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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

IN RE EARGO, INC. SECURITIES
LITIGATION

Case No. 21-cv-08597-CRB

**ORDER GRANTING MOTIONS TO
DISMISS**

This document relates to all consolidated cases.

This consolidated putative securities class action alleges violations of the Securities Act of 1933 (“Securities Act”) and the Securities Exchange Act of 1934 (“Exchange Act”). Lead Plaintiffs IBEW Local 353 Pension Plan and Xiaobin Cai, purchasers of Eargo, Inc.’s publicly traded stock, allege that the company and its executives, directors and IPO underwriters falsely or misleadingly inflated Eargo’s revenue and growth opportunities because the company’s business model was incompatible with the requirements for federal insurance reimbursement. Plaintiffs also claim that Eargo falsely or misleadingly downplayed an insurance audit, which eventually became the subject of a Department of Justice investigation for insurance fraud.

Pending before the Court are the Eargo Defendants and the IPO Underwriters’ motions to dismiss the amended consolidated class action complaint for failure to state a claim under Federal Rules of Civil Procedure 12(b)(6) and 9(b). As explained below, the Court grants the motions and dismisses the Complaint in its entirety.

1 **I. BACKGROUND**

2 **A. Factual Background¹**

3 **1. The Parties**

4 Defendant Eargo, Inc. was founded in San Jose, California in 2010. Compl. ¶ 2
5 (dkt. 59). It went public in October 2020. Id. ¶ 3. Eargo makes and directly sells air
6 conduction hearing aids to people with mild-to-moderate hearing loss. Id. ¶ 31. Eargo’s
7 president and chief executive officer is Christian Gormsen, and its chief financial officer is
8 Adam Laponis. Id. ¶¶ 27–28. Both corporate officers are named as defendants in this suit,
9 along with members of Eargo’s board of directors, id. ¶ 315, and its IPO underwriters—
10 J.P. Morgan Securities LLC, BofA Securities, Inc., Wells Fargo Securities, LLC, and
11 William Blair & Company, L.L.C., id. ¶ 320.

12 Lead Plaintiffs are IBEW Local 353 Pension Plan, a multi-employer defined benefit
13 pension plan, and Xiaobin Cai, an individual. Id. ¶¶ 24–25. Lead Plaintiffs purchased
14 shares of Eargo common stock and now allege that they purchased the shares at artificially
15 inflated prices and suffered damages because of Defendants’ alleged violations of federal
16 securities laws. Id. They purport to represent investors who purchased or otherwise
17 acquired the common stock of Eargo between November 20, 2020 and March 2, 2022
18 (“Class Period”).

19 **2. Eargo’s Business Model**

20 Eargo began selling its hearing aids in 2015. Id. ¶ 31. Eargo considers itself as a
21 “disruptor” in the hearing aid industry. Id. ¶ 32. The traditional hearing aid sales model
22 usually requires customers to make in-person visits to hearing aid professionals who
23 examine the customer, perform an audiogram, and prescribe certain hearing aids. Id. The
24 hearing aids are then tested on and fitted to the customer. Id. Eargo found this sales model

25 ¹ These facts are drawn primarily from the Consolidated Complaint. See Dkt. 59.
26 Defendants request that the Court take judicial notice of Eargo’s SEC filings and
27 transcripts from earning calls and investor conferences. Dkt. 77. Judicial notice of these
28 documents, which are heavily referenced in the Complaint, is proper under the incorporate-
by-reference doctrine. Khoja v. Orexigen Therapeutics, Inc., 899 F.3d 988, 999 (9th Cir.
2018). SEC filings “can be accurately and readily determined from sources whose
accuracy cannot reasonably be questioned.” See Fed. R. Evid. 201(b).

1 both archaic and inconvenient for customers because it unnecessarily separates the hearing
2 aid manufacturer from its customers and adds an incremental layer of cost. Id. ¶¶ 32, 34.
3 So Eargo developed a telecare business model that cuts out the middleman.

4 Under its telecare business model, Eargo has an in-house team of hearing aid
5 dispensers who are licensed in one or more states to advise customers on their hearing aid
6 needs. Id. ¶¶ 34, 37. Eargo believes that because it “sells its products online, rather than
7 in physical stores, a dispenser that’s licensed in one state can sell to customers in all of
8 them.” Id. According to Eargo, “potential customers are not required to have a hearing
9 test to order the Eargo hearing solution.” Id. ¶ 36. Eargo tells customers that there is “no
10 need to call an audiologist before calling or buying Eargo. Our team of pros here will
11 work closely with you to understand your hearing situation and determine if Eargo is right
12 for you.” Id. Eargo also provides customers with a “do-it-yourself” hearing test. Id.
13 Under its business model, Eargo touts that a customer could receive its hearing aid “as
14 little as 3 days,” compared to “weeks to months” under the traditional way. Id. ¶ 37.

15 **3. Eargo Accepts Insurance by Federal Carriers.**

16 Before 2017, Eargo had marketed and sold its products primarily to customers who
17 pay out-of-pocket. Id. ¶¶ 38, 65. Eargo then embarked on a new strategy to target
18 customers with a Federal Employees Health Benefits Program (“FEHBP”) insurance
19 benefit. Id. ¶ 17.

20 FEHBP is the largest employer-sponsored health insurance program in the world.
21 Id. ¶ 4. It provides health benefits through various insurance carriers, such as the Blue
22 Cross Blue Shield Federal Employee Plan (“BCBS FEP”). Id. FEHBP covers over eight
23 million former and current federal employees and their family. Id. Unlike most other
24 medical insurance plans, FEHBP offers hearing aid benefits. Id. BCBS FEP, for example,
25 offers a \$2,500 benefit for hearing aids. Id. Eargo priced its hearing aids to commensurate
26 with FEHBP benefits: Eargo’s top-end model costs around \$2,500. Id. ¶ 350.

27 To submit a claim for hearing aid reimbursement, FEHBP carriers require that the
28 claims include a hearing loss-related diagnosis code. Id. ¶ 350. These diagnosis codes

1 must be supported by a hearing loss diagnosis, which typically is based on a hearing test
2 performed by a health care provider. See id. ¶¶ 350–51. FEHBP insurance carriers often
3 condition claim reimbursements on a determination of “medical necessity.” Id. ¶ 352.
4 “Over-the-counter” hearing aids generally are “not covered.” See id. ¶ 353.

5 Eargo’s strategy of targeting the FEHBP insurance market initially was a success.
6 It allowed Eargo to expand its customer base beyond cash-pay customers. Id. ¶ 5. Eargo
7 also realized that customers with FEHBP benefits were less likely than cash-pay customers
8 to return the hearing aids because the insurer paid most or all the cost. Id. With these
9 insurance payments, in 2019, Eargo’s net revenue more than doubled: from \$32.7 million
10 at year-end 2019 to \$69.2 million in 2020. Id. And by the end of 2020, insurance
11 customers comprised approximately 45-percent of Eargo’s total customer base. Id.

