for sale" of all hearing aids, including that prospective hearing aid users must have a medical evaluation by a licensed physician within the six months prior to hearing aid dispensation or sign a waiver of medical evaluation, the FDA has stated that it does not intend to enforce these medical evaluation and waiver requirements prior to the dispensing of Class I air-conduction and Class II wireless air-conduction hearing aids to individuals 18 years of age and older. Accordingly, while we are required to comply with other FDA requirements, including specific hearing aid labeling requirements and provision of a User Instructional Brochure, our products have not been reviewed by the FDA and are not

dispensed by licensed physicians. If the FDA were to determine that our products do not properly satisfy the conditions for marketing Class I or Class II air-conduction hearing aid devices, we could be forced to cease distribution of our products until we obtain regulatory clearance or approval, and we could be subject to additional enforcement action by the FDA. In addition, many states have laws regarding the provision of hearing aid devices, and if we are found to be in violation of the laws of any state in which our devices are sold, we could be subject to further sanctions at the state level.

The regulatory landscape for hearing aid devices has been subject to recent changes that may alter or increase our requirements for regulatory compliance. The FDARA set forth a process to create a new category of OTC hearing aids that are intended to be available without supervision, prescription, or other order, involvement or intervention of a licensed practitioner. The language in FDARA is not self-implementing, which means that the OTC hearing aid category does not exist until the effective date of a published final regulation. On October 20, 2021, the FDA published a notice of proposed rulemaking to establish new regulatory categories for OTC and prescription hearing aids ("Proposed Rule"). The Proposed Rule also includes revised requirements for labeling, conditions for sale, performance standards and other provisions applicable to either OTC or prescription hearing aids, or both. Under FDARA, the OTC hearing aid controls that are the subject of the rulemaking, if finalized, would preempt any state or local requirement specifically related to hearing products that would restrict or interfere with commercial activity involving OTC hearing aids. The comment period on the Proposed Rule, in which we participated, ended on January 18, 2022, after which the FDA will review the comments and make any revisions the FDA deems necessary prior to publishing the Final Rule. The Final Rule becomes effective 60 days after the publication of the Final Rule. Under the Proposed Rule, devices that require 510(k) clearance to come into compliance with the new requirements would need to be cleared by the effective date of the Final Rule to continue marketing; for all other currently marketed devices, the proposed compliance date is 180 days after the effective date of the Final Rule (240 days after the publication of the Final Rule).

We market the Eargo system devices as Class I or Class II air-conduction hearing aids under existing regulations at 21 CFR 874.330 and 874.3305, both of which are exempt from 510(k) premarket review. Our hearing aids may be marketed under the current FDA framework during the FDA's rulemaking proceeding. However, we cannot know to what extent the Final Rule may differ from the Proposed Rule. Once the FDA issues a Final Rule, 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 in order to market our products in line with our primary direct-to-consumer business and omni-channel models in the future. It is possible that a finalized regulatory framework for OTC hearing aids may lead to additional commercial partnership, omni-channel, including retail, or other opportunities, although there are no assurances that it will do so. The Final Rule and the responses thereto by leading insurance providers could also materially impact our efforts to resume submitting claims for customers with potential insurance benefits or have other unforeseen impacts on our business and results of operations.

In addition, in May 2018, the FDA granted a de novo classification request from Bose for a direct-to-consumer "self-fitting air-conduction hearing aid," and effective October 28, 2019, the FDA published 21 CFR 874.3325, establishing the product classification for the self-fitting air conduction hearing aid as a Class II device with special controls subject to 510(k) premarket review. We do not consider our devices to be "self-fitting" hearing aids similar to the cleared Bose device, but the FDA could disagree. In such case, the FDA may require us to remove our devices from the market while we seek FDA clearance. In addition, even if our current products remain Class I or Class II exempt devices, it is possible that any future products we may develop could fail to meet the requisite criteria for similar regulation and could be subject to more stringent requirements and premarket review, increasing our costs for regulatory compliance.

Finally, in October 2021, the Biden administration outlined its plan to expand government healthcare programs as part of its broader domestic spending bill, which includes, among other things, extending Medicare coverage to include hearing benefits. Congress has considered and is considering legislation that would provide for such coverage, for example, the Build Back Better Act (H.R. 5376), which was passed by the House on November 19, 2021. The bill, as passed by the House, would provide Medicare coverage for certain hearing aids to individuals with specific types of hearing loss, furnished pursuant to a written order of a physician, qualified audiologist or other hearing aid professional, physician assistant, nurse practitioner or clinical nurse specialist. This bill has not yet been passed by the Senate, and we cannot predict the likelihood, nature, or extent to which Medicare or other government healthcare programs will cover hearing aids, if at all, or specifically our hearing aids, which are intended for "mild" or "moderate" hearing loss, or the impact of any such changes on our business, financial condition or results of operations.

If we cannot innovate at the pace of our hearing aid manufacturing competitors, we may not be able to develop or exploit new technologies in time to remain competitive.

The hearing aid industry has in the past experienced rapid shifts to new key technologies, including for example the switch from analog to digital hearing aids in the 1990s, that disrupted existing market patterns and led to a large-scale market realignment among customers and hearing aid manufacturers. For us to remain competitive, it is essential to develop and bring to market new technologies or to find new applications for existing technologies at an increasing speed. If we are unable to meet customer demands for new technology, or if the technologies we introduce are viewed less favorably than our competitors' products, our results of operations and future prospects may be negatively affected. To meet our customers' needs in these areas, we must continuously design new products, update existing products and invest in and develop new technologies. We will also need to anticipate consumer demand with respect

to these technologies and which technological advances are most desirable in the hearing aids we sell. This need will result in requiring our employees to continue learning and adapting to new technologies, and our competing for highly skilled talent in a competitive market. Our operating results depend to a significant extent on our ability to anticipate and adapt to technological changes in the hearing aid market, maintain innovation, maintain a strong product pipeline and reduce the costs of producing high-quality new and existing hearing aids. Any inability to do so could have a material adverse effect on our business, financial condition and results of operations.

We are deploying a new business model in an effort to disrupt a relatively mature industry. In order to successfully challenge incumbent business models and become profitable, we will need to continue to refine our product and strategy.

Our direct-to-consumer business model is relatively new to the hearing aid industry. Our products are currently primarily available direct-to-consumer and are therefore generally not sold by channels which consumers would traditionally look to for the treatment of their hearing loss. Because audiologists and hearing clinics do not offer our products, they are unlikely to recommend our products to their patients. If we are unable to reach this population through our online or direct and channel marketing, the estimated market size for our products may be lower than we anticipate.

Delivery of hearing aids via a direct-to-consumer model represents a change from the traditional channel, which requires in-person visits to one or more hearing care professionals, and consumers may be reluctant to accept this model or may not find it preferable to the traditional channel. In addition, consumers may not respond to our direct and channel marketing campaigns or efforts, or we may be unsuccessful in reaching our target audience, particularly if we expand our sales efforts in foreign jurisdictions where our advertising and distribution model may be more heavily regulated. If consumers prove unwilling to adopt our model as rapidly or in the numbers that we anticipate, our business, financial condition and results of operations could be materially harmed.

Historically, the majority of hearing aids sold to customers who used insurance benefits as a method of direct payment to Eargo corresponded to claims for reimbursement to third-party payors under the FEHB program. While we will need to work with applicable third-party payors to align on the process and required documentation for potentially submitting claims through the FEHB program in the future, we may be unable to validate and establish processes to support the submission of claims for reimbursement to health plans under the FEHB program in the future. As such, our future growth prospects may be dependent upon other opportunities, such as the pending OTC hearing aid regulatory framework and any potential Medicare coverage for certain hearing aids that we may be able to access.

We operate in a highly competitive industry, and competitive pressures could have a material adverse effect on our business.

The worldwide market for hearing aids is competitive in terms of pricing, product quality, product innovation and time-to-market. We face strong competitors, which have greater resources and stronger financial profiles that may enable them to better exploit changes in our industry on a cost-competitive basis and to be more effective and faster in capturing available market opportunities, which in turn may negatively impact our market share. There are five major traditional manufacturer competitors in the industry—GN Store Nord, Sonova, Starkey, William Demant and WS Audiology—who together control a significant majority of the hearing aid market.

In addition to these manufacturer competitors, Costco sells multiple brands of hearing aids, including those of the traditional manufacturers and Costco's own white-label Kirkland Signature brand of hearing aid, at prices ranging from approximately $1,400 to $2,950 per pair. We estimate that during 2019, Costco dispensed approximately 14% of the hearing aids distributed in the United States, which percentage is expected to increase going forward. The United States Department of Veterans Affairs (the "VA") is also a significant provider of hearing aids and provides hearing aids at no charge to its patients. We estimate that, in 2019, the VA dispensed approximately 19% of the hearing aids distributed in the United States. Our products are not distributed by Costco, or on contract or currently eligible to be distributed by the VA.

We also face competition from companies that introduce new technologies, including consumer electronics companies that sell direct to consumers. For example, in May 2018, the FDA granted marketing clearance to Bose Corporation for a "self-fitting air-conduction hearing aid." The Bose self-fitting hearing aid was cleared under the FDA's de novo premarket review pathway with the intended use to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment, with no pre-programming or hearing test necessary. We view our consumer-first model as a competitive advantage, and competitors, including Bose or other consumer electronics companies, or any other companies following the anticipated implementation of a pending OTC hearing aid regulatory framework, that sell hearing aids directly to consumers may erode that advantage. Please see the Risk Factor titled, "Changes in the regulatory landscape for hearing aid devices could render our direct-to-consumer business model contrary to applicable regulatory requirements, and we may be required to seek additional clearance or approval for our products."

We also face competition from other direct-to-consumer hearing aid providers. Similar to our business model, these hearing aid companies allow consumers to purchase hearing aids remotely, with no need to visit a clinic and they provide remote clinical support. Given the similarities in our business model to these providers, if potential consumers opt to buy their hearing aids from these direct-to-consumer competitors, our business could be adversely affected.

We may be unable to compete with these or other competitors, and one or more of such competitors may render our technology obsolete or economically unattractive. Please see the Risk Factor titled "If we cannot innovate at the pace of our hearing aid

manufacturing competitors, we may not be able to develop or exploit new technologies in time to remain competitive." To the extent we expand internationally, we will face additional competition in geographies outside the United States. If we are unable to compete effectively with existing products or respond effectively to any new products developed by competitors, our business could be materially harmed. Increased competition may result in price reductions, reduced gross margins and loss of market share. There can be no assurance that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material adverse effect on our business, financial condition and results of operations.

We rely on the timely supply of high-quality components, parts and finished products, and our business could suffer if suppliers or manufacturers are unable to procure raw materials or other components of an acceptable quality (or at all) or otherwise fail to meet their delivery obligations, raise prices or cease to supply us with components, parts or products of acceptable quality.

We rely on a limited number of critical suppliers for many of the components that are used in the manufacture of our products, including for semiconductor components, such as integrated circuits, as well as batteries, microphones and receivers. We are dependent on these third-party manufacturers and suppliers to identify and purchase quality raw materials, semi-finished goods and finished goods while seeking to preserve our quality standards. This reliance and dependence on third parties adds additional risks to the manufacturing process that are beyond our control. For example, the occurrence of epidemics or pandemics, such as the COVID-19 pandemic, may cause labor shortages and/or disrupt the supply of various raw materials and components, causing price spikes and/or shortages. As a result, one or more of our suppliers or manufacturers may suspend, close or otherwise reduce the scope of their operations either temporarily or permanently.

In addition, many of these suppliers also provide components and products to our competitors. The industry's reliance on a limited number of key components and product suppliers subjects us to the risk that in the event of an increase in demand or shortage of key materials or components, our suppliers may fail to provide supplies to us in a timely manner while they continue to supply our competitors, many of which have greater purchasing power than us, or seek to supply components to us at a higher cost. Lead times for materials, components and products ordered by us or by our contract manufacturers can vary significantly and depend on factors such as contract terms, demand for a component, and supplier capacity. From time to time, we may experience and have experienced component shortages and extended lead times, as well as increased component costs and increased logistics costs, including on semiconductor components and batteries, and other components used in our products.

