UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

GLAZING EMPLOYERS AND GLAZIERS UNION LOCAL #27 PENSION AND RETIREMENT FUND,

Plaintiff,

v.

IRHYTHM TECHNOLOGIES, INC., et al.,

Defendants.

Case No. 24-cv-00706-JSC

ORDER RE: DEFENDANTS' MOTION TO DISMISS

Re: Dkt. Nos. 51, 52

Plaintiff brings this putative class action against iRhythm Technologies ("iRhythm" or the "Company") and its executives ("Individual Defendants") for allegedly false or misleading statements regarding iRhythm's Zio AT, a device which transmits heart event data for physician monitoring. (Dkt. No. 43.)[1] Now pending before the Court is Defendants' motion to dismiss Plaintiff's Second Amended Complaint ("SAC") for failure to state a claim. (Dkt. No. 51.) After careful consideration of the briefing, and having had the benefit of oral argument on April 24, 2025, the Court GRANTS IN PART and DENIES IN PART Defendants' motion to dismiss.

BACKGROUND

I. SAC Allegations

Plaintiff is "a public pension fund that provides retirement allowances and other benefits to Firefighters in Oklahoma." (Dkt. No. 43 ¶ 28.) "During the Class Period, [between November 5, 2021, and August 9, 2024,] [it] purchased iRhythm common stock at inflated prices due to the misrepresentations alleged in this Complaint." (*Id.*) The Company "is a digital healthcare company that manufactured during the Class Period just two heart monitoring devices—the Zio

[1] Record Citations are to material in the Electronic Case File ("ECF"); pinpoint citations are to the ECF-generated page numbers at the top of the document.

XT and Zio AT—designed to diagnose arrythmia." (*Id.* ¶ 29.) Individual Defendants are:

(1) Mr. Blackford (iRhythm's CEO since 2021);

(2) Mr. Bobzien (iRhythm's CFO from August 2022 through August 2024);

(3) Mr. Devine (iRhythm's CFO from June 2020 through August 2022 and COO from December 2021 through March 2023);

(4) Mr. Day (iRhythm's CTO from 2022 through 2024 and "formerly the Executive Vice President of Research & Development");

(5) Mr. Patterson (iRhythm's CCO since July 2022); and

(6) Mr. Turakhia (iRhythm's Chief Medical Officer and Chief Scientific Officer since June 2022, and Executive Vice President since June 2022).

(*Id.* ¶¶ 29-42.)

The Zio XT is "a monitoring patch" which "provides doctors with a patient's arrhythmia and electrocardiogram ('ECG') information following a 14-day wear period." (*Id.* ¶ 43.) The Company developed the Zio XT in 2009 and "gained a significant foothold in the ECG market as one of the first extended-wear wireless monitors in the market." (*Id.*) Then, in 2017, "iRhythm developed the Zio AT, a device the Company described as 'offer[ing] the full benefits of [its] Zio XT Service, with the addition of real-time data transmission and notification of actionable clinical events.'" (*Id.* ¶ 44.) "The Zio AT comes with a cellular transmittal device that transmitted data between the Zio AT and iRhythm's proprietary algorithmic software, which analyzed the ECG data, detected arrhythmic events, and transmitted notification of cardiac arrhythmic events to doctors in 'real time.'" (*Id.*) When ECG data is collected by the Zio AT, it is first sent to iRhythm's "Certified Cardiographic Technicians ('CCTs') [who] conduct a 'final quality assessment review of the data,'" after which "reports are issued to doctors 'following observations by' these technicians." (*Id.*)

Because of the Zio AT's capabilities, the Company "explicitly marketed the Zio AT device to 'high-risk' patients as a 'mobile cardiac telemetry' ('MCT') device." (*Id.* ¶ 45.) MCT is a "continuous cardiac monitoring test that uses the mobile device to monitor cardiac activity." (*Id.*) Specifically, an MCT device "provides near-real-time data, the ability to analyze the patient's

heart rhythm, and overview monitoring by certified technicians 24/7 in order to alert a patient's care team of critical events as they are observed." (*Id.*) So, while the Zio AT was marketed as an MCT, the Zio XT, which "did not transmit real or near-real-time cardiac activity data," was marketed as an ECG device. (*Id.* ¶ 46.)