12 **4. BCBS Audits Eargo.**

13 BCBS was Eargo’s largest third-party insurance payor. Id. ¶ 364. On March 15,
14 2021, BCBS mailed a letter to Eargo informing it that BCBS “is required by federal
15 mandates and state statutes to conduct audits and reviews of claims to ensure
16 appropriateness of claims and adequate documentation of clinical services provided to our
17 members. . . . Accordingly, [BCBS is] requesting [Eargo to] provide office/medical
18 records for [28 listed BCBS FEP members] showing all supporting documentation.” Pls.’
19 Opp., Ex. A at 2 (dkt. 84-2). The letter noted that “[f]ailure to submit the requested
20 information could result in a negative decision being rendered against you regarding these
21 claim payment(s).” Id.

22 A week later, on March 22, Eargo received a faxed letter from BCBS. Id., Ex. B at
23 2 (dkt. 84-3). The March 22 letter included Eargo’s mailing address but appears to be
24 directed at another company. Id. The letter stated: “Dear [unrelated company]: . . . In a
25 review of claims that you submitted, Blue Shield has identified irregularities in your
26 billing: **Your office is submitting Claims for a non-covered service.**” Id. (emphasis
27 original).

28 Then, on April 7, 2021, BCBS mailed another letter to Eargo. Id., Ex. C at 2 (dkt.

1 84-4). This time, the letter was both addressed to and directed at Eargo. The letter stated:
2 “In a review of claims that you submitted, Blue Shield has identified irregularities in your
3 billing: **Your office is submitting Claims for services that require additional review.**”).
4 The letter also stated that “**effective March 01, 2021, you will be required to supply**
5 **supporting documentation with all claims submitted.**” Id. (emphasis original).

6 On May 12, 2021, in its Q1 2021 SEC Form 10-Q filing, Eargo stated that it was
7 “currently subject to a routine audit with our largest third-party payor, who accounted for
8 approximately 57% of the Company’s gross accounts receivable as of March 21, 2021.”
9 Eargo MTD, Ex. C at 25 (dkt. 76-3).

10 Eargo updated investors on August 12, 2021 in its Q2 2021 filing, disclosing that in
11 addition to being subject to the audit, “claims submitted since March 1, 2021 have not
12 been paid.” Id., Ex. D at 29 (dkt. 76-4). Eargo also stated: “Reimbursement claims
13 submitted to another insurance company are also currently undergoing an audit, and to date
14 claims from this insurance company have been processed and approved consistent with
15 normal business practices during the audit. In addition to the risk that the insurance
16 companies may deny the claims subject to the current audits, and we have received some
17 denials to date, it is possible that they may seek recoupments of previous claims paid and
18 deny any future claims.” Id. Eargo continued: “While we believe the claims submitted are
19 valid and reimbursement with these insurance companies, and there exist processes for
20 appeal . . . an unfavorable outcome of the ongoing audits could have a material adverse
21 effect on our future financial results[.]” Id.

22 On the August 12 earnings call, C.F.O. Laponis stated: “These kind of audits are—
23 on claims are pretty common, particularly given the growth in our business. We believe
24 all the claims we submitted are valid, reimbursable and have had a very productive call
25 even this week with the payor and we’re confident we’re able to provide them all the
26 requested documentation.” Id. ¶ 157. Laponis continued: “[T]his is more as I see it an
27 education of our business model and how our business model works differently from the
28 classic way of distributing hearing aids.” Id.

1 After the August 12 filing, Eargo’s stock price dropped over 24-percent, from a
2 close of \$32.70 on August 12, 2021 to a close of \$24.70 the following day. Id. ¶ 260.

3 A few days later, in an August 16 meeting with analysts, Gormsen and Laponis said
4 the audit “was not ‘an issue with the benefit amount, the device delivered, or a dispute
5 denial.” Id. ¶ 158. Later, on September 9, 2021, at the Wells Fargo Healthcare
6 Conference, Gormsen said: “[A]udits in the hearing aid industry happen all the time, right.
7 You’re audited by large customers. . . . [BCBS is] not questioning claims, so we are not
8 denying claims, they are not questioning product. . . . They’re not questioning our delivery
9 of audiology there either. So it’s really about—it’s more, how do we define a process that
10 allows for them to approve our claims in a more streamlined manner, right.” Id.; Eargo
11 MTD, Ex. I at 2.

12 **5. The DOJ Investigates Eargo’s Insurance Claims.**

13 On September 22, 2021, Eargo filed a SEC Form 8-K notifying shareholders that
14 the Department of Justice had begun conducting a criminal investigation into Eargo’s
15 insurance reimbursement claims made to federal employee health plans. Compl. ¶ 99.
16 The 8-K filing also stated that “the DOJ is now the principal contact related to the subject
17 matter of the [BCBS] audit.” See id. ¶ 100. After this announcement, Eargo’s stock price
18 dropped approximately 68-percent, from \$21.86 on September 22 to a close price of \$6.86
19 on September 23. Id. ¶ 102.

20 Months later, in January 2022, Eargo disclosed that the DOJ has referred the matter
21 to the Civil Division and that the criminal investigation was no longer active. Id. ¶ 112.
22 As the DOJ investigation was pending, in March 2022, Eargo further disclosed that it had
23 offered affected customers—those who used insurance benefits for the purchase—the
24 option to return their hearing aids or purchase their hearing aids without using insurance
25 benefits. Id. ¶ 114.

26 On April 29, 2022, the DOJ issued a press release announcing a \$34.37 million
27 settlement with Eargo “to settle common law and False Claims Act allegations of
28 unsupported diagnosis code.” Id. ¶ 115. In the Settlement Agreement and the press

1 release, DOJ stated its allegations as follows:

2 The United States alleged that, from Jan. 1, 2017, through Jan. 31,
3 2021, Eargo included unsupported hearing loss-related diagnosis codes on
4 claims for hearing aid devices that Eargo submitted to the FEHBP and on
5 invoices—called superbills—that Eargo provided to FEHBP beneficiaries to
6 obtain reimbursement for such devices from the FEHBP. The United States
7 further alleged that between Feb. 1, 2021, and Sept. 22, 2021, Eargo
8 continued to include these unsupported hearing loss-related diagnosis codes
9 on claims and superbills—even after completing an internal review of its
10 billing and coding practices in January 2021—resulting in Eargo knowingly
11 submitting or causing the submission of false claims for payment to the
12 FEHBP.

13 See id. ¶ 116; Eargo MTD, Ex. F.

14 In the press release, the DOJ noted that “[t]he claims settled by this agreement are
15 allegations only and there has been no determination of liability.” Eargo MTD, Ex. G (dkt.
16 76-7). Eargo denied any wrongdoing. Id.

17 **B. Procedural History**

18 While the DOJ investigation was ongoing, several investors filed separate suits
19 alleging violations of federal securities law. See Dkt. 44. This Court consolidated the
20 cases and appointed IBEW Local 353 Pension Plan and Xiaobin Cai as Lead Plaintiffs. Id.
21 at 2.