While we continue to monitor our supply chain and have taken and are taking actions to address limited supply and increasing lead times, including outreach to critical suppliers and spot market purchases, future disruptions in our supply chain, including the sourcing of certain components and raw materials by us or our suppliers, such as semiconductor and memory chips, as well as increased logistics and inflationary costs, could impact our sales and gross margins as well as launch and shipment of our products. The failure of our suppliers or manufacturers to deliver components or products in a timely fashion could have disruptive effects on our ability to produce our products in a timely manner, or we may be required to find new suppliers or manufacturers at an increased cost, if at all. Shortages or interruptions in the supply of components or subcontracted products, or our inability to procure these components or products from alternate sources at acceptable prices in a timely manner, could delay launch or shipment of our products or increase our production costs, which could adversely affect our business and operating results. The effects of climate change, including extreme weather events, long-term changes in temperature levels and water availability may exacerbate these risks. Such disruption has in the past impacted our costs and could in the future impact costs or interrupt our ability to source certain product components. A severe weather event in countries from which we source components and parts could cause disruptions in the Company's supply chain which could, in turn, cause product shortages, delays in delivery and/or increases in the Company's cost incurred to manufacture its products.

Any shortage, delay or interruption in the availability of our products, or key inputs used in their production, may negatively affect our ability to meet consumer demand. Additionally, our reputation and the quality of our products are in part dependent on the quality of the components that we source from third-party suppliers. If we are unable to control the quality of the components supplied to us or to address known quality problems in a timely manner, our reputation in the market may be damaged and sales of our products may suffer. As a result, we may experience a material adverse effect on our business, financial condition and results of operations.

Certain components needed to manufacture our hearing aids are only available from a limited number of suppliers.

Several of our suppliers provide products for our hearing aids and accessories for which they own the design and/or intellectual property rights. This includes semiconductor components, including integrated circuits, as well as transducers, batteries and various electrical components, some of which are highly customized. Although there may be several potential suppliers for our components, as our components are highly customized, there is a risk that these components may not be readily substituted by similar products of other suppliers or that any substitution may take a lengthy period of time to implement. Even if we do identify new suppliers, we may experience increased costs and product shortages as we transition to alternative suppliers. If any of these limited suppliers cease to supply us with their products, significantly increase their costs, or any of the foregoing events occurs, we could experience a material adverse effect on our business, financial condition and results of operations.

We rely on a limited number of manufacturers for the assembly of our hearing aids. If we encounter manufacturing problems or delays, we may be unable to promptly transition to alternative manufacturers and our ability to generate revenue will be limited.

We have no manufacturing capabilities of our own. We currently rely on a limited number of manufacturers: one headquartered in Taiwan, with manufacturing facilities in Suzhou, China, Pegatron Corporation, for the manufacture of Eargo 5 and Eargo 6, and one located in Thailand, Hana Microelectronics, for the manufacture of all other products currently available for sale. For us to be successful, our contract manufacturers must be able to provide us with products in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. While our existing manufacturers have generally met our demand requirements on a timely basis in the past, their ability and willingness to continue to do so going forward may be limited for several reasons, including our relative importance as a customer of the manufacturer or its ability to provide assembly services to manufacture our products, which may be affected by the COVID-19 pandemic. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these manufactured products if we cannot obtain an acceptable substitute.

Any transition to a new contract manufacturer, or any transition of products between existing manufacturers, could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products or could require that we modify the design of our products. If we are required to change either of our contract manufacturers, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. We cannot assure you that we will be able to identify and engage alternative contract manufacturers on similar terms or without delay. Furthermore, our contract manufacturers could require us to move to a different production facility. The occurrence of any of these events could harm our ability to meet the demand for our products in a timely and cost-effective manner, which could have a material adverse effect on our business, financial condition and results of operations.

The manufacture of our products is complex and requires the integration of a number of components from several sources of supply. Our contract manufacturers must manufacture and assemble these complex products in commercial quantities in compliance with regulatory requirements and at an acceptable cost. Our hearing aids require significant expertise to manufacture, and our contract manufacturers may encounter difficulties in scaling up production of the hearing aids, including problems with quality control and assurance, component supply shortages, including any semiconductor components, increased costs, shortages of qualified personnel, the long lead time required to develop additional facilities for purposes of testing our products and/or difficulties associated with compliance with local, state, federal and foreign regulatory requirements. There can be no assurance that manufacturing or quality control problems will not arise in connection with the scale-up of the manufacture of our products. If we are unable to obtain a sufficient supply of product, maintain control over product quality and cost or otherwise adapt to challenges in managing our business, we may not have the capability to satisfy market demand, and our business and reputation in the marketplace will suffer. If demand for our products decreases, as it has recently as a result of the DOJ investigation and claims audits (see "Management's Discussion and Analysis of Financial Condition and Results of Operations—DOJ investigation and settlement and claims audits"), we may have excess inventory, which could result in inventory write-offs that may adversely affect our business, financial condition and results of operations. We may also encounter defects in materials and/or workmanship, which could lead to a failure to adhere to regulatory requirements. Any defects could delay operations at our contract manufacturers' facilities, lead to regulatory fines or halt or discontinue manufacturing indefinitely. Any of these outcomes could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to successfully develop and effectively manage the introduction of new products, our business may be adversely affected.

We must successfully manage introductions of new or advanced hearing aid products. Introductions of new or advanced hearing aid products could also adversely impact the sales of our existing products to consumers. For instance, the introduction or announcement of new or advanced hearing aid products may shorten the life cycle of our existing devices or reduce demand, thereby reducing any benefits of successful hearing aid introductions and potentially lead to challenges in managing write-downs or write-offs of inventory of existing products. We may also not have success in transitioning customers from legacy hearing aids to new products. In addition, new hearing aid products may have higher manufacturing costs than legacy products, which could negatively impact our gross margins and operating results. As the technological complexity of our products increases, the infrastructure to support our products, such as our design and manufacturing processes and technical support for our products, may also become more complex. Accordingly, if we fail to effectively manage introductions of new or advanced products, our business may be adversely affected.

We experience challenges managing the inventory of existing hearing aids, which can lead to excess inventory and discounting of our existing devices. Inventory levels in excess of consumer demand may result in inventory write-downs or write-offs and the sale of inventory at discounted prices, which has affected our gross margin and could impair the strength of our brand. Reserves and write-downs for rebates, promotions and excess inventory are recorded based on our forecast of future demand. Actual future demand could be less than our forecast, which may result in additional reserves and write-downs in the future, or actual demand could be stronger than our forecast, which may result in a reduction to previously recorded reserves and write-downs in the future and increase the volatility of our operating results.

If the quality of our hearing aid products does not meet consumer expectations, or if our products wear out more quickly than expected, then our brand and reputation or our business could be adversely affected.

Our products may not perform as well in day-to-day use as we or our customers expect. Although we designed our Eargo hearing aids to provide high quality audio, we have collected limited data comparing our products to competitive devices. In September 2021, we conducted a series of comparative electroacoustic benchmarking tests (the "Bench Study") to compare our Eargo Neo HiFi and Eargo 5 hearing aids with hearing aids from four major manufacturers. While each of the devices tested in the Bench Study, including our Eargo Neo HiFi and Eargo 5 hearing aids, met or exceeded the identified benchmarks for appropriate levels of sound quality and amplification to improve speech audibility, the design, methodology and results of the Bench Study have not been subject to external review and may not be reliable or replicable indicators of the general performance of our Eargo Neo HiFi and Eargo 5 hearing aids or the other manufacturers' hearing aids that were the subject of the Bench Study. Further, the benchmarks for appropriate levels of sound quality and amplification that we identified in the Bench Study may not be appropriate proxies for hearing aid performance or reflect the real-world performance of any tested device. Future studies, including our internal studies or those of our competitors or other third parties, may not yield the results that we expect to obtain and may not demonstrate that our products are superior to, or may demonstrate that our products are inferior to, existing or future products with regard to functional or economic measures. These study results may be published in medical journals or other publications, or by our competitors and result in adverse publicity for our products. The performance of our Eargo hearing aids may not live up to customer expectations, and our brand, reputation, customer satisfaction, return rates and sales may be adversely affected as a result.

Furthermore, because of our products' limited time in the market, we cannot be certain about the usable life of our products. Due to the design constraints applicable to our rechargeable, in-the-canal form factor, our hearing aids may offer a shorter usable life compared to our competitors' hearing aids. Thus, even though our products may be more affordable than competitive devices, they may need to be replaced more often. Although we believe the advantages of our design justify this tradeoff, customers may expect a longer useful life, and failure to live up to this expectation could result in reduced sales, decreased customer loyalty, higher-than-expected warranty claims and adverse publicity.

Certain components of our hearing aids may also offer reduced performance or wear out over time. For example, the rechargeable technology used in our hearing aids and charging cases has a limited lifespan, and recharging performance will degrade over time. We designed our Eargo Neo HiFi hearing aids to provide up to 20 hours of continuous use between charges when new and up to 16 hours after 1,000 charging cycles, but charging capacity may decrease more quickly than expected. Moreover, certain components of our hearing aids that can be purchased online will require more frequent replacement than the device itself. If the quality, longevity and durability of our products does not meet the expectations of customers, then our brand and reputation and our business, financial condition and results of operations, could be adversely affected.

Customer or third-party complaints or negative reviews or publicity about our company or our hearing aids could harm our reputation and brand.

We are heavily dependent on customers who use our hearing aids to provide good reviews and word-of-mouth recommendations to contribute to our reputation and brand. Customers who are dissatisfied with their experiences with our products or services or their ability to receive reimbursement from their insurance companies may post negative reviews. We have and may continue to be the subject of blog, forum or other media postings that include inaccurate statements and create negative publicity. In addition, traditional hearing aid supply chain participants may express and publish negative views regarding our direct-to-consumer model and products. Any negative reviews or negative publicity, including in relation to the DOJ investigation, the claims audits, and other legal proceedings have harmed and could continue to harm our reputation and brand and severely diminish consumer confidence in our products. Please also see the Risk Factor titled, "We are subject to risks from legal proceedings, investigations, and inquiries, including a number of recent legal proceedings and investigations, which have had and could continue to have a material adverse effect on our reputation, business, financial condition, cash flows and results of operations, and could result in additional claims and material liabilities."

We spend significant amounts on advertising and other marketing campaigns to acquire new customers, which may not be successful or cost effective.

We market our hearing aids through a mix of digital and traditional marketing channels. These include paid search, digital display advertising, email marketing, affiliate and channel marketing, direct response television, national reach television, direct mail and select print and radio advertising. We also leverage our database of prospects and customers to further drive customer acquisition and referrals. We spend significant amounts on advertising and other marketing campaigns to acquire new customers, and we expect to continue to spend significant amounts to acquire new customers and increase awareness of our products. Beginning on December 8, 2021, we do not currently accept insurance benefits as a method of direct payment. As a result, we have reduced sales and marketing resources that were previously focused on insurance customers to prioritize the conversion of cash-pay consumers into satisfied customers. The shift to a cash-pay only model is likely to increase the cost to acquire new customers, based on the historically lower conversion rate for cash-pay customers as compared to customers with potential insurance benefits. This shift to a cash-pay only model may be reinforced by the OTC regulatory framework, if finalized, and if our products are marketed as OTC hearing aids, which

may not be covered under certain plans even if medical necessity is otherwise established. While we seek to structure our marketing campaigns in the manner that we believe is most likely to encourage consumers to use our products while lowering our acquisition costs, we may fail to identify marketing opportunities that satisfy our anticipated return on marketing spend as we scale our investments in marketing, accurately predict customer acquisition or fully understand or estimate the conditions and behaviors that drive consumer behavior. If any of our marketing campaigns prove less successful than anticipated in attracting new customers, we may not be able to recover our marketing spend, and our rate of customer acquisition may fail to meet market expectations, either of which could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that our marketing efforts will result in increased sales of our products.

In addition, we believe that building a strong brand and developing and achieving broad awareness of our brand is critical to achieving market success. Negative publicity, including in relation to the DOJ investigation, the claims audits, and other legal proceedings has harmed and could continue to harm our reputation and brand and severely diminish consumer confidence in our products. If any of our brand-building activities prove less successful than anticipated, or such activities are inhibited by negative publicity in relation to the DOJ investigation, the claims audits and other legal proceedings, it could materially adversely impact our ability to attract new customers. If this were to occur, we may not be able to recover our brand-building spend, and our rate of customer acquisition may fail to meet market expectations, either of which could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that our brand-building efforts will result in increased sales of our products. See also the Risk Factors titled, “Customer or third-party complaints or negative reviews or publicity about our company or our hearing aids could harm our reputation and brand” and “We are subject to risks from legal proceedings, investigations, and inquiries, including a number of recent legal proceedings and investigations, which have had and could continue to have a material adverse effect on our reputation, business, financial condition, cash flows and results of operations, and could result in additional claims and material liabilities.”