A. False Statements and Misrepresentations

Defendants made statements that the Zio AT "(i) provided 'near real-time' notifications of significant arrhythmias to the prescribing physician; and was therefore (ii) appropriate for 'high risk' patients and (iii) was a 'mobile cardiac telemetry' or 'MCT' monitor," and (iv) "provided accurate data to patients and doctors." (*Id.* ¶ 54.)

First, iRhythm's statements about the timeliness of Zio AT's notifications, (*id.* ¶ 179-99), were false or misleading for three reasons:

(1) "[A]s attested to by both former employees and the FDA after an investigation … when the device reached an undisclosed and arbitrary transmission limit, the Zio AT stopped transmitting ***any*** telemetry data, and accordingly a provider would not learn of even serious cardiac events until a report was generated at the end of the wear-period." (*Id.* ¶ 200.) "Defendants were aware of many instances where serious cardiac events," some which even resulted in death of the patient, "were not reported to providers during the wear period because the device exceeded the transmission limit." (*Id.*)

(2) According to a former iRhythm CCT ("Former Employee 3"), the Zio AT "had a lag time of about four hours or more before the arrythmia data could even reach the technicians' queue for review," and there was an additional lag between when the technicians received the data and actually reviewed it. (*Id.* ¶ 201.) "[T]echnicians had to work their way down the queue to analyze events one by one, with no way to sort the queue so that critical arrhythmias could be reviewed first." (*Id.*) And the queue grew "overnight and on weekends, when there were not as many technicians on those shifts." (*Id.*)

(3) The Company required "patients to fully register with iRhythm" before any data could be transmitted to a provider. (*Id.* ¶ 202.) And "[b]ecause iRhythm did not notify

patients when their registration was incomplete, patients were often unaware that they had not completed iRhythm's registration requirements." (*Id.*)

Next, statements about the appropriateness of Zio AT for "high-risk" or "at-risk" patients (*id.* ¶¶ 203-11) were false or misleading because the FDA told iRhythm in a May 25, 2023 Warning Letter that "iRhythm did not have FDA clearance to market the Zio AT as intended for 'high-risk patients,' or patients who 'require timely notifications.'" (*Id.* ¶ 212.) Instead, in a 2022 FDA Form 483, it notified iRhythm that "the Zio AT was inappropriate or even dangerous for use in high-risk patient populations." (*Id.*) Indeed, the FDA had cleared the Zio AT only for "'long-term monitoring of arrythmia events for non-critical care patients where real-time monitoring is not needed as reporting timeliness is not consistent with life-threatening arrythmias.'" (*Id.*) Meanwhile, Defendants were aware the transmission limit issue had resulted in serious cardiac events not being timely reported and "admitted to the FDA that based on their own risk assessment, the transmission-limit posed a 'hazardous situation.'" (*Id.*) So, "because 'the transmission limit is exceeded more than rarely, this introduces a nonconformance because the device is unable to transmit ECG information for monitoring and is not remotely capable of delivering near-real time monitoring for high-risk patients.'" (*Id.*)

Third, iRhythm's statements that the Zio AT is an MCT device (*id.* ¶¶ 213-22) were false or misleading or omitted necessary facts because the FDA told iRhythm in a May 25, 2023 Warning Letter that marketing the Zio AT as an MCT incorrectly "implies this device is intended for high-risk patients and near real-time monitoring." (*Id.* ¶ 223.)

Finally, iRhythm's statements about the Zio AT's accuracy (*id.* ¶¶ 224-231) were false or misleading because iRhythm had, at the time the statements were made, received complaints about the accuracy of the Zio AT and the product's reports to physicians routinely included inaccurate information. (*Id.* ¶ 232.) The FDA's Form 483s dated July 2024 warned:

> [T]he Company failed to analyze these thousands of complaints, failed to take any action to investigate the cause of these complaint[s], failed to evaluate this risk of misreporting patients' arrhythmias, failed to appropriately monitor the functionality of the algorithm used to detect and identify arrhythmias, and manipulated the data used to evaluate the accuracy of the Company's reports.