22 On May 20, 2022, Lead Plaintiffs filed a 128-page amended consolidated class
23 action complaint, alleging (1) violations of the Securities Act against Defendants Eargo,
24 Inc. and its executives, board of directors and IPO underwriters; and (2) violations of the
25 Exchange Act against Eargo, Gormsen and Laponis. See generally Compl. Plaintiffs
26 generally allege that Defendants made numerous false or misleading statements in Eargo’s
27 Offering Documents and in later SEC disclosures and acted with scienter. The Complaint
28 alleges that prior to the IPO, Eargo and its executives knew, or it was reckless that they did
not know, that Eargo’s telecare business model for selling hearing aids was incompatible
with FEHBP insurance policies, which require a diagnosis of “medical necessity.”
Plaintiffs allege that Eargo submitted “false” insurance claims that purport to meet FEHBP

1 insurance requirements even though they did not. According to Plaintiffs, Eargo
2 overstated its revenue and guidance in public filings by accounting for insurance
3 reimbursements, and Eargo and its executives falsely or misleadingly touted significant
4 business growth opportunity through the federal insurance market even though that market
5 was out-of-reach for Eargo because the company does not require its customers to undergo
6 in-person diagnosis or audiograms. Plaintiffs allege that it was negligent for Eargo’s board
7 of directors and IPO underwriters to not investigate and disclose that Eargo’s business
8 model did not comport with insurance billing standards. Plaintiffs also allege that the
9 Eargo Defendants significantly downplayed the BCBS audit and failed to promptly
10 disclose that BCBS was not making payments for claims submitted since March 1, 2021.

11 Pending now are separate motions to dismiss filed by the Eargo Defendants and the
12 Underwriter Defendants. See Eargo MTD (dkt. 75); Underwriters MTD (dkt. 78). The
13 Court heard oral argument on these motions on January 27, 2023.

14 **II. LEGAL STANDARD**

15 To survive a motion to dismiss, a complaint must contain sufficient factual matter to
16 state a claim that is facially plausible. Fed. R. Civ. P. 12(b)(6); Ashcroft v. Iqbal, 556 U.S.
17 662, 678 (2009). A claim is facially plausible when “the plaintiff pleads factual content
18 that allows the court to draw the reasonable inference that the defendant is liable for the
19 misconduct alleged.” Ashcroft, 556 U.S. at 678. The court “must take all of the factual
20 allegations in the complaint as true,” but it is “not bound to accept as true a legal
21 conclusion couched as a factual allegation.” Id. The plausibility standard does not impose
22 a “probability requirement, but it asks for more than a sheer possibility that a defendant
23 acted unlawfully.” Id.

24 A complaint alleging fraud must also “state with particularity the circumstances
25 constituting fraud.” Fed. R. Civ. P. 9(b); Kearns v. Ford Motor Co., 567 F.3d 1120, 1125
26 (9th Cir. 2009). Rule 9(b) requires a plaintiff to set forth the “who, what, when, where,
27 and how” of the alleged fraud. Vess v. Ciba Geigy Corp. USA, 317 F.3d 1097, 1106 (9th
28 Cir. 2003). The purpose of Rule 9(b)’s heightened pleading requirement is to provide

1 notice to defendants of the specific fraudulent conduct against which they must defend.
2 Bly-Magee v. California, 236 F.3d 1014, 1018 (9th Cir. 2001); Semegen v. Weidner, 780
3 F.2d 727, 732 (9th Cir. 1985) (the complaint “must be specific enough to give defendants
4 notice of the particular misconduct which is alleged to constitute fraud”).

5 **III. DISCUSSION**

6 Plaintiffs assert claims under (A) Sections 11, 12(a)(2) and 15 of the Securities Act
7 against Eargo, Gormsen, and Laponis, plus members of Eargo’s Board of Directors who
8 signed the Offering Materials, and the underwriters for Eargo’s IPO. Plaintiffs also bring
9 claims under (B) Section 10(b) and 20(a) of the Exchange Act against Eargo, Gormsen,
10 and Laponis. Each set of claims are discussed in turn.

11 **A. Securities Act**

12 Under Section 11(a) of the Securities Act, a stock purchaser may sue based on
13 material omissions or misrepresentations in the stock’s IPO registration statement.
14 15 U.S.C. § 77k(a). Board directors of the issuer company, professionals who participated
15 in the preparation of the registration statement, and underwriters of the security may be
16 held liable under Section 11(a). Id.; see In re Software Toolworks Inc., 50 F.3d 615, 621
17 (9th Cir. 1994).

18 **1. Securities Act claims sounding in fraud must be pleaded with**
19 **particularity.**

20 As a preliminary matter, the parties dispute whether Rule 8(a) or the heightened
21 pleading standard of Rule 9(b) governs the Section 11 claims. Plaintiffs argue that the
22 Rule 8(a) pleading standard should apply because the Complaint separates allegations for
23 the negligence-based claims under the Securities Act and the fraud-based claims under
24 Exchange Act. Opp. at 31–32. Eargo and the Underwriters disagree because both set of
25 Plaintiffs’ claims are premised on fraud allegations. Eargo MTD at 6–8 & n.3;
26 Underwriters Reply at 2–3.

27 Defendants have the better argument. It is well established that Securities Act
28 claims may be subject to Rule 9(b) if the complaint is “grounded in fraud” or “sounds in

1 fraud.” In re Rigel Pharm., Inc. Sec. Litig., 697 F.3d 869, 885–86 (9th Cir. 2012); Rubke
2 v. Capitol Bancorp Ltd., 551 F.3d 1156, 1161 (9th Cir. 2009). To decide whether a
3 complaint sounds in fraud, a court must “determine, after a close examination of the
4 language and structure of the complaint, whether the complaint alleges a unified course of
5 fraudulent conduct and relies entirely on that course of conduct as the basis of a claim.”
6 Rubke, 551 F.3d at 1161

7 In this case, Plaintiffs cannot circumvent the heightened pleading standard because
8 their Securities Act allegations generally mirror their fraud-based allegations under the
9 Exchange Act. That is, both the Securities Act and Exchange Act claims are based on
10 Eargo’s alleged fraudulent act of submitting false or improper insurance claims. Tellingly,
11 in pleading the Securities Act violations, Plaintiffs expressly incorporate and reallege the
12 fraud-based allegations from the Exchange Act section of the Complaint. See Compl.
13 ¶¶ 450, 461, 470. As both set of claims are premised on fraud, the heightened pleading
14 requirements of Rule 9(b) apply to assess the sufficiency of Plaintiffs’ Securities Act
15 claims. See In re Daou Sys., Inc., 411 F.3d 1006, 1028 (9th Cir. 2005).

16 **2. Plaintiffs do not adequately plead falsity from statements made in**
17 **Eargo’s Offering Documents.**

18 To survive dismissal of a Section 11 claim sounding in fraud, a plaintiff must plead
19 with particularity (i) that the registration statement contained a misrepresentation or
20 omission; and (ii) that the misrepresentation or omission was material. Id. at 1027. A
21 misrepresentation or omission is material where it “would have misled a reasonable
22 investor about the nature of his or her investment.” Id. Unlike the requirements under the
23 Exchange Act, see infra III.B, Section 11 liability does not require a showing of scienter,
24 and defendants will be held liable for innocent or negligent material misrepresentations or
25 omissions. In re Stac Electronics Sec. Litig., 89 F.3d 1399, 1404 (9th Cir. 1996).