Our products are complex to design and manufacture and could contain defects. The production and sale of defective products could adversely affect our business, financial condition and results of operations. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We make hearing aids that include highly complex electronic components, which are sourced from external third parties, and there is an inherent risk that defects may occur in the production of any of our products. Although we rely on the suppliers’ internal procedures designed to minimize risks that may arise from quality issues, there can be no assurance that we or our suppliers will be able to eliminate or mitigate occurrences of these issues and associated liabilities. Under consumer product legislation in many jurisdictions, we may be forced to recall or repurchase defective products, and more restrictive laws and regulations relating to these matters may be adopted in the future. We also face exposure to product liability claims in the event that any of our devices are alleged to have resulted in personal injury or damage to property, or otherwise to have caused harm. For example, we may be sued if any of our hearing aids allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our current or future products;
- injury to our reputation;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to customers;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to sell our current or any future products.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the sale of our current or any future products we develop. Although we currently carry product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

In addition, any product defects, recalls or claims that result in significant adverse publicity could have a negative effect on our reputation, result in loss of market share or failure to achieve market acceptance. For example, our first-generation hearing aid, launched in 2015, had a high incidence of product returns and warranty claims. As a result, we voluntarily withdrew the product from the market. The production and sale of defective products in the future could have a material adverse effect on our business, financial condition and results of operations.

We are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business, and changes in such regulations or laws could require us to modify our products or marketing or advertising efforts.

In connection with the marketing or advertisement of our products, we could be the target of claims relating to false, misleading, deceptive or otherwise noncompliant advertising or marketing practices, including under the auspices of the Federal Trade Commission and state consumer protection statutes. If we rely on third parties to provide any marketing and advertising of our products, we could be liable for, or face reputational harm as a result of, their marketing practices if, for example, they fail to comply with applicable statutory and regulatory requirements.

If we are found to have breached any consumer protection, advertising, unfair competition or other laws or regulations, we may be subject to enforcement actions that require us to change our marketing and business practices in a manner which may negatively impact us. This could also result in litigation, fines, penalties and adverse publicity that could cause reputational harm and loss of customer trust, which could have a material adverse effect on our business, financial condition and results of operations.

There are a variety of hearing aid products and technologies, and consumer confusion about product features and technology could lead consumers to purchase competitive products instead of our products, or to conflate any adverse events or safety issues associated with third-party hearing aid products with our products, which could adversely affect our business, financial condition and results of operations.

We believe that many individuals do not have full information regarding the types of hearing aids and hearing aid features and technologies available in the market, in part due to the lack of consumer education in the traditional hearing industry sales model. Consumers may not have sufficient information about hearing aids generally or how hearing aid products and technologies compare to each other. This confusion may result in consumers purchasing hearing aids from our competitors instead of our products, even if our hearing aids would provide them with their desired product features. In addition, any adverse events or safety issues relating to competitive hearing aid products and related negative publicity, even if such events are not attributable to our products, could result in reduced purchases of hearing aids by consumers generally. Any of these occurrences could lead to reduced sales of our products and adversely affect our business, financial condition and results of operations.

Our business, financial condition and results of operations may be impacted by the effects of the COVID-19 pandemic.

We are subject to risks related to public health crises such as the global pandemic associated with COVID-19. The COVID-19 pandemic may negatively impact our operations and revenues and overall financial condition by harming the ability or willingness of customers to pay for our products due to macro-economic conditions resulting from the pandemic or the operations of manufacturers, suppliers and other third parties with which we do business. These challenges will likely continue for the duration of the pandemic, which is uncertain, and the macro-economic effects of the pandemic will likely continue far beyond the duration of the pandemic.

Since the start of the pandemic, numerous state and local jurisdictions have imposed, and others in the future may impose, “shelter-in-place” orders, quarantines, orders requiring non-essential businesses to remain closed, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. The pandemic and such restrictions have resulted in a majority of our employees working remotely, work stoppages, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. Other potential disruptions may include delays in processing registrations or approvals by applicable state or federal regulatory bodies; delays in product development efforts; disruptions to our supply chain, including any impacts from global semiconductor shortages; and additional government requirements or other incremental mitigation efforts that may further impact our capacity to manufacture, sell and support the use of our Eargo systems. Disruptions in supply chain have resulted in industry-wide component supply (such as semiconductors) shortages, and we may not be able to obtain adequate inventory on a timely basis or at all. To date, increases in component pricing have occurred but have not had a material impact on supply continuity or gross margin. We have taken steps to monitor our supply chain and actions to address limited supply and increasing lead times, including outreach to critical suppliers and spot market purchases. Future disruptions in our supply chain, including the sourcing of certain components and raw materials, such as semiconductor and memory chips, as well as increased logistics costs, could impact our sales and gross margins.

The ultimate impact of COVID-19 on our business, financial conditions and results of operations depends on many factors and future developments beyond our control, which are highly uncertain and difficult to predict, including: the duration of the pandemic, a potential resurgence, the impact of variants, new or renewed restrictions, the timing, availability, acceptance and effectiveness of vaccines and treatments against COVID-19 as well as vaccination rates among the population, the pace of recovery when the COVID-19 pandemic subsides, and the severity and duration of the global economic downturn that results from the ongoing pandemic.

While the potential economic impact brought by and the duration of COVID-19 may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity, including our ability to repay our existing indebtedness. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. The COVID-19 pandemic has also resulted in volatility in the unemployment rate in the United States, which may continue even after the pandemic subsides. The occurrence of any such events may lead to reduced disposable income and access to health insurance which could adversely affect the number of our products sold after the pandemic has subsided. Further, although our sales volume has been positively impacted during the COVID-19 pandemic, this and any other favorable impacts we have experienced in connection with the pandemic may subside, and the ultimate effect of COVID-19 on our sales volume and other results of operations could differ substantially from our expectations and our experience to date.

Repair or replacement costs due to guarantees we provide on our products could have a material adverse effect on our business, financial condition and results of operations.

We provide product guarantees to our customers, both as a result of contractual and legal provisions and for marketing purposes.

We generally allow for the return of products from direct customers within 45 days after the original sale and record estimated sales returns as a reduction of sales in the same period revenue is recognized. We also generally allow customers to return defective or damaged products for a replacement or refund. The term of the warranty provided is typically two years for our latest device and one year for all other devices. Existing and future product guarantees place us at the risk of incurring future repair and/or replacement costs. As of March 31, 2022, we had provisions of approximately $4.2 million relating to warranties. Substantial amounts of product guarantee claims could have a material adverse effect on our business, financial condition and results of operations.

In addition, we reserve for the estimated cost of product warranties when revenue is recognized, and we evaluate our warranty reserves periodically by reviewing our warranty repair experience. While we engage in product quality programs and processes, including monitoring and evaluating the quality of our components sourced from our suppliers and instituting methods to remotely detect and correct defects, our warranty obligation is affected by actual product defect rates, parts and equipment costs and service labor costs incurred in correcting a product defect. Our warranty reserves may be inadequate due to undetected product defects, unanticipated component failures or changes in estimates for material, labor and other costs we may incur to replace projected product defects. As a result, if actual product defect rates, parts and equipment costs or service labor costs exceed our estimates, it could have a material adverse effect on our business, financial condition and results of operations.

Our failure to successfully anticipate sales returns may have a material adverse effect on our business, financial condition and results of operations.

Our reported net revenue and net losses are affected by changes in reserves to account for sales returns and product credits. The reserve for sales returns accounts for customer returns of our products after purchase. We record a reserve for sales returns estimated based on historical return trends together with current product sales performance in each reporting period. If actual returns are greater than those projected and reserved for by management, additional sales returns reserve may be recorded in the future and reported net revenue may be reduced accordingly. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—DOJ investigation and settlement and claims audits” for more information.

We do not currently have the ability to resell all products that are returned. Our refurbishment capabilities include full refurbishment, conversion, and components, and allow us to refurbish and resell or reuse certain returned devices. To the extent we are unable to successfully refurbish devices in the future, we will not be able to resell such devices. Further, the introduction of new products, changes in product mix, changes in consumer confidence or other competitive and general economic conditions may cause actual returns to differ from product return reserves. Any significant increase in product returns that exceeds our reserves could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to reduce our return rates or if our return rates continue to increase, our net revenue may decrease, and our business, financial condition and results of operations could be adversely affected.

Our customer sales returns rate was approximately 34% in the first quarter of 2022. Our return policy allows our customers to return hearing aids for any reason within the first 45 days of delivery for a full refund, subject to a handling fee in certain states. Additionally, following learning of the DOJ investigation and prior to shifting to our current upfront payment requirement, we offered customers with potential insurance benefits the option to return their hearing aids or purchase their hearing aids without use of their insurance benefits if their claim is denied or ultimately not submitted by us to their insurance plan for payment (see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—DOJ investigation and settlement and claims audits” for more information).

We report revenue net of expected returns, which is an estimate informed in part by historical return rates. As such, our return rate impacts our reported net revenue and profitability. Our net revenue and profitability have been and will continue to be negatively impacted by the inability to recognize revenue related to shipments to customers with potential insurance benefits, which customers generally have had a significantly lower rate of return as compared to cash-pay customers. As we have shifted to selling on a “cash-

pay" basis only, we have experienced a significantly higher sales return rate. If actual sales returns differ significantly from our estimates, an adjustment to revenue in the current or subsequent period is recorded. Furthermore, if we are unable to reduce our return rates or if they continue to increase, our net revenue may continue to decrease, and our business, financial condition and results of operations could be adversely affected. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Factors affecting our business—Sales returns rate."

Accelerated consolidation and formation of purchasing groups increases the pricing pressure on hearing aids.

Many purchasing groups, such as hearing aid clinics, retailers and hospital systems, are consolidating to create new entities with greater market power. Such groups, such as Costco and the VA, have used and may continue to use their increased purchasing power to negotiate price reductions or other concessions across our industry. This pricing leverage has resulted, and will likely continue to result, in downward pressure on the average selling prices of hearing aid products generally, including our own products. The forthcoming OTC Final Rule could further contribute to the pace of consolidation as well as the introduction of new entrants in the hearing aid market, which would further increase pricing pressure on hearing aid manufacturers. Please see the Risk Factor titled, "Changes in the regulatory landscape for hearing aid devices could render our direct-to-consumer business model contrary to applicable regulatory requirements, and we may be required to seek additional clearance or approval for our products." These factors could have a material adverse effect on our business, financial condition and results of operations.

Alternative technologies or therapies that improve or cure hearing loss could adversely affect our business, financial condition and results of operations.

If medical research were to lead to the discovery of alternative therapies or technologies that improve or cure the various forms of hearing loss as an alternative to the hearing aid, such as by surgical techniques, the use of pharmaceuticals or breakthrough bio-technological innovations or therapies, our profitability could suffer through a reduction in sales. The discovery of a cure for the various forms of hearing loss and the development of other alternatives to hearing aids could result in decreased demand for our products and, accordingly, could have a material adverse effect on our business, financial condition and results of operations.

Adapting our production capacities to evolving patterns of demand is expensive, time-consuming and subject to significant uncertainties. We may not be able to adequately predict consumer trends and may be unable to adjust our production in a timely manner.

We market our products directly to consumers in the United States, where we face the risk of significant changes in the demand for our products. If demand decreases, we will need to implement capacity and cost reduction measures involving restructuring costs. If demand increases, we will be required to make capital expenditures related to increased production and expenditures to hire and train production and sales and product support personnel. Adapting to changes in demand inherently lags behind the actual changes because it takes time to identify the change the market is undergoing and to implement any measures taken as a result. Finally, capacity adjustments are inherently risky because there is imperfect information, and market trends may rapidly intensify, ebb or even reverse. We have in the past not always been, and may in the future not be, able to accurately or timely predict trends in demand and consumer behavior or to take appropriate measures to mitigate risks and exploit opportunities resulting from such trends. Any inability in the future to identify or to adequately and effectively react to changes in demand could have a material adverse effect on our business, financial condition and results of operations.

We are dependent on international manufacturers and suppliers, as well as certain international contractors we engage from time to time with respect to select research and development activities, which exposes us to foreign operational and political risks that may harm our business.