(*Id.*) Former employees reported to Capitol Forum, "we were told that it is 'important that the final report match what the patient experienced during wear time,'" even going so far as to omit arrhythmias from reports. (*Id.*) And Former Employee 3 "explained that the Company wanted to show doctors very 'clean' reports instead of 'ugly' reports, and when a report was 'ugly,' technicians were sometimes instructed to 'artifact' the data in question." (*Id.*)

B. Scienter Allegations

The Company "has known since June 2019 that the transmission limit caused a serious failure to transmit arrhythmia data, resulting in a failure to notify physicians of serious arrhythmic incidents, causing customer injury, and that this failure posed a 'hazardous situation.'" (*Id.* ¶ 158.) By that date, the Company had received at least two complaints "where the patient was killed by the arrhythmia that went un-notified." (*Id.*) "The FDA's inspectional findings on Form 483 explained that since June 2019, iRhythm had 'received 28 complaints reporting patient episodes deemed severe enough to warrant MD Notification that were not reported to the physicians during the wear period' due to the transmission limit." (*Id.*) And the FDA's Warning Letter noted "'[r]ecords reviewed during [its] inspection indicate that your firm has been aware of customer complaints related to this issue since at least 2019.'" (*Id.*) In response to the FDA Letter, Mr. Blackford admitted "the transmission limit posed a 'hazardous situation,' but was 'crucial' and 'essential' and a 'known design constraint … [for] the purpose of conserving power consumption to allow for continuity of wear and data capture.'" (*Id.*) These same issues were also outlined in private findings issued to iRhythm "in [the FDA's] Form 483 inspectional findings on August 12, 2022, following the FDA's inspection of iRhythm's manufacturing facility." (*Id.* ¶ 161.)

A former senior compliance officer at iRhythm ("Former Employee 2") attested that Mr. Blackford and Mr. Devine "served on iRhythm's Compliance Committee," which "received reports on these complaints on a quarterly basis, including from [that officer]." (*Id.* ¶ 162.) And the Compliance Committee also regularly received "iRhythm's interactions with healthcare providers," which likely included "[c]omplaints from doctors who were never notified of" events resulting in patient deaths. (*Id.*) And "days after receiving the FDA's 483 Letter" warning the product was "inappropriate or even dangerous for use in 'high-risk' patient populations, iRhythm

quietly scrubbed references to the Zio AT's intended use by 'high-risk' patients from its website." (*Id.* ¶ 167.) But Defendants continued to represent to investors that Zio AT was appropriate for "high-risk" patients after the website was changed. (*Id.* ¶¶ 168, 209, 210.) Further, Mr. Day "worked extensively on the 'product side' of iRhythm" including how the Zio AT "worked 'underneath the hood,' and how it was developed." (*Id.* ¶ 177.)

In 2024, the FDA issued a second round of Forms 483, finding "'[iRhythm] routinely do[es] not report complaints and events alleging that [][CCT] personnel have misread or misinterpreted cardio-graphic arrhythmia event data.'" (*Id.* ¶ 169.) As former CCTs told Capital Forum, "'That means that if I find a life-threatening arrhythmia while doing the final report, and said life-threatening arrhythmia was not found during the wear time, that I do not mention the life[-]threatening arrhythmia I found on the final report the doctor sees.'" (*Id.* ¶ 170.) And "[a]ccording to [Former Employee] 3, the Company wanted to show doctors very 'clean' reports instead of 'ugly' reports because the Company wanted to maintain the appearance that the Zio AT gave perfect data every time." (*Id.* ¶ 85.) So, Former Employee 3 was "sometimes instructed to 'artifact' the data in question—which resulted in deletion of the data, and it would never be seen by the patient's physician in the final report." (*Id.*) "[Former Employee] 3 explained that this was clear from the training [Former Employee] 3 received; the technicians were in a tiered system where they received more autonomy as they moved up about what they could post for final Zio AT and XT reports, and the training was to give a 'cleaner' report." (*Id.*)

* * *

"[W]hen the alleged misrepresentations and fraudulent conduct were disclosed to the market … the price of iRhythm common stock fell precipitously," which resulted in Plaintiff suffering economic loss. (*Id.* ¶ 233.)

II. Procedural History

Plaintiff asserts claims under: (1) § 10(b) of the Exchange Act and SEC Rule 10b-5 as against all Defendants, and (2) § 20(a) of the Exchange Act as against Individual Defendants. (*Id.*) The putative class is defined as "all persons or entities that purchased or otherwise acquired iRhythm common stock during the Class Period." (*Id.* ¶ 239.)