26 The same standard applies for pleading a violation of Section 12(a)(2), which
27 creates a private cause of action against a person who offers or sells a security by means of
28 a prospectus or oral communication that includes a false or misleading statement. See

1 15 U.S.C. § 77i; see also In re Morgan Stanley Info. Fund Sec. Litig., 592 F.3d 347, 359
2 (2d Cir. 2010) (noting Sections 11 and 12(a)(2) are “Securities Act siblings” with similar
3 elements).

4 The truthfulness of the challenged statements is assessed from the standpoint at
5 which time the statement was made. Stac, 89 F.3d at 1404 (“[S]tatement or omission must
6 be shown to have been false or misleading when made.”). So, for purpose of evaluating
7 the truthfulness of the statements made in Eargo’s Offering Documents, the Court need not
8 consider post-IPO events.

9 The hundreds of challenged statements, as pleaded in the Complaint, generally fall
10 into three categories: (a) unaudited financial results; (b) statements concerning available
11 insurance coverage; and (c) risk factors concerning uncertainty surrounding available
12 insurance and Eargo’s compliance with law.

13 **a. Unaudited financial results**

14 Plaintiffs argue that Eargo’s revenue figures in the Offering Documents were false
15 or misleading because the amounts were improperly inflated by revenue derived from
16 fraudulent insurance claims. *Opp.* at 36. Plaintiffs aver that the insurance “claims
17 submitted by Eargo were not reimbursable without the proper submission of medical
18 necessity.” *Compl.* ¶¶ 402–03. From this, Plaintiffs conclude that Eargo’s unaudited
19 financial results were inaccurate, misleading, or false because it was not probable that
20 Eargo could collect insurance reimbursements as revenue. And under the accounting
21 standards of ASC 606, companies should recognize revenue only to the extent that the
22 company expects to receive the recognized amount. *See id.* ¶ 141. Plaintiffs estimate that
23 the unaudited, reported revenue were improperly inflated by approximately 45-percent,
24 i.e., the share of Eargo’s revenue attributed to insurance reimbursements. *See id.* ¶ 145. In
25 response, Eargo and the Underwriters argue that the reported revenues, which have not
26 been restated, are inactionable statements of opinion. *Eargo MTD* at 17–18; *Underwriters*
27 *MTD* at 6–7.

28 The Supreme Court has recognized that “[g]enerally accepted accounting

1 principles,” such as ASC 606, “tolerate a range of reasonable treatments, leaving the
 2 choice among alternatives to management.” Thor Power Tool Co. v. C.I.R., 439 U.S. 522,
 3 544 (1979). It is well established in this circuit that accounting judgments may constitute
 4 statements of opinion. City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align
 5 Tech., Inc., 856 F.3d 605, 621 (9th Cir. 2017); accord, e.g., Hunt v. Bloom Energy Corp.,
 6 No. 19-cv-02935-HSG, 2021 WL 4461171, at *5 (N.D. Cal. Sept. 29, 2021) (“The Ninth
 7 Circuit has [] recognized that the application of GAAP—at least at times—requires a
 8 company to exercise its judgment, such that a company’s financial statements may
 9 constitute opinions.”).

10 For accounting statements of opinion to be actionable, the opinion must (1) “itself
 11 constitute[] a factual misstatement” or (2) is “rendered misleading by the omission of
 12 discrete factual representations.” Omnicare, Inc. v. Laborers Dist. Council Const. Industry
 13 Pension Fund 575 U.S. 175, 182–84 (2015). Put another way, an opinion itself may be a
 14 misrepresentation of fact if a speaker says something is true but does not actually believe it
 15 is true. Id. at 183–86. And for omissions, the “investor must identify particular (and
 16 material) facts going to the basis for the issuer’s opinion—facts about the inquiry
 17 [underlying the opinion] the issuer did or did not conduct or the knowledge it did or did
 18 not have—whose omission makes the opinion statement at issue misleading to a
 19 reasonable person reading the statement fairly and in context.” Id. at 194. Satisfying the
 20 Omnicare framework is, as the Supreme Court recognized, “no small task.” Id.

21 Here, Plaintiffs have fallen short of meeting the Omnicare requirements. The
 22 Complaint contains no allegations of subjective falsity—that is, Plaintiffs do not allege,
 23 with particularity, facts showing that Defendants believed that FEHBP insurance
 24 companies would not reimburse the claims. Plaintiffs merely speculate that Defendants
 25 must know, or it was reckless that they did not know, from BCBS’s policy manual that
 26 Eargo’s claims would be rejected for falsehood. But their speculation is undercut by the
 27 fact that federal insurance carriers, including BCBS, have reimbursed Eargo’s claims for
 28 nearly three years prior and without issue. Plaintiffs do not plead facts to the contrary.

1 Therefore, nothing in the Complaint suggests that Defendants “must have known” that
2 their accounting statements were misleading. See Dearborn Heights, 856 F.3d at 618.

3 A statement of opinion, moreover, “is not necessarily misleading when an issuer
4 knows, but fails to disclose, some fact cutting the other way,” because opinions generally
5 “rest on a weighing of competing facts.” Omnicare, 575 U.S. at 189. Though BCBS’s
6 policy manual states that it does not cover “[o]ver the counter hearing aids,” see Eargo
7 MTD, Supp. Decl., Ex. W at 57 (dkt. 93-1), the Complaint does not plead with
8 particularity facts showing that the Defendants considered Eargo’s hearing aids to be
9 “over-the-counter” products.² Of course, different people may have different
10 interpretations of what an insurance policy covers. And insurance companies may have
11 different interpretations from providers and patients. Here, Plaintiffs at best may have
12 established a legitimate difference in opinion as to what BCBS’s policy required, but that
13 is hardly sufficient to state a securities fraud claim.

14 Plaintiffs also argue that the Defendants violated Item 303 of Regulation S-K. See
15 Opp. at 50. Under Item 303, issuers must “[d]escribe any known trends or uncertainties
16 that have had or that the registrant reasonably expects will have a material favorable or
17 unfavorable impact on net sales or revenues or income from continuing operations.” 17
18 C.F.R. § 229.303(a)(3)(ii). An Item 303 violation has three elements: (1) a defendant
19 knew of an adverse trend, (2) the trend would have a material impact, and (3) the material
20 impact is reasonably likely to occur. Steckman v. Hart Brewing, Inc., 143 F.3d 1293,
21 1296–97 (9th Cir. 1998). Plaintiffs’ allegations here are inadequate because the Complaint
22 does not mention that any FEHBP carrier denied Eargo’s claims prior to the IPO. Put
23 differently, Plaintiffs make no allegations that establish a trend that Eargo knew its
24 insurance claims were false or improper and that consequently its submissions would be
25 denied.