We currently rely on a limited number of manufacturers: one headquartered in Taiwan, with manufacturing capabilities in Suzhou, China, Pegatron Corporation, for the manufacture of Eargo 5 and Eargo 6, and one located in Thailand, Hana Microelectronics, for the manufacture of all other products currently available for sale. In addition, we rely on some third-party suppliers in Europe, Southeast Asia, Japan, China and the United States, who supply, among other things, certain of the technology and raw materials used in the manufacturing of our products. We also engage certain international consultants, contractors and other specialists in connection with our research and development activities.

Our reliance on international operations exposes us to risks and uncertainties, including:

- controlling quality of supplies and finished product;
- trade protection measures, tariffs and other duties, especially in light of trade disputes between the United States and several foreign countries, including China and countries in Europe;
- political, social and economic instability (for example, Russia's invasion of Ukraine in February 2022 and the resultant sanctions and export controls introduced against Russia have created such instability and have and may continue to disrupt business activity both in the immediately affected region and around the world, the full effects of which remain unknown);

- the outbreak of contagious diseases, such as COVID-19;
- laws and business practices that favor local companies;
- interruptions and limitations in telecommunication services;
- product or material delays or disruption, including logistics challenges such as delays or disruptions in shipping;
- import and export license requirements and restrictions;
- difficulties in the protection of intellectual property;
- inflation and/or deflation;
- the threat of nationalization and expropriation;
- exchange controls, currency restrictions and fluctuations in currency values; and
- potential adverse tax consequences.

If any of these risks were to materialize, it could have a material adverse effect on our business, financial condition and results of operations.

We or the third parties upon whom we depend may be adversely affected by disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Any interruption in the operations of our or our suppliers' manufacturing or other facilities may have a material adverse effect on our business, financial condition and results of operations.

Our corporate headquarters are located in the San Francisco Bay Area, which has experienced both severe earthquakes and wildfires. We do not carry earthquake insurance. Our manufacturers and many of our suppliers are located in Asia, which regions have experienced natural disasters such as earthquakes, landslides, flooding, tropical storms and tsunamis, and tornadoes. Our customer support operations are based in Nashville, Tennessee, and our third-party provider's distribution facilities are based in Louisville, Kentucky, both of which have experienced flooding and tornadoes. Severe weather (including any potential effects of climate change), natural disasters and other calamities, such as pandemics (including COVID-19), earthquakes, tsunamis and hurricanes, fires and explosions, accidents, mechanical failures, unscheduled downtimes, civil unrest, strikes, transportation interruptions, unpermitted discharges or releases of toxic or hazardous substances, other environmental risks, sabotage, geopolitical unrest, political instability, terrorism or acts of war, could severely disrupt our operations, or our third-party manufacturers' and suppliers' operations, and have a material adverse effect on our business, financial condition and results of operations.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or other facilities, or those of our third-party manufacturers or suppliers, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. A mechanical failure or disruption affecting any major operating line may result in a disruption to our ability to supply customers, and standby capacity may not be available. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. The potential impact of any disruption would depend on the nature and extent of the damage caused by a disaster. There can be no assurance that alternative production capacity will be available in the future in the event of a major disruption or, if it is available, that it could be obtained on favorable terms. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business, financial condition and results of operations.

We depend on sales of our hearing aids for our revenue. Demand for our hearing aids may not increase due to a variety of factors.

We expect that revenue from sales of our hearing aids will continue to account for our revenue for the foreseeable future. Continued and widespread market acceptance of hearing aids by consumers is critical to our future success. Consumer spending habits are affected by, among other things, prevailing economic conditions, levels of employment, salaries and wage rates, interest rates, inflation rates, consumer confidence and consumer perception of economic conditions, which have been adversely affected by the COVID-19 pandemic and may continue to be materially adversely affected by the COVID-19 pandemic. Hearing aids are often paid for directly by the consumer and, as a result, demand can vary significantly depending on economic conditions. The uncertainty regarding the extent to which we are able to validate and establish processes to support the submission of claims for reimbursement to health plans, including those under the FEHB program, if at all, in the future, the anticipated implementation of a pending OTC hearing aid regulatory framework (which may lead insurance providers to take actions limiting our ability to access insurance coverage and may also generally result in additional compliance or other regulatory requirements for Eargo and may limit our ability

to access insurance coverage) and potential Medicare coverage for certain hearing aids (which may not include Eargo hearing aids) will require that we evaluate and consider any changes to our business model as new information becomes available, including a potential long-term shift to a model excluding insurance as a method of payment to Eargo, which would likely result in a sustained increased cost of customer acquisition and a reduction in shipments, revenue, gross margin, and higher operating expenses, which could have a material negative impact on our profitability and growth prospects. Without the benefit of customers with insurance coverage, the future growth prospects and profitability of the Company are uncertain, unless we can identify new sources of profitable growth.

Further, a general slowdown in the U.S. economy and international economies into which we may expand or an uncertain economic outlook could adversely affect consumer spending habits, which may result in, among other things, a reduction in consumer spending on elective or higher value products, or a reduction in demand for hearing aids generally, each of which would have an adverse effect on our sales and operating results. Weakness in the global economy results in a challenging environment for selling hearing loss technologies. In such circumstances, consumers may opt to purchase less expensive hearing loss technologies. If there is a reduction in consumer demand for hearing aids generally, if consumers choose to use a competitive product rather than our hearing aids or if the average selling price of our hearing aids declines as a result of economic conditions, including employment levels and inflation, competitive pressures or any other reason, these factors could have a material adverse effect on our business, financial condition and results of operations. If we are not successful in adapting our production and cost structure to the market environment, we may experience further adverse effects that may be material to our business, financial condition and results of operations. See also the Risk Factor titled, "We face considerable uncertainty in our business prospects, as a significant portion of our revenue has historically been dependent upon reimbursement from third-party payors participating in the FEHB program but we have operated on a "cash pay" only basis since December 8, 2021. Following the civil settlement with the U.S. government on April 29, 2022, we may be unsuccessful in validating and establishing processes to support the submission of claims for reimbursement from third-party payors participating in the FEHB program in the future. As a result, we have faced a significant reduction in revenue and any failure to establish processes to support reimbursement from third-party payors in the future may significantly and adversely impact our business and growth prospects and our ability to sell our products."

We will be subject to "conflict minerals" reporting obligations.

We will be required to diligence the origin of minerals used in the manufacture our products that have been designated "conflict minerals" under the Dodd-Frank Wall Street Reform and Consumer Protection Act and, beginning in 2023, disclose and report whether or not such minerals originated in the Democratic Republic of the Congo or adjoining countries. These requirements could adversely affect the sourcing, availability and pricing of minerals used in the manufacture of our products. In addition, we will incur additional costs to comply with the disclosure requirements, including costs related to determining the source of the relevant minerals and metals used in our products.

Any future international expansion will subject us to additional costs and risks that may have a material adverse effect on our business, financial condition and results of operations.

Historically, all of our sales have been to customers in the United States. To the extent we enter into international markets in the future, there are significant costs and risks inherent in conducting business in international markets. If we expand, or attempt to expand, into foreign markets, we will be subject to new business risks, in addition to regulatory risks. In addition, expansion into foreign markets imposes additional burdens on our executive and administrative personnel, finance and legal teams, research and marketing teams and general managerial resources.

We have limited experience with regulatory environments and market practices internationally, and we may not be able to penetrate or successfully operate in new markets. We may also encounter difficulty expanding into international markets because of limited brand recognition in certain parts of the world, leading to delayed acceptance of our products by consumers in these international markets. If we are unable to expand internationally and manage the complexity of international operations successfully, it could have a material adverse effect on our business, financial condition and results of operations. If our efforts to introduce our products into foreign markets are not successful, we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for expansion into foreign markets could exceed the results of operations generated from this expansion.

Our Loan Agreement contains restrictions that limit our flexibility in operating our business.

In June 2018, we entered into a loan agreement, as amended in January 2019, May 2020 and in September 2020, with Silicon Valley Bank (the loan to which such loan agreement, as amended, relates, the "2018 Loan"). We borrowed $15.0 million upon the closing of the September 2020 amendment, a portion of which was used to repay in full the outstanding principal amount of the previously funded term loan. As of March 31, 2022, $15.5 million in aggregate principal amount was outstanding under the term loan facility. The 2018 Loan has a maturity date of September 1, 2024. The 2018 Loan contains various covenants that limit our ability to engage in specified types of transactions without Silicon Valley Bank's prior consent. These covenants limit our ability to, among other things:

- encumber or license our intellectual property subject to certain exceptions;
- sell, transfer, lease or dispose of our assets subject to certain exclusions;

- create, incur or assume additional indebtedness;
- encumber or permit liens on any of our assets other than certain permitted liens;
- make restricted payments, including paying dividends on, repurchasing or making distributions with respect to any of our capital stock;
- make specified investments (including loans and advances);
- consolidate, merge with, or acquire any other entity, or sell or otherwise dispose of all or substantially all of our assets; and
- enter into certain transactions with our affiliates.

In addition, the 2018 Loan requires us to maintain a certain percentage of our total cash holdings in accounts with Silicon Valley Bank. The covenants in the 2018 Loan limit our ability to take certain actions and, in the event that we breach one or more covenants, Silicon Valley Bank may choose to declare an event of default and require that we immediately repay all amounts outstanding of the aggregate principal amount of term loans funded under the 2018 Loan, plus exit fees, prepayment premiums, penalties and interest, and foreclose on the collateral granted to it to secure such indebtedness. Such repayment could have a material adverse effect on our business, financial condition and results of operations.

We primarily rely on our own direct sales force, and if we are unable to maintain or expand our sales force, it could harm our business. Additionally, our reliance on our direct sales force may result in higher fixed costs than our competitors and may slow our ability to reduce costs in the face of a sudden decline in demand for our products.

We primarily rely on our own direct sales force to market and sell our products. We do not have any long-term employment contracts with the members of our direct sales force. Our operating results are directly dependent upon the sales and marketing efforts of our sales and customer support team. If our employees fail to adequately promote, market and sell our products, our sales could significantly decrease. As we launch new products, expand our product offerings and increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to attract, hire, train, retain and motivate skilled employees with significant technical knowledge in various areas. New hires require training and take time to achieve full productivity.

Additionally, most of our competitors rely predominantly on third-party distributors. A direct sales force may subject us to higher fixed costs than those of competitors that market their products through independent third parties, due to the costs that we will bear associated with employee benefits, training and managing sales personnel. As a result, we could be at a competitive disadvantage. Additionally, these fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products, which could have a material adverse effect on our business, financial condition and results of operations.

We rely on our relationship with a professional employer organization for our human relations function and as a co-employer of our personnel, and if that party failed to perform its responsibilities under that relationship, our relations with our employees could be damaged and we could incur liabilities that could have a material adverse effect on our business.

All of our U.S. personnel, including our executive officers, are co-employees of Eargo and a professional employer organization, Insperity. Under the terms of our arrangement, Insperity is the formal employer of all of our U.S. personnel and is responsible for administering all payroll, including tax withholding, and providing health insurance and other benefits for these individuals, and our employees are governed by the work policies created by Insperity. We reimburse Insperity for these costs and pay Insperity an administrative fee for its services. If Insperity fails to comply with applicable laws or its obligations under this arrangement or creates work policies that are viewed unfavorably by employees, our relationship with our employees could be damaged. We could, under certain circumstances, be held liable for a failure by Insperity to appropriately pay, or withhold and remit required taxes from payments to, our employees. In such a case, our potential liability could be significant and could have a material adverse effect on our business.

We experience seasonality in our business, which may cause fluctuations in our financial results.

Historically, we have experienced and may continue to experience seasonality in our business, with higher sales volumes in quarters when we commercially launch new products and in the fourth calendar quarter as a result of holiday promotional activity. However, since our public disclosure of the DOJ investigation on September 22, 2021 and our related decision to stop accepting insurance benefits as a method of direct payment, we have experienced and may continue to experience a material decline in gross systems shipped. Negative publicity, including in relation to the DOJ investigation, the claims audits, and other legal proceedings has and could continue to harm our reputation and brand and severely diminish consumer confidence in our products. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—DOJ investigation and settlement and claims audits” for more information.