Now pending before the Court are Defendants' motion for incorporation by reference and judicial notice and their motion to dismiss the SAC under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. (Dkt. No. 51, 52.) Specifically, Defendants urge Plaintiff fails to plead with particularity any statements were materially false or misleading, that any Defendant acted with requisite scienter, or that Plaintiff's loss was caused by the statements.

III. The Challenged Statements

Plaintiff organizes the allegedly false or misleading statements into four categories: (1) Zio AT's near-real-time reporting (Dkt. No. 43 ¶¶ 179-99); (2) Zio AT's appropriateness for use by high-risk populations (*id.* ¶¶ 203-11); (3) Zio AT as an MCT (*id.* ¶¶ 213-22); and (4) Zio AT's accuracy (*id.* ¶¶ 224-231). Defendants' motion also uses these categories. (*See generally* Dkt. No. 51.) The Court does not reproduce every statement below. For ease of analysis and because Plaintiff and Defendants categorize the statements in this manner, this Order refers to the statements using the above categories.

ANALYSIS

I. Motion for Incorporation by Reference and Judicial Notice

Defendants ask the Court to consider 20 exhibits and a web archive link in ruling on its motion to dismiss. (Dkt. No. 52.) While district courts generally "may not consider material outside the pleadings when assessing the sufficiency of a complaint under Rule 12(b)(6)," the doctrines of incorporation-by-reference and judicial notice are two exceptions to this rule. *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018). And though "Plaintiff does not concede that consideration of any of the 21 extrinsic sources Defendants present in their [Request for Judicial Notice] is appropriate, Plaintiff specifically objects to the improper use of Exhibits B, C, J, K, N, Q, and S to draw inferences directly disputed by the Complaint." (Dkt. No. 68 at 4.)

A. Incorporation by Reference

While "mere mention of the existence of a document is insufficient to incorporate the contents of a document, the document is incorporated when its contents are described and the document is integral to the complaint." *Tunac v. United States*, 897 F.3d 1197, 1207 (9th Cir. 2018) (cleaned up). Both conditions are satisfied for the documents containing the challenged

statements. (Dkt. Nos. 51-2 (2019 Earnings Call Transcript); 51-3 (iRhythm 2022 Response to Form 483); 51-6 (2022 Form 10-K); 51-7 (Customer Advisory Notice); 51-8 (2022 Q3 Form 10-Q); 51-9 (2023 Q1 Form 10-Q); 51-10 (May 30, 2023 Form 8-K); 51-13 (2021 Q3 Form 10-Q); 51-14 (2022 Q1 Form 10-Q); 51-16 (iRhythm Webpage); 51-17 (2022 Q2 Form 10-Q); 51-21 (November 2019 Information Pamphlet).) The Court thus incorporates these documents by reference.

The Clinical Reference Manuals ("CRMs") are not incorporated by reference, however, because the SAC does not describe their contents; instead, the CRMs are only referenced through indirect statements in various FDA documents attached to the SAC. (Dkt. Nos. 51-18 (April 2018 Clinic Reference Manual); 51-20 (April 2020 CRM); *Khoja*, 899 F.3d at 1002 ("the mere mention of the existence of a document is insufficient to incorporate the contents of a document.") (cleaned up).) But because FDA correspondence incorporated by reference refers to these CRMs, the Court considers whether to judicially notice them.

B. Judicial Notice

Judicial notice permits courts to notice an adjudicative fact if it is "not subject to reasonable dispute," meaning the fact is "generally known" or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *Khoja*, 899 F.3d at 999 (quoting Fed. R. Evid. 201). While a court may take judicial notice of matters of public record, "a court cannot take judicial notice of disputed facts contained in such records." *Id.*

Because "[c]ourts routinely take judicial notice of SEC filings in securities cases where authenticity is not disputed," *In re Apple Inc. Sec. Litig.*, No. 19-CV-02033-YGR, 2020 WL 2857397, at *6 (N.D. Cal. June 2, 2020), the Court takes notice of iRhythm's SEC filings. (Dkt. Nos. 51-5, 6, 8-9, 10, 13, 14, 17.) Likewise, because "websites and their contents may be judicially noticed," *Threshold Enters. Ltd. v. Pressed Juicery, Inc.*, 445 F. Supp. 3d 139, 146 (N.D. Cal. 2020), the Court notices iRhythm's website (Dkt. No. 51-16), the FDA website (Dkt. No. 51-19),[2] and the Wayback Machine link in the footnote of Defendants' motion. (Dkt. No. 51