26 _____
27 ² In post-IPO statements, Eargo has expressly disclaimed that its hearing aids are “over-
28 the-counter” products under then-existing FDA regulations. See Ex. A at 20–21; see also,
e.g., Ex. E at 5 (on the August 12, 2021 Q2 Earnings Call: “As another reminder, Eargo is
not an OTC [over-the-counter] hearing aid as this regulatory category does not yet exist.”).

b. Statements on insurance opportunities

1 Plaintiffs allege that the Offering Documents contained false or misleading
 2 statements about Eargo’s ability to obtain insurance coverage and its growth opportunities
 3 through the insurance market. See, e.g., Compl. ¶ 411 (“Eargo stated that ‘the increase in
 4 customers with insurance coverage has been a significant driver of our growth in 2020, and
 5 we intend to pursue additional coverage in the future.’”); id. ¶¶ 412–13 (“‘we intend to
 6 pursue additional coverage in the future’ as a growth strategy”); id. ¶ 414 (“In describing
 7 its pool of potential insurance customers, Eargo stated that ‘there are approximately 12
 8 million adults in the United States over 50 years of age with both hearing loss and access
 9 to an existing hearing aid benefit under these plans.’”). Plaintiffs allege that statements
 10 about the size or importance of the FEHBP insurance market were misleading because
 11 “Eargo’s FEHBP customers (including BCBS FEP customers) were ineligible for
 12 insurance reimbursement,” and “Eargo had been systematically submitting unsupported,
 13 false reimbursement requests to obtain reimbursement.” Id. ¶¶ 412, 417. In response,
 14 Defendants argue that these statements are (i) inactionable expressions of corporate
 15 optimism, (ii) forward-looking statements protected by the PSLRA’s safe harbor
 16 provision; or (iii) puffery.

i. Corporate optimism

18 It is well established that statements expressing corporate optimism generally are
 19 not actionable. See In re Cutera Sec. Litig., 610 F.3d 1103, 1111 (9th Cir. 2010). An
 20 exception to that general rule is if the challenged statements “address specific aspects of a
 21 company’s operation that the speaker knows” is false. In re Quality Sys., Inc. Sec. Litig.,
 22 865 F.3d 1130, 1143 (9th Cir. 2017); see, e.g., Warsaw v. Xoma Corp., 74 F.3d 955, 959
 23 (9th Cir. 1996) (telling investors FDA approval was “going fine” when the company knew
 24 approval would never come was materially misleading); Fecht v. Price Co., 70 F.3d 1078,
 25 1081 (9th Cir. 1995) (saying the company “anticipates a continuation of its accelerated
 26 expansion schedule” when the expansion already failed was misleading).

27 In this case, the statements made in the Offering Documents—e.g., that Eargo
 28

1 “intends to pursue additional coverage in the future” and “there are approximately 12
2 million adults in the United States over 50 years of age with both hearing loss and access
3 to an existing hearing aid benefit under these plans,” Compl. ¶¶ 411–14—simply conveyed
4 corporate optimism. Plaintiffs have not pleaded in the Complaint that Defendants believed
5 that the mechanism for revenue growth through insurance coverage was unattainable.

6 Plaintiffs’ reliance on SEC v. Richman, No. 21-CV-01911-CRB, 2021 WL 5113168
7 (N.D. Cal. Nov. 3, 2021), is misplaced. In Richman, this Court found that the SEC
8 adequately pleaded falsity based on allegations that the company knew its insurance
9 practices were risky or dubious. Id. at *7. Specifically, almost a year before the
10 company’s Series C funding, “the company’s general counsel emailed defendants that ‘any
11 tests prescribed based solely on consumers’ questionnaires, versus a live consultation
12 between consumer and doctor, would be a reimbursement risk.’” Id. at *2. Afterward, not
13 only did the executive defendants continue to use the wrongful practice, “they also
14 allegedly ‘concealed’ [its] the use ‘from the general counsel and the [company’s] board.’”
15 Id. And at the start of the Series C funding rounding, the company falsified
16 “documentation in response to insurer inquiries” and the “insurers challenged the
17 company’s practices, including allegations of ‘fraud and abuse.’” Id. at *7.

18 The allegations from Plaintiffs’ Complaint are poles apart from the SEC’s
19 allegations in Richman. In its Offering Documents, Eargo made clear that its telecare
20 business model was nontraditional in that customers could “complete their purchase over
21 the phone with [Eargo’s] sales consultant or directly on [its] website, without the need to
22 navigate multiple visits to the hearing clinic for tests and fittings,” Compl. ¶ 329, and
23 through “‘do-it-yourself’” assessments, id. ¶ 331. Plaintiffs do not plead with particularity
24 any facts showing that Eargo knew or should have known its telecare business model was
25 seriously incompatible with FEHBP insurance policies. And unlike in Richman where the
26 company’s general counsel raised concerns with its founders and executives, Plaintiffs
27 here do not plead facts showing that the two former Eargo employees who spoke with the
28 DOJ during the investigation—and who allegedly expressed concerns about Eargo’s

1 business model—even interacted with the Eargo’s executives. Plaintiffs do not offer any
 2 contemporaneous witness accounts that the Defendants knew that their conduct of
 3 submitting claims to federal insurance carriers was wrong. Without more, the excerpts
 4 from the former employees’ statements “cannot substitute for reports during the Class
 5 Period required to establish each statement was false when made.” City of Sunrise
 6 Firefighters’ Pension Fund v. Oracle Corp., No. 18-cv-4844-BLF, 2019 WL 6877195, at
 7 *14 (N.D. Cal. Dec. 17, 2019); In re Rackable Sys., Inc. Sec. Litig., No. 09-cv-222-CW,
 8 2010 WL 3447857, at *9 (N.D. Cal. Aug. 27, 2010) (rejecting former employee allegations
 9 when they had no “interaction or communication with any of the defendants”).

10 **ii. Safe harbor**

11 The PSLRA carves out a safe harbor from liability for statements that are identified
 12 as “forward-looking” and are “accompanied by meaningful cautionary statements.” 15
 13 U.S.C. § 78u-5(c)(1)(A)(i). A forward-looking statement is “any statement regarding (1)
 14 financial projections, (2) plans and objectives of management for future operations, (3)
 15 future economic performance, or (4) the assumptions ‘underlying or related to’ any of
 16 these issues.” No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W.
 17 Holding Corp., 320 F.3d 920, 936 (9th Cir. 2003). A projection may contain an implied
 18 factual misstatement where (1) the speaker does not actually believe the statement, (2)
 19 there is no reasonable basis to believe the statement is true, or (3) the speaker is aware of
 20 undisclosed facts that seriously undermine the statement’s accuracy. Provenz v. Miller,
 21 102 F.3d 1478, 1487 (9th Cir. 1996). Under the PSLRA, forward-looking statements are
 22 not actionable (i) if they are identified as forward looking and accompanied by meaningful
 23 cautionary language; or (ii) if Plaintiffs fail to prove Defendants made the statements with
 24 actual knowledge that they were materially false or misleading. Park v. GoPro, Inc., No.
 25 18-cv-193-EMC, 2019 WL 1231175, at *15 (N.D. Cal. Mar. 15, 2019). When meaningful
 26 cautionary language accompanies a forward-looking statement, the speaker’s state of mind
 27 “is irrelevant.” Cutera, 610 F.3d at 1112.