Because of these fluctuations, among other factors, it is possible that in future periods our operating results will fall below the expectations of securities analysts or investors, in which case the market price of our stock would likely decrease. These fluctuations,

among other factors, also mean that our operating results in any particular period may not be relied upon as an indication of future performance.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We do not expect to become profitable in the near future, may never achieve profitability, and have incurred substantial net operating losses ("NOLs") during our history. Unused NOLs will carry forward to offset a portion of future taxable income, if any, until such unused NOLs expire, if ever. Federal NOLs generated after December 31, 2017 are not subject to expiration, but the yearly utilization of such federal NOLs is limited to 80 percent of taxable income for taxable years beginning after December 31, 2020. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" (within the meaning of Section 382 of the Code) is subject to limitations on its ability to utilize its prechange NOLs or tax credits to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation's stock increases by more than 50 percentage points over the lowest percentage of the corporation's stock owned by such stockholders within a specified testing period.

We have experienced an ownership change within the meaning of Section 382 of the Code in the past, which has been accounted for in our deferred tax disclosure. We may experience additional ownership changes in the future as a result of shifts in our stock ownership (some of which shifts may be outside our control). While we do not expect any limitation would impact our ability to use our tax attributes before they expire, we may be unable to use a material portion of our NOLs and other tax attributes even if we attain profitability.

Risks relating to intellectual property and legal and regulatory matters

If we fail to comply with U.S. or foreign federal and state healthcare regulatory laws, we could be subject to penalties, including, but not limited to, administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs and the curtailment of our operations, any of which could adversely impact our reputation and business operations.

We operate in a complex regulatory environment with an extensive and evolving set of federal, state and local governmental laws, regulations, and other requirements. These laws, regulations and other requirements are promulgated and overseen by a number of different legislative, regulatory, administrative and quasi-regulatory bodies, each of which may have varying interpretations, judgments or related guidance. For example, broadly applicable fraud and abuse and other healthcare laws and regulations apply to our operations and business practices. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including our sales and marketing practices, consumer incentive and other promotional programs and other business practices.

Such laws include, without limitation:

- the U.S. federal civil and criminal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare, state Medicaid programs and TRICARE. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims laws, including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- state law equivalents of each of the above federal laws, including state anti-kickback, self-referral and false claims laws that apply more broadly to healthcare items or services paid by all payors, including self-pay patients and private insurers, that govern our interactions with consumers or restrict payments that may be made to healthcare providers and other potential referral sources;
- the Federal Trade Commission Act and federal and state consumer protection, advertisement and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), and similar regulations in other countries, which prohibit, among other things, companies and their employees and agents from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office and foreign political parties or officials thereof and require companies to keep books and records that accurately and fairly reflect the transactions of the company and to maintain an adequate system of internal accounting controls;
- foreign or U.S. analogous state laws and regulations, which may apply to our business practices, including but not limited to, state laws that require manufacturers to comply with the voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government; state laws and regulations that require manufacturers to file reports relating to pricing and marketing information or that require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and
- similar healthcare laws and regulations in the EU and other jurisdictions in which we may conduct activities in the future, including reporting requirements detailing interactions with and payments to healthcare providers.

Foreign laws and regulations in this regard may vary greatly from country to country. For example, the advertising and promotion of our products in the European Economic Area (the "EEA") would be subject to EEA Directives concerning misleading and comparative advertising and unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. We are also subject to healthcare fraud and abuse regulation and enforcement by the countries in which we conduct our business. These healthcare laws and regulations vary significantly from country to country.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. We utilize considerable resources on an ongoing basis to monitor, assess and respond to applicable legislative, regulatory, and administrative requirements, but there is no guarantee that we will be successful in our efforts to adhere to all of these requirements. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as state Medicaid programs, TRICARE or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Our hearing aids are subject to extensive government regulation at the federal and state level, and our failure to comply with applicable requirements could harm our business.

Our hearing aids are medical devices that are subject to extensive regulation in the United States, including by the FDA and state agencies. The FDA regulates, among other things, the design, development, research, manufacture, testing, labeling, marketing, promotion, advertising, sale, import and export of hearing aid devices, such as those we market. Applicable medical device regulations are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry out or expand our operations.

The FDA classifies medical devices into one of three classes (Class I, II, or III) based on the degree of risk associated with a device and the level of regulatory control deemed necessary to ensure its safety and effectiveness. Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's general controls for medical devices, which include compliance with the FDA's current good manufacturing practices for devices, as reflected in the Quality System Regulation ("QSR"), establishment registration and device listing, reporting of adverse events, and truthful, non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the premarket notification process set forth in Section 510(k) of the Federal Food, Drug and Cosmetic Act ("FDCA").

The FDA has classified air-conduction and wireless air-conduction hearing aids, such as those we market, as Class I and Class II devices, respectively, which are exempt from premarket review procedures; although we comply with applicable Class I and Class II medical device requirements, none of our devices have been reviewed by the FDA. Moreover, because the FDA has stated that it does not intend to enforce the medical evaluation requirements for dispensation of Class I or Class II air-conduction hearing aids to individuals 18 years of age and older, our devices are available directly to consumers without the medical evaluation of a licensed practitioner. If our current or future products become subject to the pending OTC hearing aid framework, are deemed to be Class II "self-fitting air-conduction hearing aids," or are otherwise required to undergo premarket review, for example, to come into compliance with the OTC Final Rule, we may be required to first receive clearance under Section 510(k) of the FDCA or approval of a premarket approval ("PMA") application from the FDA. If this were to occur for our currently marketed devices, the FDA could require us to remove our products from the market until we receive applicable regulatory clearance or approval, which would significantly impact our business.

In the 510(k) clearance process, before a device may be marketed, the FDA must determine that the proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (a "pre-amendments" device), a device that was originally on the U.S. market pursuant to an approved PMA application and later down-classified, or a legally marketed 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics that do not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for Class III devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from 3 to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, we cannot assure you that any particular device will be approved or cleared by the FDA.

Any delay or failure to obtain necessary regulatory clearances or approvals if required in the future could harm our business.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- inability to demonstrate to the FDA's satisfaction that the product or modification is substantially equivalent to the proposed predicate device or safe and effective for its intended use, as applicable;
- the data from pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities do not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay our ability to introduce new products or modify our current products on a timely basis. For example, in November 2018, FDA officials announced forthcoming steps that the agency intends to take to modernize the 510(k) premarket notification pathway, and in September 2019, the FDA finalized guidance to describe an optional "safety and performance based" premarket review pathway for manufacturers of certain "well-understood device types," which would allow manufacturers to demonstrate substantial equivalence by meeting objective safety and performance criteria established by the FDA, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. As another example, in the FDA's OTC Proposed Rule, the FDA states they are "undertaking other separate efforts to minimize regulatory burdens for manufacturers by proposing the harmonization of part 820 with an international consensus standard." If we are required to seek premarket review of our devices in the future or if the FDA proposes modifications to quality system requirements, these proposals and reforms could impose additional regulatory requirements on us and increase the costs of compliance.

We operate in a regulated industry and changes in the regulations or the implementation of existing regulations could affect our operations and prospects for future growth globally.

Our products and our business activities are subject to rigorous regulation in any jurisdictions in which we operate, now or in the future. In particular, these laws generally govern: (i) coverage and reimbursement by the national health services or by private health insurance services for the purchase of hearing aids; (ii) the supply of hearing aids to the public and, more specifically, the training and qualifications required to practice the profession of hearing aid fitting specialist; and (iii) the development, testing, manufacturing, labeling, premarket clearance or approval and marketing, advertising, promotion, export and import of our hearing aids. Accordingly, our business may be affected by changes in any such laws and regulations and, in particular, by changes to the conditions for coverage, the way in which reimbursement is calculated, the ability to obtain national health insurance coverage or the role of the ear, nose and throat specialists.

While the FDA is the primary regulatory body affecting our business, which is currently based in the United States, there are numerous other regulatory schemes at the international, national and sub-national levels to which we are subject and, to the extent we expand internationally, we could become subject to international agencies and regulatory bodies such as the various agencies that enforce the European Union ("EU") Medical Device Directive, the Japanese Ministry of Health, Labor and Welfare, and sub-national regulatory schemes in such jurisdictions. These regulations can be burdensome and subject to change on short notice, exposing us to the risk of increased costs and business disruption, and regulatory premarket clearance or approval requirements may affect or delay our ability to market our new products. We cannot guarantee that we will be able to obtain marketing clearance or approval for our new products, or enhancements or modifications to existing products. If we do, such clearance or approval may take a significant amount of time and require the expenditure of substantial resources. Further, such clearance or approval may involve stringent testing procedures, modifications, repairs or replacements of our products and could result in limitations on the proposed uses of our products. Regulatory authorities and legislators have been recently increasing their scrutiny of the healthcare industry, and there are ongoing regulatory efforts to reduce healthcare costs that may intensify in the future. Our business is also sensitive to any changes in tort and product liability laws.

Regulations pertaining to our products have become increasingly stringent and more common, particularly in developing countries whose regulations approach standards previously attained only by some Organisation for Economic Co-operation and Development countries, and we may become subject to more rigorous regulation by governmental authorities in the future. Conversely, however, the regulation of hearing aids as medical devices provides a barrier to entry for new competitors. For example, if certain of our products were made subject to less stringent regulation by the FDA in the United States, for example, in connection with the FDA's promulgation of a regulatory framework for OTC hearing aids, then products similar to ours may be marketed and sold more freely, and our products may become commoditized. If the markets in which we operate become less regulated, those barriers to entry may be eliminated or reduced, which could have a material adverse effect on our business, financial condition and results of operations.

Both before and after a product is commercially released, we have ongoing responsibilities under various laws and regulations. If a regulatory authority were to conclude that we are not in compliance with applicable laws or regulations, or that any of our hearing aids are ineffective or pose an unreasonable risk for the end-user, the authority may ban such hearing aids, detain or seize adulterated or misbranded hearing aids, order a recall, repair, replacement or refund of such instruments, and require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. A regulatory authority may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal penalties against our officers, employees or us. The regulatory authority may also recommend prosecution by law enforcement agencies. Any governmental law or regulation, existing or imposed in the future, or enforcement action taken may have a material adverse effect on our business, financial condition and results of operations. Please also see the Risk Factor titled, "Changes in the regulatory landscape for hearing aid devices could render our direct-to-consumer business model contrary to applicable regulatory requirements, and we may be required to seek additional clearance or approval for our products."

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise delay or prevent necessary regulatory clearances or approvals, which could negatively impact our business.

The ability of the FDA to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new medical devices or modifications to be cleared or approved by government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system, which it utilized to assist in determining when and where it was safest to conduct prioritized domestic inspections. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Legislative or regulatory healthcare reforms may make it more difficult and costly to produce, market and distribute our products or to do so profitably.

Recent political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare, improve quality of care and expand access to healthcare, among other purposes. For example, the implementation of the Affordable Care Act has changed healthcare financing and delivery by both governmental and private insurers substantially and has affected medical device manufacturers significantly. Other legislative changes have also been proposed and adopted since the Affordable Care Act was enacted, which included, among other things, reductions to Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional action is taken by Congress. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, further reduced Medicare payments to certain providers, including hospitals. The Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments which began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. Future legislation and regulatory changes, including, for example, the pending OTC regulatory framework, may result in, directly or indirectly, decreased coverage and reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged and market demand for medical devices. This could harm our ability to market and generate sales from our products.

Our hearing aids may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our hearing aids may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the initial use of the hearing aid device. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, seizure of our products or, if premarket review is required in the future, delay in clearance of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized medical device products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. We cannot assure you that product defects or other errors will not occur in the future. Recalls involving our hearing aids could have a material adverse effect on our business, financial condition and results of operations.

Medical device manufacturers are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our hearing aid devices in the future that we determine do not require

notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales.

We must manufacture our products in accordance with federal and state regulations, and we could be forced to recall our products or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of our hearing aid devices must comply with the FDA's QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors, and such inspections can result in warning letters, untitled letters and other regulatory communications and adverse publicity. Our hearing aid devices are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

We cannot guarantee that we or any subcontractors will take the necessary steps to comply with applicable regulations, which could cause delays in the manufacture and delivery of our products. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things:

- fines, injunctions or civil penalties;
- suspension or withdrawal of future clearances or approvals;
- refusal to clear or approve pending applications;
- seizures or recalls of our products;
- total or partial suspension of production or distribution;
- administrative or judicially imposed sanctions;
- refusal to permit the import or export of our products; and
- criminal prosecution.

Any of these actions could significantly and negatively impact supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and suffer reduced revenue and increased costs.