[2] "Courts in this circuit routinely take judicial notice of material contained [in] government agency websites." *Santos v. Minnesota Life Ins. Co.*, 571 F. Supp. 3d 1120, 1126 (N.D. Cal. 2021) (citing

at 10 n.3.) And because conference call transcripts are "proper subjects of judicial notice," the Court also notices Docket Nos. 51-11 and 51-12. *Sneed v. Acel Rx Pharms.*, 21-cv-04353-BLF, 2022 WL 4544721, at *3 (N.D. Cal. Sept. 28, 2022) (citing *In re Extreme Networks, Inc. Sec. Litig.*, No. 15-cv-04883-BLF, 2018 WL 1411129, at *10 (N.D. Cal. Mar. 21, 2018)).

The CRMs are also judicially noticeable. (Dkt. Nos. 51-18 (April 2018 Clinic Reference Manual); 51-20 (April 2020 CRM).) First, Plaintiff does not dispute their authenticity. Second, Defendants show other incorporated by reference or judicially noticed documents describe these documents as part of Zio AT's labeling. (*See, e.g.* Dkt. Nos. 51-3, 51-7.) Given the CRMs were publicly distributed and widely available, the Court judicially notices the CRMs from April 2018 and April 2020. Insofar as the parties dispute the truth of facts stated within the CRMs—or any of the judicially noticed documents—the Court takes judicial notice of them "not for the truth of their contents," but only for non-hearsay purposes, such as "to determine the information available to the market." *Weston v. DocuSign, Inc.*, 669 F. Supp. 3d 849, 872 (N.D. Cal. 2023).

II. Motion to Dismiss

Section 10(b) of the Exchange Act makes it unlawful "to use or employ, in connection with the purchase or sale of any security, … any manipulative or deceptive device or contrivance" in contravention of SEC regulations. 15 U.S.C. § 78j(b). Under Rule 10b-5, promulgated under the authority of section 10(b), it is unlawful "[t]o make any untrue statement of fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b–5(b). "To be viable, a claim brought under § 10(b) and Rule 10b–5 must contain six essential elements:

> (1) a material misrepresentation or omission by the defendant;
> (2) scienter;
> (3) a connection between the misrepresentation or omission and the purchase or sale of a security;
> (4) reliance upon the misrepresentation or omission;
> (5) economic loss; and
> (6) loss causation."

Daniels-Hall v. Nat'l Educ. Ass'n, 629 F.3d 992, 998-99 (9th Cir. 2010)).

Retail Wholesale & Dep't Store Union Loc. 338 Ret. Fund v. Hewlett-Packard Co., 845 F.3d 1268, 1274 (9th Cir. 2017).

To survive a motion to dismiss, a Section 10(b) claim must satisfy three pleading standards. First are the general pleading requirements of Federal Rule of Procedure 8(a), mandating a short and plain statement of the claim. Second, the complaint must "state with particularity the circumstances constituting fraud." Fed. R. Civ. Proc. 9(b). The specificity is intended "to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Neubronner v. Milken*, 6 F.3d 666, 671 (9th Cir. 1993). Third, the complaint must satisfy the requirements of the Private Securities Litigation Reform Act ("PSLRA"), which mandate "plead[ing] with particularity both falsity and scienter." *Gompper v. VISX, Inc.*, 298 F.3d 893, 895 (9th Cir. 2002) (cleaned up). To do so, the complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." *Id.* (quoting 15 U.S.C. § 78u–4(b)(1).)

A. False or Misleading Statements

A statement is false if it "directly contradict[s] what the defendant knew at that time." *Weston Fam. P'ship LLP v. Twitter, Inc.*, 29 F.4th 611, 619 (9th Cir. 2022). "Even if a statement is not false, it may be misleading if it omits material information." *Khoja*, 899 F.3d at 1008-09. Put another way, "a statement is misleading if it would give a reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists." *Hewlett-Packard*, 845 F.3d at 1275.