28 Here, statements in the Offering Documents that Eargo intended to target customers

1 with eligible insurance coverage are forward-looking statements regarding plans and
2 objectives for future operations. Furthermore, the Offering Documents disclosed that
3 Eargo’s “products were primarily purchased on a cash-pay basis” and expressly warned
4 that continued insurance coverage was uncertain due to insurance or regulatory changes.
5 See, e.g., Eargo MTD, Ex. A (Registration Statement) at 27 (“Third party coverage and
6 reimbursement ... could decrease for our products, which could reduce our market
7 share.”).

8 **iii. Puffery**

9 Statements that are mere “puffery” are non-actionable as securities fraud. Police
10 Ret. Sys. of St. Louis v. Intuitive Surgical, Inc., 759 F.3d 1051, 1060 (9th Cir. 2014).
11 Puffery comprises generalized, vague, nonquantifiable statements of corporate optimism.
12 See Omnicare, 575 U.S. at 183–84 (differentiating between “mere puffery” and
13 “determinate, verifiable statement[s]” about a company’s products).

14 Though Plaintiffs point to a handful of statements containing concrete facts that are
15 quantifiable and verifiable—e.g., “insurance customers comprised 45–48% of Eargo’s
16 customer base,” Opp. at 15—most of the challenged statements simply convey optimism
17 for business growth. See, e.g., Compl. ¶ 52 (“‘huge opportunity long term to expand []’ to
18 FEHBP customers”); id. ¶ 211 (“Regarding further penetration of the insurance market,
19 Gormsen further touted the ‘enormous head room and long-term grown.’”). More to that,
20 the challenged numbers are “false” if only there is merit to Plaintiffs’ accounting argument
21 about excluding insurance payments as revenue—there is not. See supra III.A.2.a.

22 After reviewing the Complaint and the Offering Documents, the Court finds that the
23 challenged statements about Eargo’s insurance opportunities fall into one or more of the
24 recognized defenses.

25 **c. Risk factors**

26 Plaintiffs challenge various risk factors in Eargo’s SEC filings related to the
27 uncertainty surrounding available insurance, its compliance with law, and its business
28 model. Specifically, Plaintiffs allege that Eargo’s risk disclosures were meaningless and

1 generic—e.g., Eargo warning that “[c]hanges in third-party coverage and reimbursement
2 may impact our ability to grow and sell our products” and that “[t]hird-party coverage
3 and reimbursement may never become available to us at sufficient levels.” Compl. ¶ 418.
4 Plaintiffs argue that because Eargo already “had submitted numerous unsupported, false
5 claims to BCBS and other insurers that were not eligible for payment at all,” “[i]t was
6 misleading for Defendants to describe generic, abstract risks regarding potential ‘changes
7 in third-party coverage’” or potential civil penalties or fines. Id. ¶¶ 419–21. Defendants
8 argue that the risk factors were genuine and appropriate because at the time of the IPO,
9 none of the described risks were realized.

10 The Ninth Circuit has held that “risk factors” are not actionable without further
11 factual allegations indicating that the risks had already “come to fruition.” Siracusano v.
12 Matrixx Initiatives, Inc., 585 F.3d 1167, 1181 (9th Cir. 2009); accord, e.g., In re Pivotal
13 Sec. Litig., No. 19-cv-3589-CRB, 2020 WL 4193384, at *6–7 (N.D. Cal. July 21, 2020).
14 Here, the Complaint does not contain well-pleaded facts showing that, at the time of the
15 IPO, any insurer audit or regulatory investigation had begun such that it would make
16 Eargo’s risk disclosures inaccurate. Plaintiffs therefore have not stated an actionable claim
17 based on the risk factors.

18 Accordingly, the Court finds that Plaintiffs have not pleaded actionable claims
19 under Sections 11 and 12(a)(2) of the Securities Act.

20 And because Plaintiffs have not pleaded underlying violations of Sections 11 or 12,
21 their Section 15 claim against a “control person” of the company fails, too. See 15 U.S.C.
22 § 77o; e.g., In re Rigel Pharm., Inc. Sec. Lit., 697 F.3d 869, 886 (9th Cir. 2012) (“Because
23 Plaintiff here has failed to adequately plead a violation of the federal securities laws, it
24 follows that Plaintiff also has failed to adequately plead violations of [] section 15.”).

25 **B. Exchange Act**

26 Plaintiffs’ second set of claims is brought under Sections 10(b) and 20(a) of the
27 Exchange Act against Eargo, Gormsen and Laponis.

28 To plead a violation under Rule 10b–5, which was promulgated under the Securities

1 Act, a plaintiff must allege: “(1) a material misrepresentation or omission of fact, (2)
2 scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss
3 causation, and (5) economic loss.” Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981,
4 990 (9th Cir. 2009). Eargo challenges the sufficiency of Plaintiffs’ allegations with respect
5 to only the first two elements: (1) the falsity of Eargo’s statements and (2) whether they
6 were made with scienter. The “more exacting pleading requirements” of the PSLRA
7 require that the complaint plead both falsity and scienter with particularity. Id.; see also 15
8 U.S.C. § 78u4(b)(1).

9 **1. Falsity or Misrepresentation**

10 To begin with, Plaintiffs’ claims under the Exchange Act largely hinge on the same
11 or similar categories of challenged statements as those under their Securities Act claims—
12 that is, statements about Eargo’s revenue, insurance coverage, and risk factors. Thus, most
13 of Plaintiffs’ Exchange Act claims are not actionable for the reasons why their Securities
14 Act claims fail. See supra III(A)(2)(a)–(c).

15 Nonetheless, for their Section 10(b) claims, Plaintiffs also allege that Eargo’s
16 representation that it “validates customer eligibility and reimbursement amounts prior to
17 shipping the product,” Compl. ¶¶ 135, 202, was false or misleading. Plaintiffs also allege
18 that Eargo falsely or misleadingly characterized and downplayed the BCBS audit as
19 “routine”; an “opportunity” to “educate” BCBS” of Eargo’s business model; “pretty
20 common”; and something that “happen[s] all the time.” See id. ¶¶ 88, 156, 242, 253.

21 **a. Validation of customer eligibility³**

22 Plaintiffs contend that Eargo falsely or misleadingly conveyed to investors that the
23 company precleared benefits reimbursements prior to submitting them to the insurance
24 carriers. Plaintiffs repeatedly take a snippet from Eargo’s March 16, 2021 Form 10-K that
25 said Eargo “validates customer eligibility and reimbursement amounts prior to shipping the
26 product.” E.g., Compl. ¶¶ 41, 135, 202. Plaintiffs and Eargo disagree what “validates
27

28 ³ Plaintiffs concede that the language about validating customers’ eligibility does not expressly appear in Eargo’s Offering Documents. See Hr’g Tr. 4:10–16 (Jan. 27, 2023).