We are subject to numerous state and local hearing aid and licensure laws and regulations as well as state laws regulating the corporate practice of audiology or fee splitting, and non-compliance with these laws and regulations may expose us to significant costs or liabilities and negatively impact our business, financial condition and ability to operate in those states.

We are subject to numerous state and local hearing aid laws and regulations relating to, among other matters, licensure and registration of audiologists and other individuals we employ or contract with to provide services and dispense hearing aids. Many states also have laws that regulate the corporate practice of audiology, including exercising control, interfering with or influencing an audiologist or other hearing care specialist's professional judgment and entering into certain financial arrangements, such as splitting professional fees with audiologists. Other state and local laws and regulations require us to maintain warranty and return policies for consumers allowing for the return of product and restrict advertising and marketing practices. These state and local laws and regulations are complex, change frequently and have tended to become more stringent over time; additionally, these laws and their interpretations vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion.

The FDCA preempts state laws relating to the safety and efficacy of medical devices and state laws that are different from or in addition to federal requirements; some state laws relating to licensure, business registration, or administrative requirements may not be considered to be related to the safety and efficacy of medical devices and therefore may not be preempted. In Missouri Board of Examiners for Hearing Instrument Specialists v. Hearing Help Express, Inc. and METX, LLC v. Wal-Mart Stores Texas, LLC, the Eighth Circuit Court of Appeals and the U.S. District Court for the Eastern District of Texas, respectively, have held that certain state laws relating to the fitting and dispensing of hearing aids are preempted because they relate to the safety and efficacy of medical devices. Interpretative legal precedent and regulatory guidance vary by jurisdiction and are often sparse and not fully developed, including which laws and regulations are preempted, complicating our compliance efforts. Accordingly, we cannot be certain that our interpretation of laws and regulations applicable to our operations is correct, and regulatory authorities or other third parties may challenge our existing organization. If such a claim were successful, we could be subject to adverse judicial or administrative interpretations and to civil or criminal penalties. Our ability to operate profitably will depend, in part, on our ability to obtain and maintain any necessary licenses and other approvals and operate in compliance with applicable state laws and regulations. A determination that we are in violation of applicable laws and regulations in any jurisdiction in which we operate could have a material

adverse effect on us, particularly if we are unable to restructure our operations and arrangements to comply with the requirements of that jurisdiction, if we are required to restructure our operations and arrangements, including those with our audiologists and other licensed professionals, at a significant cost, or if we are subject to penalties or other adverse action.

Additionally, applicable federal laws and regulations continue to evolve. For example, the FDARA set forth a process to create a category of OTC hearing aids that are intended to be available without supervision, prescription, or other order, involvement or intervention of a licensed practitioner. The FDA is currently engaged in a rulemaking process to publish a final regulation regarding OTC hearing aids. Under FDARA, the OTC hearing aid controls that are the subject of the rulemaking, if finalized, would preempt any state or local requirement specifically related to hearing products that would restrict or interfere with commercial activity involving OTC hearing aids. Additionally, the Biden Executive Order July 9, 2021 instructed the FTC to review overly restrictive occupational licensing requirements that may impede the ability for licensed individuals to move between states. We cannot predict the impact on our business of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits. See the Risk Factor titled, "Changes in the regulatory landscape for hearing aid devices could render our direct-to-consumer business model contrary to applicable regulatory requirements, and we may be required to seek additional clearance or approval for our products."

We may face risks related to any future international sales, including the need to obtain necessary foreign regulatory clearance or approvals.

Sales of our products outside the United States will subject us to foreign regulatory requirements that vary widely from country to country. The time required to obtain clearances or approvals required by other countries may be longer than that required for FDA clearance or approval, and requirements for such approvals may differ from FDA requirements. We may be unable to obtain regulatory approvals and may also incur significant costs in attempting to obtain foreign regulatory approvals. If we experience delays in receipt of approvals to market our products in new jurisdictions, or if we fail to receive these approvals, we may be unable to market our products in international markets in a timely manner, if at all, which could materially impact our international expansion and adversely affect our business as a whole. Some international regulations may also limit the availability of our hearing aids to customers in certain jurisdictions without our first obtaining a license or engaging a third party to provide such financing, or limit the financing options we can offer our customers. If any of these risks were to materialize, they could limit our expected international expansion opportunities, which could have a material adverse effect on our business, financial condition and results of operations.

Regulations in certain foreign countries may challenge our direct-to-consumer sales model.

Our business may also be affected by actions of domestic and foreign governments to restrict the activities of direct-to-consumer companies for various reasons, including a limitation on the ability of direct-to-consumer companies to operate without the involvement of a traditional retail channel. To the extent that we begin to offer our products in international markets, foreign governments may also introduce other forms of protectionist legislation, such as limitations or requirements on where the products can or must be produced or requirements that non-domestic companies doing or seeking to do business place a certain percentage of ownership of legal entities in the hands of local nationals to protect the commercial interests of its citizens. Customs laws, tariffs, import duties, export and import quotas and restrictions on repatriation of foreign earnings and/or other methods of accessing cash generated internationally, may negatively affect our local or corporate operations. Additionally, the U.S. government may impose restrictions on our ability to engage in business in other countries in connection with the foreign policy of the United States. Any such restrictions on our direct-to-consumer sales model in international jurisdictions could limit our ability to grow internationally, which could have a material adverse effect on our business, financial condition and results of operations.

Our success depends in part on our proprietary technology, and if we are unable to obtain, maintain or successfully enforce our intellectual property rights, the commercial value of our products and services will be adversely affected and our competitive position may be harmed.

Our success and ability to compete depend in part on our ability to maintain and enforce existing intellectual property and to obtain, maintain and enforce further intellectual property protection for our products and services, both in the United States and in other countries. We attempt to protect our intellectual property rights through a combination of patent, trademark, copyright and trade secret laws, as well as licensing agreements and third-party confidentiality and assignment agreements. Our inability to do so could harm our competitive position. As of March 31, 2022, we had 23 issued U.S. patents, 22 patents outside the United States, 7 pending U.S. patent applications and 9 pending foreign patent applications.

We rely on our portfolio of issued and pending patent applications in the United States and other countries to protect our intellectual property and our competitive position. However, the patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Accordingly, we cannot provide any assurances that any of our issued patents have, or that any of our currently pending or future patent applications that mature into issued patents will include, claims with a scope sufficient to protect our products and services. Our pending and future patent applications may not result in the issuance of patents or, if issued, may not issue in a form that will be advantageous to us. While we generally apply for patents in those countries where we intend to make, have made, use or sell patented products, we may not accurately predict all of the countries where patent protection will

ultimately be desirable. If we fail to timely file for a patent, we may be precluded from doing so at a later date. Additionally, any patents issued to us may be challenged, narrowed, invalidated, held unenforceable or circumvented, or may not be sufficiently broad to prevent third parties from producing competing products similar in design to our products.

Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection, which in turn could diminish the commercial value of our products and services. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patent and intellectual property laws. There can be no assurance that any of our patents, any patents licensed to us or any patents which we may be issued in the future will provide us with a competitive advantage or afford us protection against infringement by others, or that the patents will not be successfully challenged or circumvented by third parties, including our competitors. Further, there can be no assurance that we will have adequate resources to enforce our patents.

In addition, from time to time we engage international consultants, contractors and other specialists to assist in our research and development activities. Certain of these third parties may operate in jurisdictions where it is difficult or impossible for us to assert our intellectual property rights in case of infringement or theft, either as a statutory or practical matter. We have engaged in, and may in the future engage in, various contractual relationships with third parties outside the United States in connection with the development of our products, which may expose our technology and intellectual property to a heightened risk of unauthorized use or theft.

Any of the foregoing risks, individually or in the aggregate, could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be harmed.

We rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. There can be no assurance that our trademark applications will be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, there can be no assurance that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. We also license third parties to use our trademarks. In an effort to preserve our trademark rights, we enter into license agreements with these third parties, which govern the use of our trademarks and require our licensees to abide by quality control standards with respect to the goods and services that they provide under our trademarks. Although we make efforts to monitor the use of our trademarks by our licensees, there can be no assurance that these efforts will be sufficient to ensure that our licensees abide by the terms of their licenses. In the event that our licensees fail to do so, our trademark rights could be diluted. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful.

Third parties, including our competitors, could be infringing, misappropriating or otherwise violating our intellectual property rights. While we are not aware of any unauthorized use of our intellectual property, we do not regularly conduct monitoring for unauthorized use at this time. In the future, we may from time to time, seek to analyze our competitors' products and services, or seek to enforce our rights against potential infringement, misappropriation or violation of our intellectual property. However, the steps we have taken to protect our proprietary rights may not be adequate to enforce our rights as against such infringement, misappropriation or violation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully enforce our intellectual property rights could harm our ability to compete and reduce demand for our products and services.

We may in the future become involved in lawsuits to protect or enforce our intellectual property rights. An adverse result in any litigation proceeding could harm our business. In any lawsuit we bring to enforce our intellectual property rights, a court may refuse to stop the other party from using the technology at issue on grounds that our intellectual property rights do not cover the technology in question. If we initiate legal proceedings against a third party to enforce a patent covering a product, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office ("USPTO") or made a misleading statement, during prosecution. Mechanisms for such challenges include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our products, or any future products that we may develop.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearing, motions, or other interim developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Even if we ultimately prevail, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Furthermore, the monetary cost of such litigation and the diversion of the attention of our management could outweigh any benefit we receive as a result of the proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business.

If we infringe, misappropriate or otherwise violate the intellectual property rights of third parties or are subject to an intellectual property infringement or misappropriation claim, our ability to grow our business may be severely limited and our business could be adversely affected.

We may in the future be the subject of patent or other litigation. Our products and services may infringe, or third parties may claim that they infringe, intellectual property rights covered by patents or patent applications under which we do not hold licenses or other rights. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successfully asserted against us, could cause us to pay substantial damages. Further, if a patent infringement or other intellectual property-related lawsuit were brought against us, we could be forced to stop or delay production or sales of the product that is the subject of the suit. From time to time, we have received and may in the future receive letters from third parties drawing our attention to their patent rights. While we take steps to ensure that we do not infringe upon, misappropriate or otherwise violate the rights of others, there may be other more pertinent rights of which we are presently unaware. The defense and prosecution of intellectual property lawsuits could result in substantial expense to us and significant diversion of effort by our technical and management personnel. An adverse determination of any litigation or interference proceeding to which we may become a party could subject us to significant liabilities. As a result of patent infringement claims, or in order to avoid potential claims, we may choose or be required to seek a license from the third party and be required to pay significant license fees, royalties or both. Licenses may not be available on commercially reasonable terms, or at all, in which event our business would be materially and adversely affected. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, if we are unable to obtain such licenses, we could be forced to cease some aspect of our business operations, which could harm our business significantly.

Changes in U.S. patent laws may limit our ability to obtain, defend and/or enforce our patents.

Any patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") included a number of significant changes to U.S. patent law. These include provisions that affected the way patent applications are prosecuted and also affect patent litigation. The USPTO developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, which became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business.

However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the Leahy-Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board ("PTAB") provides a venue for challenging the validity of patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long-term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them.

We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.

Many of our employees and consultants were previously employed at or engaged by other medical device companies, including our competitors or potential competitors. Some of these employees, consultants and contractors may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our

employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers, competitors or other third parties. Additionally, we may be subject to claims from third parties challenging our ownership interest in or inventorship of intellectual property we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages or a settlement payment, a court could prohibit us from using technologies, features or other intellectual property that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies, features or other intellectual property that are important or essential to our products could have a material adverse effect on our business and competitive position, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

If we are unable to continue to drive consumers to our website, it could cause our revenue to decrease.

Many consumers find our website by searching for hearing aid information through internet search engines or from word-of-mouth and personal recommendations. A critical factor in attracting visitors to our website is how prominently we are displayed in response to search queries. Accordingly, we use search engine marketing as a means to provide a significant portion of our customer acquisition. Search engine marketing includes both paid website visitor acquisition on a cost-per-click basis and visitor acquisition on an unpaid basis, often referred to as organic or algorithmic search.

One method we employ to acquire visitors via organic search is commonly known as search engine optimization ("SEO"). SEO involves developing our website in a way that enables the website to rank high for search queries for which our website's content may be relevant. We also rely heavily on favorable recommendations from our existing customers to help drive traffic to our website. If our website is listed less prominently or fails to appear in search result listings for any reason, it is likely that we will attract fewer visitors to our website, which could adversely affect our revenue.