Defendants argue Plaintiff fails to adequately allege how any statement is false or misleading. (Dkt. No. 51.)

1. High Risk/At-Risk Patients

Plaintiff alleges Defendants' statements that the Zio AT was appropriate for "high-risk"

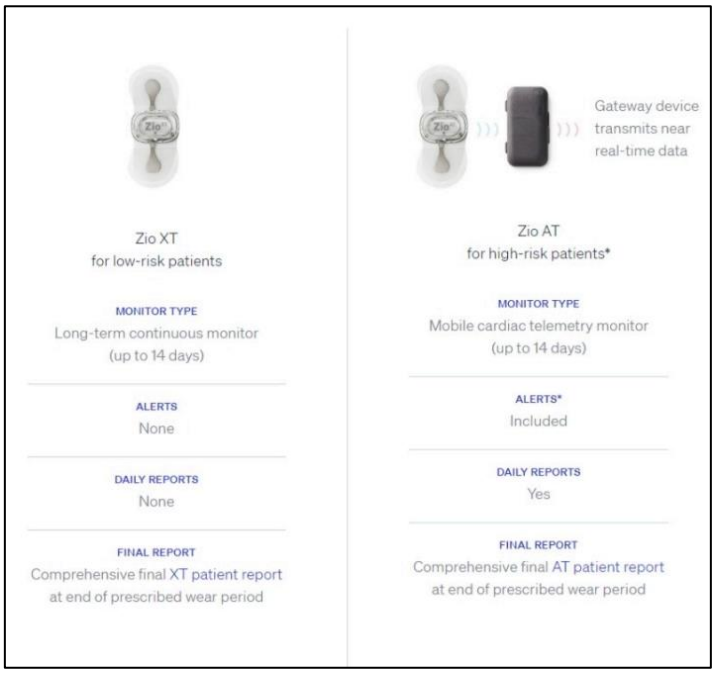
and "at-risk" patients were false or misleading.[3]

a) "High Risk" is Capable of Being False or Misleading

Preliminarily, drawing all reasonable inferences in Plaintiff's favor, the term "high risk" is not so vague that it is "impossible to evaluate the truth or falsity of" these statements. *In re Cloudera, Inc.*, 121 F.4th 1180, 187 (9th Cir. 2024). The 2023 FDA Warning Letter found "High risk patients need near real-time monitoring because they are more likely to have a life-threatening arrhythmia, which requires timely treatment to prevent serious injury or death." (Dkt. No. 43-2 at 2.) And the Company represented "'Zio AT is appropriate for the smaller percentage of the population that requires timely notification.'" (Dkt. No. 43 ¶ 57.) The meaning of "high risk" is further clarified by graphics iRhythm used to market and promote the Zio AT. In June and August 2022 presentations to investors, the Company provided the following graphic specifically identifying high risk patients:

(*Id.* ¶ 57.) And as late as August 10, 2022, iRhythm displayed the following visual on its website regarding "high-risk patients":

[3] Not every allegedly false statement in this category uses the words "at-risk" or "high-risk." The Court uses the term "high-risk" as shorthand for all alleged statements the parties placed into this category.



(Dkt. No. 51-16 at 2.) In SEC filings, iRhythm similarly describes its target patient population:

> Our goal is to be the leading provider of ambulatory cardiac monitoring for patients at risk for arrhythmias. … Zio XT System, which provides continuous long-term ECG monitoring, is appropriate for the majority of patients that require ambulatory cardiac monitoring while Zio AT System, which includes near real-time monitoring, is appropriate for more acute patients that require timely notification.

(Dkt. No. 51-6 at 15.) Based on the Company's own statements, "high-risk" or "at-risk" meant patients who had a risk of arrhythmias and so were likely to need near-real-time monitoring for their condition. This is how the FDA understood the term: "High risk patients need near real-time monitoring because they are more likely to have a life-threatening arrhythmia, which requires timely treatment to prevent serious injury or death." (Dkt. No. 43-2 at 3; *see also id.* at 4 ("'Near real time cardiac event monitoring' implies that the device provides monitoring for high-risk patients that require clinically actionable, timely notification of life-threatening arrythmias to prevent serious injury or death.").)