1 customer eligibility” means. On the one hand, Plaintiffs argue that “validates customer
2 eligibility” meant that Eargo “pre-clear[ed] customer eligibility with FEHBP insurers.”
3 Opp. at 14–15. On the other hand, Eargo argues that validation in this sentence meant only
4 that Eargo “verif[ied] the customer had an insurance policy that included hearing-aid
5 benefits.” Eargo Reply at 7. This verification, Eargo argues, did not mean that “it would
6 pre-clear customer eligibility with FEHBP insurers.” Id.

7 This statement about validation of customer eligibility is ambiguous, and both
8 readings of the phrase are plausible. At the motion-to-dismiss stage, the Court cannot
9 undertake the necessarily factual inquiry to determine how a reasonable investor would
10 understand the phrase “validates customer eligibility.” The inquiry at this stage is whether
11 Plaintiffs have pleaded adequately and with particularity that the “representations, viewed
12 as a whole, would have misled a reasonable investor.” Rombach v. Chang, 355 F.3d 164,
13 178 n.11 (2d Cir. 2004). In other words, the question is whether a reasonable investor
14 would have been misled by Eargo’s statement about validating insurance eligibility. See
15 S.E.C. v. Stratocomm Corp., No. 15-1538-CV, 2016 WL 3355378, at *1 (2d Cir. 2016)
16 (“[U]ntrue assertions, ambiguous statements, and half-truths can render a statement
17 misleading.”). Perhaps an investor would interpret the phrase as Plaintiffs suggest. Or
18 perhaps it wouldn’t. At the pleadings stage, however, the Court cannot make this factual
19 determination. Nor does the Court need to because, regardless, Plaintiffs do not plead a
20 strong inference of scienter. See infra III.B.2.

21 **b. Eargo’s characterization of the BCBS audit**

22 Plaintiffs also claim that Eargo did not timely reveal the BCBS audit and that they
23 mischaracterized and downplayed the audit to investors. Opp. at 16. Eargo disagrees and
24 asserts that it timely disclosed the insurance audit and its executives reasonably believed
25 that the audit was routine. Eargo Reply at 8–9.

26 The Court finds that Plaintiffs have not adequately pleaded that Eargo should have
27 disclosed the BCBS audit in its Q4 2020 SEC Form 10-K. The first BCBS letter to Eargo
28 requesting documentations was dated March 15, 2021 and sent via certified mail.

1 Plaintiffs do not allege any facts suggesting that Eargo received the letter a day later after it
2 was mailed—i.e., on March 16, the day of the Q4 2020 filing. Eargo disclosed the audit in
3 its next scheduled SEC filing on May 13, 2021. See Compl. ¶ 230.

4 Furthermore, Plaintiffs fail to adequately plead that the Eargo executives did not
5 believe the insurance audit was routine. BCBS’s March 15 letter stated that the insurance
6 company was “required by federal mandates and state statutes to conduct audits and
7 reviews of claims. . . . Accordingly, we are requesting your office to provide
8 office/medical records for [approximately 30] members showing all supporting
9 documentation.” Opp., Ex. A at 2. Plaintiffs do not plead whether or how this letter
10 sounded any alarm at Eargo.

11 In making their argument, Plaintiffs put more weight on BCBS’s March 22, 2021
12 letter. This letter stated that the certain submitted claims were “for a non-covered service.”
13 Id., Ex. B at 2. But whether the March 22 letter pertained to Eargo is unclear because it
14 addressed another company. Id., Ex. B at 2. Eargo argues that this letter “was plainly sent
15 by mistake.” Eargo Reply at 7–8. Plaintiffs do not plead how Eargo treated the March 22
16 letter. Perhaps Eargo followed up with BCBS? Or perhaps Eargo disregarded it? It’s
17 unclear.

18 Then came a third letter from BCBS on April 7, 2021. This time, instead of saying
19 insurance claims were submitted for a non-covered service, the correctly addressed letter
20 stated that Eargo’s claims “require additional review.” Opp., Ex. C at 2. Importantly,
21 neither the March 15 letter nor the April 7 letter—letters that were unmistakably
22 addressing Eargo—said that BCBS was ceasing payment. Rather, the April 7 letter stated:
23 “[E]ffective March 01, 2021, you will be required to supply supporting documentation
24 with all claims submitted.” Id. at 2.

25 A misleading statement is one that “affirmatively create[s] an impression of a state
26 of affairs that differs in a material way from the one that actually exists.” Brody v.
27 Transitional Hosps. Corp., 280 F.3d 997, 1006 (9th Cir. 2002). Plaintiffs do not
28 adequately plead facts showing that Eargo’s characterization of the BCBS audit was false

1 or misleading at the time they made its SEC disclosure. That is, Plaintiffs fail to plead
2 with particularity any facts showing that Eargo or its executives did not believe that the
3 audit was routine. Moreover, Plaintiffs do not plead facts showing that Eargo immediately
4 knew that BCBS would freeze payments on all claims submitted since March 1, 2021.
5 BCBS’s letters asked for additional documents on Eargo’s submitted claims; they did not
6 expressly say that payment would cease. And when the payment freeze became evident
7 later on, Eargo disclosed BCBS’s nonpayment in August 2021 on its Q2 2021 SEC Form
8 10-Q—i.e., approximately four months after receiving the April 7 letter.

9 Though most of Eargo’s statements about the BCBS audit were not false or
10 misleading, Plaintiffs do adequately plead that Gormsen downplayed the audit at the Wells
11 Fargo Investor Conference. At the conference, Gormsen said, “[BCBS is] not questioning
12 claims, so we are not denying claims, they are not questioning product.” Eargo MTD, Ex.
13 I at 2. Putting aside whatever Gormsen meant when he said “we are not denying
14 claims”—that is, whether he attempted to convey that BCBS was not denying claims or
15 that Eargo was not accepting insurance payments—his statement that BCBS was “not
16 questioning claims” could appear false or misleading to a reasonable investor. The April 7
17 letter from BCBS expressly stated that “[Eargo’s] billing activity shows non-compliance
18 with Blue Shield’s payment policy and standards of industry billing, [so] Blue Shield will
19 be performing pre-payment reviews of your claims.” Opp., Ex. C at 2. So contrary to
20 what Gormsen said at the conference, BCBS appears to be “questioning claims.”

21 Regardless, as explained next, Plaintiffs fail to plead with particularity that the
22 Eargo Defendants acted with scienter.

23 **2. Scienter**

24 It takes more than identifying snippets from past misstatements to plead an
25 actionable Exchange Act claim. A Section 10(b) claim must also “state with particularity
26 facts giving rise to a strong inference that the defendant acted” with scienter. Tellabs, Inc.
27 v. Makor Issues & Rts., Ltd., 551 U.S. 308, 321 (2007); 15 U.S.C. § 78u-4(b)(2)(A).