Risks relating to our common stock

If we fail to meet continued listing standards of the Nasdaq Stock Market LLC, our common stock may be delisted, which would have a material adverse effect on the price of our common stock.

Our common stock is currently traded on the Nasdaq under the symbol "EAR." In order for our securities to be eligible for continued listing on Nasdaq, we must remain in compliance with certain Nasdaq continued listing standards. We were notified by Nasdaq on November 18, 2021 that we were not in compliance with Nasdaq Listing Rule 5250(c)(1) for continued listing as a result of the delay in filing our Form 10-Q for the period ended September 30, 2021 (our "Q3 2021 10-Q") with the SEC. In accordance with Nasdaq Listing Rules, we submitted a plan to regain compliance. Nasdaq granted us an exception of up to 180 days from our Q3 2021 10-Q's original filing due date, or until May 16, 2022, to regain compliance. On March 2, 2022, we filed a Form 12b-25 notifying the SEC that we would be unable to timely file our annual report on Form 10-K for the year ended December 31, 2021 (our "2021 10-K"). On March 4, 2022, we were notified again by Nasdaq that we were not in compliance with Nasdaq Listing Rule 5250(c)(1) for continued listing as a result of the delay in filing the 2021 10-K. As a result, we submitted to Nasdaq an update to our original plan to regain compliance. Nasdaq's notification dated March 4, 2022 indicated that any exception to allow us to regain compliance with all untimely filings would be limited to a maximum of 180 calendar days from the due date of our Q3 2021 10-Q, or May 16, 2022.

On May 11, 2022, we filed a Form 12b-25 notifying the SEC that we would be unable to timely file our Quarterly Report on Form 10-Q for the three months ended March 31, 2022 (our "Q1 2022 10-Q"). On May 12, 2022, we received a letter from Nasdaq notifying us that because we remained delinquent in filing our Q3 2021 10-Q and 2021 10-K, and, in addition, because we were delinquent in filing our Q1 2022 10-Q, we had not regained compliance and would not meet the terms of the exception. The letter indicated that our securities would be subject to delisting on May 23, 2022 as a result of our non-compliance, unless on or before May 19, 2022 we requested a hearing before the Nasdaq Hearings Panel and requested an extended stay of suspension or delisting. We timely requested a hearing and further stay.

On May 13, 2022, we filed our Q3 2021 10-Q and our 2021 10-Q.

On May 19, 2022, we received a letter from Nasdaq scheduling a hearing for June 16, 2022, and noting that any suspension of delisting of our securities was stayed until June 3, 2022. The stay could be further extended at the option of the Nasdaq Hearings Panel, and we have asked the Nasdaq Hearings Panel for a further stay. On May 20, 2022, we received a letter from Nasdaq

confirming that the Nasdaq Listing Qualifications Staff has determined that due to filing our Q3 2021 10-Q and our 2021 10-K on May 13, 2022, we now comply with Nasdaq Listing Rule 5250(c)(1) for those filings. However, we will still be required to address our delinquent Q1 2022 10-Q filing at the hearing on June 16, 2022, unless Nasdaq determines that through our filing of this Q1 2022 10-Q we have regained compliance with all criteria for continued listing and determines to cancel the hearing.

If Nasdaq should delist our common stock for any reason and we are unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially and adversely affect our stockholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to raise additional capital;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

We have identified material weaknesses in our internal control over financial reporting and entity level controls. If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

In connection with the preparation of our financial statements at the time of our IPO and through the financial reporting period ended December 31, 2021, we identified material weaknesses in our internal control over financial reporting and our entity level controls. A material weakness is a deficiency, or combination of deficiencies, in internal controls such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

With respect to the material weakness related to internal control over financial reporting, we have implemented and are in the process of implementing additional measures designed to improve our internal control over financial reporting to remediate this material weakness, including the hiring of additional qualified supervisory resources, the engagement of additional technical accounting consulting resources and plans to hire additional finance department employees.

With respect to the material weakness related to entity level controls related to a lack of sufficient qualified healthcare industry compliance and risk management resources, including those necessary to provide appropriate oversight, monitor compliance, and to identify and mitigate risks with respect to the financial reporting and disclosures of our operations, we intend to enhance our compliance and risk management processes with respect to our operations in the healthcare industry to remediate this material weakness, including the hiring of additional qualified personnel, and the engagement of additional specialized consulting resources.

We cannot assure you that the measures we intend to take will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. While we believe that our efforts will enhance our internal control, remediation of the material weaknesses will require further validation and testing of the design and operating effectiveness of internal controls over a sustained period of financial reporting cycles, and we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or products.

Since our inception, our operations have been financed primarily by net proceeds from the sale of our convertible preferred stock and common stock, indebtedness and revenue from the sales of our products. We anticipate our future capital requirements will be substantial and that we will need to raise significant additional capital to fund our operations through equity or debt financing, or some combination thereof. We are currently exploring fundraising opportunities to meet these capital requirements. If we are unable to raise additional funding to meet our operational needs, we will be forced to limit or cease our operations.

In addition to our current capital needs, we regularly consider fundraising opportunities and may decide, from time to time, to raise capital based on various factors, including market conditions and our plans of operation. We may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings. Additional capital may not be available to us on acceptable terms on a timely basis, or at all. If adequate funds are not available, or if the terms of potential funding sources are unfavorable, our business and our ability to develop our technology and our products would be harmed. If we raise additional funds by issuing equity securities, our stockholders may suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility

in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities receive any distribution of our corporate assets. We also could be required to seek funds through arrangements with partners or others that may require us to relinquish rights or jointly own some aspects of our technologies or products that we would otherwise pursue on our own.

If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decline.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. In addition, we are required to furnish a report by management on the effectiveness of our internal control over financial reporting, pursuant to Section 404 of the Sarbanes-Oxley Act. The process of designing, implementing and testing the internal control over financial reporting required to comply with this obligation is time-consuming, costly and complicated. If we fail to remediate identified material weaknesses or identity additional material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline, and we could also become subject to investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities, which could require additional financial and management resources.

As of December 31, 2021, we no longer qualify as an "emerging growth company," and as a result, we are required to comply with increased disclosure and compliance requirements.

As of December 31, 2021, based on the market value of our common stock on the relevant measurement date exceeding $700 million, we no longer qualify as an emerging growth company and instead are deemed a "large accelerated filer" within the meaning of applicable SEC rules.

As a large accelerated filer, we are now subject to certain disclosure and compliance requirements that apply to other public companies but did not previously apply to us due to our status as an emerging growth company. We expect that the loss of emerging growth company status and compliance with the additional requirements of being a large accelerated filer will increase our legal and financial compliance costs and cause management and other personnel to divert attention from operational and other business matters to devote substantial time to public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities, which would require additional financial and management resources.

We incur significantly increased costs and are subject to additional regulations and requirements as a result of becoming a public company, which could lower our profits or make it more difficult to run our business.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred and will continue to incur costs associated with the Sarbanes-Oxley Act, and related rules implemented by the SEC and the exchange our securities are listed on. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations also could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action and potentially civil litigation.

If our operating and financial performance in any given period does not meet any guidance that we provide to the public, the market price of our common stock may decline.

Any public guidance we provided regarding our expected operating and financial results for future periods is comprised of forward-looking statements subject to the risks and uncertainties described in this Quarterly Report on Form 10-Q and in our other public filings and public statements. Our actual results may not always be in line with or exceed any guidance we provide, especially in times of economic uncertainty. If our operating or financial results for a particular period do not meet any guidance we provide or the expectations of investment analysts, or if we reduce our guidance for future periods, the market price of our common stock may decline. In September 2021, we withdrew our financial guidance for the fiscal year ended December 31, 2021 as a result of uncertainties arising with respect to the DOJ investigation and claims audits (see "Management's Discussion and Analysis of Financial Condition and Results of Operations—DOJ investigation and settlement and claims audits" for more information). While we have since provided some limited financial guidance, we cannot be certain if or when we will resume providing more fulsome financial guidance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of March 31, 2022, based on public filings, our current executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates held approximately 36.7% of our outstanding voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. Depending on the involvement and action of other stockholders, these principal stockholders and management may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

We have no current plans to pay cash dividends on our common stock; as a result, you may not receive any return on investment unless you sell your common stock for a price greater than that which you paid for it.

We have never declared or paid cash dividends on our common stock, and we do not currently intend to pay any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination related to dividend policy will be made at the discretion of our board of directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. Also, unless waived, the terms of our 2018 Loan with Silicon Valley Bank generally prohibit us from declaring or paying any cash dividends and other distributions. Additionally, our ability to pay cash dividends on our common stock may be limited by the terms of any future debt or preferred securities we issue or any future credit facilities we enter into. As a result, you may not receive any return on an investment in our common stock unless you sell your common stock for a price greater than that which you paid for it.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. We had a total of 39,344,518 shares of common stock outstanding as of March 31, 2022.

The holders of approximately 8.7 million shares of our common stock, or approximately 22% of our total outstanding common stock as of March 31, 2022, are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions include:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66⅔% of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or to repeal certain provisions of our amended and restated certificate of incorporation;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by our board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Claims for indemnification by our directors, officers and other employees or agents may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors, officers and certain other employees provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, this choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds

favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

If securities analysts publish negative evaluations of our stock or stop publishing research or reports about our business, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We currently have research coverage by several financial analysts. If one or more of these analysts should drop research coverage of us or if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. For example, certain of our analysts downgraded our common stock following our announcement of the DOJ investigation and claims audits (see "Management's Discussion and Analysis of Financial Condition and Results of Operations— DOJ investigation and settlement and claims audits"), which may have contributed to a significant decline in the price of our common stock. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

General risk factors

Engaging in acquisitions or strategic partnerships may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

As part of our business strategy, we may acquire companies or businesses, enter into strategic partnerships and joint ventures and make investments to further our business. Risks associated with these transactions include the following, any of which could adversely affect our revenue, gross margin, profitability, cash flows and financial condition:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals;
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and
- causing us to become subject to additional laws and regulations.

In addition, in connection with these acquisitions or strategic partnerships, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition or partnership opportunities, and even if we do locate such opportunities we may not be able to successfully bid for or obtain them due to competitive factors or lack of sufficient resources. This inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Our effective tax rate may vary significantly from period to period.

Various internal and external factors may have favorable or unfavorable effects on our future effective tax rate. These factors include, but are not limited to, changes in tax laws both within and outside the United States, regulations and/or rates, structural changes in our business, new or changes to accounting pronouncements, non-deductible goodwill impairments, changing interpretations of existing tax laws or regulations, changes in the relative proportions of revenue and income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates, the future levels of tax benefits of equity-based compensation, changes in overall levels of pretax earnings or changes in the valuation of our deferred tax assets and liabilities. Additionally, we could be challenged by state

and local tax authorities as to the propriety of our sales tax compliance, and our results could be materially impacted by these compliance determinations.

In addition, our effective tax rate may vary significantly depending on our stock price. The tax effects of the accounting for share-based compensation may significantly impact our effective tax rate from period to period. In periods in which our stock price is higher than the grant price of the share-based compensation vesting in that period, we will recognize excess tax benefits that will decrease our effective tax rate. In future periods in which our stock price is lower than the grant price of the share-based compensation vesting in that period, our effective tax rate may increase. The amount and value of share-based compensation issued relative to our earnings in a particular period will also affect the magnitude of the impact of share-based compensation on our effective tax rate. These tax effects are dependent on our stock price, which we do not control, and a decline in our stock price could significantly increase our effective tax rate and adversely affect our financial results.

If we fail to execute invention assignment agreements with our employees and contractors involved in the development of intellectual property or are unable to protect the confidentiality of our trade secrets, the value of our products and our business and competitive position could be harmed.

In addition to patent protection, we also rely on protection of copyright, trade secrets, know-how and confidential and proprietary information. We generally enter into confidentiality and invention assignment agreements with our employees, consultants and third parties upon their commencement of a relationship with us. However, we may not enter into such agreements with all employees, consultants and third parties who have been involved in the development of our intellectual property. In addition, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist if unauthorized use or disclosure were to occur. The exposure of our trade secrets and other proprietary information would impair our competitive advantages and could have a material adverse effect on our business, financial condition and results of operations. In particular, a failure to protect our proprietary rights may allow competitors to copy our technology, which could adversely affect our pricing and market share. Further, other parties may independently develop substantially equivalent know-how and technology.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. We also have agreements with our employees, consultants and third parties that obligate them to assign their inventions to us; however, these agreements may not be self-executing, not all employees or consultants may enter into such agreements, or employees or consultants may breach or violate the terms of these agreements, and we may not have adequate remedies for any such breach or violation. If any of our intellectual property or confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, it could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

We may be unable to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

Actual or perceived failures to comply with applicable data privacy and security laws, regulations, policies, standards, contractual obligations and other requirements related to data privacy and security and changes to such laws, regulations, standards, policies and contractual obligations could adversely affect our business, financial condition and results of operations.