Defendants liken the "High Risk Patients" statements to the vague statements in *In re Siebel Sys., Ins. Sec. Lit.*, 04-cv-00983-CRB, 2005 WL 3555718, at *3 (N.D. Cal. Dec. 28, 2005) and *In re Cloudera*, 121 F.4th at 187. In *In re Siebel*, the court held the defendant's claim that its internet-based software was "a highly accurate sales forecasting tool" was "simply too vague to be

actionable." *Id.* at *3. The court reasoned the "plaintiffs ha[d] not alleged facts that show that the statement that Siebel was not a highly accurate forecasting tool was false: highly accurate compared to what?" *Id.* Similarly, in *In re Cloudera*, the court held statements that the defendant's product was "cloud-native," provided "native public cloud services," and had "hybrid cloud capabilities," were "impossible to evaluate" as to their truth or falsity." *In re Cloudera*, 121 F.4th at 187. There, the plaintiff failed to define these terms even though "experts in cloud computing acknowledge that the meaning of the term 'cloud' is, well, cloudy." *Id.* at 1188 (citations omitted). In sum, the statements lacked "specificity that would allow a claim about a 'cloud-native' platform to be provably false." *Id.* at 1189.

But here, based on the SAC's allegations, the high-risk patient statements are susceptible to a plain meaning that can be proved true or false. Unlike *In re Siebel*, Defendants answer the question "high[] [risk] compared to what?", *In re Siebel*, 2005 WL 3555718, at *3, as the Zio AT was marketed to patients who are at higher risk for "life-threatening arrhythmia, which requires timely treatment to prevent serious injury or death." (Dkt. No. 43-2 at 3.) And unlike the statements in *In re Cloudera* that lacked specificity, the statements here are concrete, for example, through iRhythm's juxtaposition of the Zio AT's targeted patient population as compared to the Zio XT's patient population. (Dkt. No. 51-6 at 15.) So, the statements can be proven true or false based on the meaning iRhythm gave them.

b) The SAC Plausibly Pleads Falsity

Second, Plaintiff's allegations support a plausible inference the "high-risk" statements were false or misleading. As noted above, a reasonable investor would have understood the Zio AT was appropriate for "[h]igh risk patients [who] need near real-time monitoring because they are more likely to have a life-threatening arrhythmia, which requires timely treatment to prevent serious injury or death." (Dkt. No. 43-2 at 3.) Plaintiff alleges "the Zio AT stopped transmitting *any* telemetry data, and accordingly a provider would not learn of even serious cardiac events until a report was generated at the end of the wear-period" (Dkt. No. 43 ¶ 200.) And according to Former Employee 3—a "Zio AT technician from before the Class Period through November 2022,"—it took "four hours for any arrhythmia events transmitted from the Zio AT to show up in

a 'queue' for technicians' review" during their tenure. (*Id.* ¶ 75.) The plausibly pled transmission limit and lag time issues support an inference the product was not appropriate for patients who "need near real-time monitoring because they are more likely to have a life-threatening arrhythmia, which requires timely treatment to prevent serious injury or death." (Dkt. No. 43-2 at 3.) As the FDA observed, "when the transmission limit is hit, the device can no longer provide near-real time monitoring for high-risk patients." (*Id.* at 5.) This inference is further supported by the two deaths noted in the FDA's 2022 Form 483, which were caused by reportable events while the patients were wearing the Zio AT, but which the device did not report until much later. (Dkt. No. 43-1 at 2-3.) And iRhythm investigated and found, in these instances "the device had reached its upper limit of notifications that can be transmitted." (*Id.* at 3.)