28 Scienter is “a mental state embracing intent to deceive, manipulate, or defraud.”

1 Tellabs, 551 U.S. at 319. To demonstrate scienter, a complaint must allege that the
 2 defendants made “false or misleading statements either intentionally or with deliberate
 3 recklessness.” Zucco, 552 F.3d at 991. Deliberate recklessness is not “mere recklessness.”
 4 Schueneman v. Arena Pharms., Inc., 840 F.3d 698, 705 (9th Cir. 2016). It is more than
 5 “mere recklessness or a motive to commit fraud.” Id. Deliberate recklessness is “an
 6 extreme departure from the standards of ordinary care . . . which presents a danger of
 7 misleading buyers or sellers that is either known to the defendant or is so obvious that the
 8 actor must have been aware of it.”

9 The “strong inference” standard under the PSLRA also “present[s] no small hurdle
 10 for the securities fraud plaintiff.” Zucco, 552 F.3d at 990. A reviewing court must
 11 “engage in a comparative evaluation [and] . . . consider, not only inferences urged by the
 12 plaintiff . . . but also competing inferences rationally drawn from the facts alleged.”
 13 Tellabs, 551 U.S. at 314. A securities-fraud plaintiff must meet this “high burden” to
 14 survive a motion-to-dismiss challenge. Prodanova v. H.C. Wainwright & Co., LLC, 993
 15 F.3d 1097, 1106 (9th Cir. 2021).

16 For a host of reasons, Plaintiffs have not met this high burden of pleading a strong
 17 inference of scienter.

18 First, Plaintiffs do not allege facts showing that any Eargo Defendants sold stocks
 19 during the Class Period, and the absence of such insider trading “supports an inference of
 20 no scienter.” See In re Rigel Pharm., Inc. Sec. Litig., 697 F.3d 869, 884 (9th Cir. 2012)
 21 (“[B]ecause none of the defendants sold stock during the period between the allegedly
 22 fraudulent statements and the subsequent public disclosure. . . , the value of the stock and
 23 stock options does not support an inference of scienter. . . . In fact, it supports the opposite
 24 inference.”); accord, e.g., In re Solarcity Corp. Sec. Litig., 274 F. Supp. 3d 972, 1011
 25 (N.D. Cal. 2017).

26 Second, Plaintiffs merely speculate that Gormsen and Laponis, as healthcare
 27 industry veterans, knew—or it was reckless that they did not know—that Eargo’s telecare
 28 business model would not comport with the publicized insurance requirement that hearing-

1 aid benefits meet the criteria for “medical necessity.” Opp. at 23–28. Plaintiffs’ argument
2 here is premised on their contested interpretation of BCBS’s insurance policy that a
3 hearing-aid prescription by a medical professional or audiologist is required. Plaintiffs do
4 not adequately plead that the Eargo Defendants shared their interpretation of the BCBS
5 policy or that Defendants even read the BCBS policy manual that was updated days before
6 Eargo’s IPO. See Hr’g Tr. 24:24–25:08.

7 Third, Plaintiffs make their allegations with the benefit of hindsight and after Eargo
8 settled with the DOJ. They say that the DOJ made “findings” that Eargo submitted
9 improper or false claims, and Eargo’s “rapid and substantial” settlement with the DOJ are
10 evidence of scienter. Opp. at 23–24. Not so. The DOJ made allegations. Allegations, of
11 course, are not tested or adjudicated findings. A government investigation is not evidence
12 of fraud, especially where the investigation ended with a settlement that disclaims liability.
13 See Veal v. LendingClub Corp., 423 F. Supp. 3d 785, 811–12 (N.D. Cal. 2019) (“Plaintiffs
14 may not allege ‘facts’ simply because they appear in [a government] Complaint.”).

15 Fourth, Plaintiffs do not identify any facts suggesting that Gormsen or Laponis
16 believed the BCBS audit was anything but routine.

17 Fifth, Plaintiffs do not offer any particularized allegation of what Eargo’s January
18 2021 “internal review”—as referenced in the DOJ settlement agreement and press
19 release—showed about Eargo’s billing practices or that Gormsen or Laponis were even
20 aware of such internal review. Plaintiffs’ descriptions of this “internal review” are vague
21 and merely borrow from the DOJ’s unadjudicated allegations.

22 Finally, Plaintiffs attempt to invoke the “core operations doctrine.” Opp. at 27–28.
23 Under this doctrine, scienter may be inferred if the fraud is based on facts “critical to a
24 business’s core operations,” such that the company’s key officers would know of those
25 facts. South Ferry LP, No. 2 v. Killinger, 542 F.3d 776, 783–84 (9th Cir. 2008). The
26 proof required under this doctrine “is not easy”: it requires “either [1] specific admissions
27 by one or more corporate executives of detailed involvement in the minutia of a company’s
28 operations, such as data monitoring, or [2] witness accounts demonstrating that executives

1 had actual involvement in creating false reports.” Police Ret. Sys. of St. Louis v. Intuitive
2 Surgical, Inc., 759 F.3d 1051, 1060 (9th Cir. 2014). Courts applying the “core operations
3 doctrine” have required plaintiffs to plead “details about the defendants’ access to
4 information within the company” related to the fraud. South Ferry, 542 F.3d 776 at 785.

5 Here, Plaintiffs cannot rely on the “core operations doctrine” to save their case
6 because the Complaint cites no particularized facts that the Eargo Defendants believed, or
7 they were deliberately reckless in disbelieving, that its insurance submissions were false or
8 improper. There also are no corroborating witness statements that Gormsen and Laponis
9 knew Eargo’s telecare business model ran afoul of FEHBP insurance rules and still
10 submitted the wrongful claims anyway.

11 Accordingly, after reviewing the Complaint, this Court finds that Plaintiffs have not
12 pleaded particularized facts showing a strong inference of scienter with respect to any of
13 the challenged statements. Plaintiffs’ Section 10(b) claim is therefore dismissed.

14 And because Plaintiffs have failed to state an underlying federal securities law
15 violation, their Section 20(a) claim against a “control person” fails, too. See In re Rigel
16 Pharms., Inc. Sec. Litig., 697 F.3d 869, 886 (9th Cir. 2012) (“Because Plaintiff here has
17 failed to adequately plead a violation of the federal securities laws, it follows that Plaintiff
18 also has failed to adequately plead violations of section 20(a).”).

19 **IV. CONCLUSION**

20 For the foregoing reasons, the Court **GRANTS** Defendants’ motions to dismiss
21 with leave to amend.

22 Should Plaintiffs elect to file an amended complaint curing the deficiencies
23 identified in this Order, Plaintiffs shall do so within 30 days of this Order. Failure to meet
24 the 30-day deadline to file an amended complaint or failure to cure the deficiencies
25 identified in this Order will result in a dismissal with prejudice of Plaintiffs’ claims.
26 Plaintiffs may not add new causes of action or parties without leave of the Court or
27 stipulation of the parties pursuant to Rule 15 of the Federal Rules of Civil Procedure.
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IT IS SO ORDERED.

Dated: February 14, 2023



CHARLES R. BREYER
United States District Judge