The global data protection landscape is rapidly evolving, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. We are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, transmission, use, disclosure, storage, retention and security of personal and personally-identifying information, such as information that we may collect in connection with conducting our business in the United States and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, fines, imprisonment of company officials and public censure, claims by third parties, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition and results of operations.

In the ordinary course of our business, we collect and store sensitive data, including protected health information ("PHI"), personally identifiable information ("PII"), intellectual property and proprietary business information owned or controlled by ourselves or our customers, third-party payors and other parties. We also collect and store sensitive data of our employees and contractors. We manage and maintain our applications and data utilizing cloud-based data centers for PII. We utilize external security and infrastructure vendors to manage parts of our data centers.

As our operations and business grow, we are and may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, HIPAA establishes, among other things, privacy and security standards that limit the use and disclosure of PHI, and imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of PHI by covered entities, such as health plans, healthcare clearinghouses and healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of PHI, and their covered subcontractors. HIPAA requires covered entities and their business associates to develop and maintain certain policies and procedures with respect to PHI that is used or disclosed. Further, in the event of a breach of unsecured protected health information, HIPAA requires covered entities to notify each individual whose PHI is breached as well as federal regulators and, in some cases, the media. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. If we are unable to properly protect the privacy and security of PHI, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable privacy and security standards, we could face civil and criminal penalties. The U.S. Department of Health and Human Services ("HHS"), has the discretion to impose penalties without attempting to resolve violations through informal means. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources, each of which could have a material adverse effect on our business financial condition, results of operations or prospects.

In addition, the California Consumer Privacy Act ("CCPA"), which took effect on January 1, 2020, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the CPRA recently passed in California, which will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Similar laws have passed in Virginia, Colorado and Utah, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. We may need to invest substantial resources in putting in place policies and procedures to comply with these evolving state laws.

In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

Data protection laws are evolving globally and may add additional compliance costs and legal risks to our operations. We are subject to the GDPR, which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. Further, as of January 1, 2021, impacted companies have to comply with the GDPR and the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. While we continue to address the implications of the recent changes to European data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. Accordingly, we must devote significant resources to understanding and complying with this changing landscape.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, negative publicity, loss of goodwill and materially adversely affect our business, financial condition and results of operations or prospects.

We are subject to a number of risks related to the credit card and debit card payments we accept.

We accept payments through credit and debit card transactions. For credit and debit card payments, we pay interchange and other fees, which may increase over time. An increase in those fees may require us to increase the prices we charge and would increase our operating expenses, either of which may adversely affect our business, financial condition and results of operations.

If we or our processing vendors fail to maintain adequate systems for the authorization and processing of credit and debit card transactions, it could cause one or more of the major credit card companies to disallow our continued use of their payment products. In addition, if these systems fail to work properly and, as a result, we do not charge our customers' credit or debit cards on a timely basis, or at all, it could adversely affect our business, financial condition and results of operations.

The payment methods that we offer also subject us to potential fraud and theft by criminals, who are becoming increasingly more sophisticated in exploiting weaknesses that may exist in the payment systems. If we fail to comply with applicable rules or requirements for the payment methods we accept, or if payment-related data is compromised due to a breach, we may be liable for significant costs incurred by payment card issuing banks and other third parties or subject to fines and higher transaction fees, or our ability to accept or facilitate certain types of payments may be impaired. In addition, our customers could lose confidence in certain payment types, which may result in a shift to other payment types or potential changes to our payment systems that may result in higher costs. If we fail to adequately control fraudulent credit card transactions, we may face civil liability, diminished public perception of our security measures and significantly higher card-related costs, each of which could have a material adverse effect on our business, financial condition and results of operations.

We are also subject to payment card association operating rules, certification requirements and rules governing electronic funds transfers, which could change or be reinterpreted to make it more difficult for us to comply. We are required to comply with payment card industry security standards. Failing to comply with those standards may violate payment card association operating rules, federal and state laws and regulations and the terms of our contracts with payment processors. Any failure to comply fully also may subject us to fines, penalties, damages and civil liability, and may result in the loss of our ability to accept credit and debit card payments. Further, there is no guarantee that such compliance will prevent illegal or improper use of our payment systems or the theft, loss or misuse of data pertaining to credit and debit cards, card holders and transactions.

If we are unable to maintain our chargeback rate or refund rates at acceptable levels, our processing vendor may increase our transaction fees or terminate its relationship with us. Any increases in our credit and debit card fees could harm our results of operations, particularly if we elect not to raise our rates for our products to offset the increase. The termination of our ability to process payments on any major credit or debit card would significantly impair our ability to operate our business.

Failure to comply with the U.S. Foreign Corrupt Practices Act, economic and trade sanctions regulations and similar laws could subject us to penalties and other adverse consequences.

We are subject to the FCPA and similar regulations in other countries, as well as other laws in the United States and elsewhere that prohibit improper payments or offers of payments to foreign governments and their officials and political parties for the purpose of obtaining or retaining business. Certain suppliers of our product components are located in countries known to experience corruption. Business activities in these countries create the risk of unauthorized payments or offers of payments by one of our employees, contractors or agents that could be in violation of various laws, including the FCPA and anti-bribery laws in these countries, even though these parties are not always subject to our control. While we have implemented policies and procedures designed to discourage these practices by our employees, consultants and agents and to identify and address potentially impermissible transactions under such laws and regulations, we cannot assure you that all of our employees, consultants and agents will not take actions in violation of our policies, for which we may be ultimately responsible.

We are also subject to certain economic and trade sanctions programs that are administered by the Department of Treasury's Office of Foreign Assets Control which prohibit or restrict transactions to or from or dealings with specified countries, their governments and in certain circumstances, their nationals, and with individuals and entities that are specially designated nationals of those countries, narcotics traffickers and terrorists or terrorist organizations.

Failure to comply with any of these laws and regulations or changes in this regulatory environment, including changing interpretations and the implementation of new or varying regulatory requirements by the government, may result in significant financial penalties or reputational harm, which could adversely affect our business, financial condition and results of operations.

Our information technology systems or those used by our third-party service providers, vendors, strategic partners or other contractors or consultants, may fail or suffer security breaches and other disruptions, which could result in a material disruption of our products and services development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business, financial condition and results of operations.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business, including our cloud-based infrastructure, mobile and web-based applications, our e-commerce platform and our enterprise software. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information of customers and our employees and contractors. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. We do not conduct audits or formal evaluations of our third-party vendors' information technology systems and cannot be sure that our third-party vendors have sufficient measures in place to ensure the security and integrity of their information technology systems and our confidential and proprietary information. If our third-party vendors fail to protect their information technology systems and our confidential and proprietary information, we may be vulnerable to disruptions in service and unauthorized access to our confidential or proprietary information and we could incur liability and reputational damage. Our internal information technology systems and those of our third-party service providers, vendors, strategic partners and other contractors or consultants are vulnerable to attack and damage or interruption from computer viruses and malware (e.g., ransomware), natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, malicious code, employee theft or misuse, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Russia's invasion of Ukraine or another war of international dispute may cause a general increase in the number and severity of such malicious incidents. The costs to us to investigate and mitigate network security problems, bugs, viruses, worms, malicious software programs, ransomware, and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems from system failure, accident and security breach, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, disruption of our development programs and our business operations, cessation of service, negative publicity and other harm to our business and our competitive position, whether due to a loss of our trade secrets or other proprietary information or other disruptions. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counterparties and data subjects could be material. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information. If such an event were to occur and cause interruptions in our operations, it could result in a

material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions.

If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of personal information, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to applicable privacy and security laws. For example, the Company retains data that is subject to HIPAA, which contain specific security and notification requirements to which we must adhere. Any security compromise affecting us, our service providers, vendors, strategic partners, other contractors, consultants, or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development and commercialization of our products and services could be delayed. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our business. Furthermore, federal, state and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, if our information technology security efforts fail. We would also be exposed to a risk of loss or litigation and potential liability, which could materially and adversely affect our business, financial condition and results of operations or prospects. Further, any losses, costs or liabilities may not be covered by, or may exceed the coverage limits of, any applicable insurance policies.

International trade disputes could result in tariffs and other protectionist measures that could have a material adverse effect on our business, financial condition and results of operations.

Tariffs could increase the cost of our products and the raw materials that go into making them. These increased costs could adversely impact the gross margin that we earn on our products. Tariffs could also make our products more expensive for customers, which could make our products less competitive and reduce consumer demand. Countries may also adopt other protectionist measures that could limit our ability to offer our products. Political uncertainty surrounding international trade disputes and protectionist measures (including as a result of the escalating conflict between Russia and Ukraine and the various sanctions and export controls being implemented by the international community against Russia) could also have a negative effect on consumer confidence and spending, which could have a material adverse effect on our business, financial condition and results of operations.

Disruptions in internet access could adversely affect our business, financial condition and results of operations.

As an online business, we are dependent on the internet and maintaining connectivity between ourselves and consumers and sources of internet traffic, such as Google. As consumers increasingly turn to mobile devices, we also become dependent on consumers' access to the internet through mobile carriers and their systems. Disruptions in internet access, whether generally, in a specific market or otherwise, especially if widespread or prolonged, could adversely affect our business, financial condition and results of operations. For example, the "denial-of-service" attack against Dyn in October 2016 resulted in a service outage for several major internet companies. It is possible that we could experience an interruption in our business, and we do not carry business interruption insurance sufficient to compensate us for all losses that may occur.

Changes in the regulation of the internet could adversely affect our business.

Laws, rules and regulations governing internet communications, advertising and e-commerce are dynamic, and the extent of future government regulation is uncertain. Federal and state regulations govern various aspects of our online business, including intellectual property ownership and infringement, trade secrets, the distribution of electronic communications, marketing and advertising, user privacy and data security, search engines and internet tracking technologies. Future taxation on the use of the internet or e-commerce transactions could also be imposed. Existing or future regulation or taxation could increase our operating expenses and expose us to significant liabilities. To the extent any such regulations require us to take actions that negatively impact us, they could have a material adverse effect on our business, financial condition and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sale of Unregistered Equity Securities

There were no unregistered sales of our equity securities during the three months ended March 31, 2022.

Use of Proceeds

On October 15, 2020, our registration statement on Form S-1, as amended (Registration No. 333-249075), for our IPO was declared effective by the SEC. There has been no material change in the intended use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on October 19, 2020.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits

Exhibit number	Exhibit description	Incorporated by reference		
		Form	Dated	Number
3.1	Amended and Restated Certificate of Incorporation	8-K	10/20/2020	3.1
3.2	Amended and Restated Bylaws	8-K	10/20/2020	3.2
10.1	Promotion Letter by and between Eargo, Inc. and Mark Thorpe.#	8-K	1/18/2022	10.1
10.2	Employment Agreement by and between Eargo, Inc. and Mark Thorpe.#	8-K	1/18/2022	10.2
10.3	Settlement Agreement.	8-K	5/2/2022	10.1
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.†			
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.†			
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.‡			
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.‡			
101.INS	Inline XBRL Instance Document†			
101.SCH	Inline XBRL Taxonomy Extension Schema Document†			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document†			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document†			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document†			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document†			
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)†			

† Filed herewith.

‡ Furnished herewith.

# Indicates management contract or compensatory plan.

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 thereunto duly authorized.

Eargo, Inc.

Date: May 24, 2022

By: /s/ Christian Gormsen

Christian Gormsen
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 24, 2022

By: /s/ Adam Laponis

Adam Laponis
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Christian Gormsen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eargo, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 24, 2022

By: /s/ Christian Gormsen

Christian Gormsen
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Adam Laponis, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eargo, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 24, 2022

By: /s/ Adam Laponis

Adam Laponis
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Eargo, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 24, 2022

By: /s/ Christian Gormsen
Christian Gormsen
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Eargo, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 24, 2022

By: /s/ Adam Laponis
Adam Laponis
Chief Financial Officer
(Principal Financial Officer)