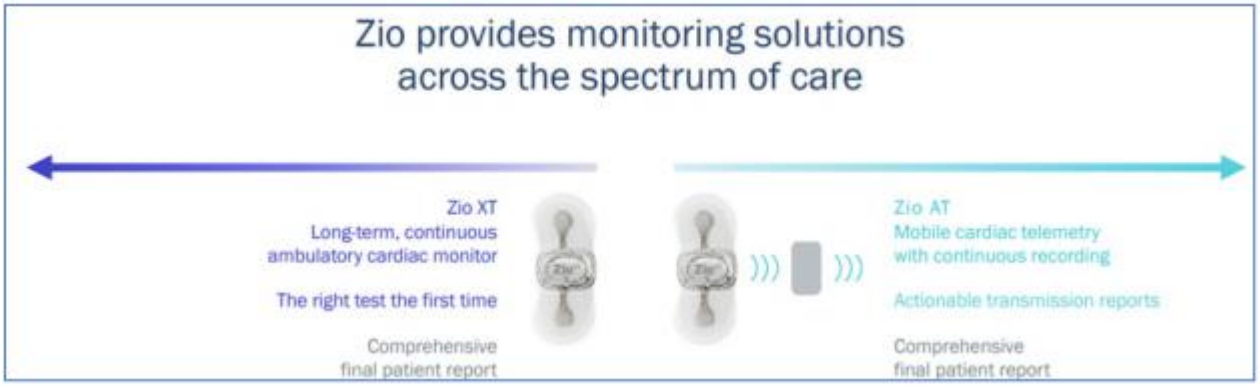
Defendants identify statements made in CRMs as well as iRhythm's website to insist that at all times iRhythm disclosed the Zio AT was inappropriate for critical care patients, and therefore their "high risk" statements could not be untrue. In particular, the iRhythm website had an asterisk on the words "high-risk patients," which led the reader to a caveat at the bottom of the page: "Zio XT and Zio AT are contraindicated for critical care patients." (Dkt. No. 51-16 at 2.) And the CRMs indicated the Zio AT "is not intended for use on critical care patients." (Dkt. No. 51-20 at 6.) The CRMs further warn the Zio AT should not be used for patients "with known history of life[-]threatening arrhythmias," or "when real-time or in-patient monitoring should be prescribed." (*Id.*) But these statements do not, as a matter of undisputed fact, make the statements that the Zio AT was appropriate for use with "at-risk" or "high-risk" patients true or not misleading. The FDA warned that labelling the product as appropriate for "high-risk" patients "suggests that the device is intended for a new patient population—high risk patients[] … [who] need near real-time monitoring because they are more likely to have a life-threatening arrhythmia." (Dkt. No. 43-2 at 3.)[4] Further the cited CRMs do not demonstrate what later CRMs—during the class period—disclosed. And while iRhythm made statements about

[4] Defendants also argue the FDA's 2023 Warning Letter does not show the high-risk statements are untruthful, but rather that iRhythm is improperly describing patients "in terms of risk." (Dkt. No. 51 at 16.) At the motion to dismiss stage, the Court must draw reasonable inferences in Plaintiff's favor, but Defendants' argument requires the Court to draw inferences in their favor.

contraindication for critical care patients, the cited materials do not define "critical care patients"; nor do they necessarily indicate the device is inappropriate for patients requiring near-real-time monitoring. (Dkt. Nos. 51-16; 51-20.) So, Defendants' argument that these disclosures show the "high risk" statements did not mislead as a matter of law is unpersuasive.[5]

c) Across the Spectrum of Care

Finally, Plaintiff challenges statements that the Zio AT provides monitoring "across the spectrum of care" (Dkt. No. 43 ¶¶ 208-09), but these statements are too vague to be actionable. While the statements about "high-risk" and "at-risk" patients are tied to specific risks and draw comparisons to the Zio XT, the "spectrum of care" statements do not specify which patients are included or excluded in the Zio AT portion of the spectrum.



(*Id.* ¶ 209.) Like the statements in *In re Cloudera*, the "spectrum of care" statements lack the "specificity that would allow a claim about a [spectrum of care] to be provably false." *In re Cloudera*, 121 F.4th at 1189.

So, Plaintiff plausibly pleads the "high-risk" statements are materially false, except for the "spectrum of care" statements.

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[5] Plaintiff also characterizes Defendants' argument as a "truth-on-the-market" defense which "is not available at the motion to dismiss stage." *Boston Ret. Sys. v. Uber Techs., Inc.*, No. 19-cv-06361-RS, 2020 WL 4569846, at *6 (N.D. Cal. Aug. 7, 2020) (citing *In re Thoratec Corp. Sec. Litig.*, No. 04-cv-03168, 2006 WL 1305226, at *4 (N.D. Cal. May 11, 2006) (citing *Asher v. Baxter Int'l Inc.*, 377 F.3d 727, 734 (7th Cir. 2004))). But Defendants do not argue the materiality of the misstatement but rather the truthfulness of the same. Because Defendants' falsity argument is unpersuasive, the Court does not hold Defendants improperly made a truth-on-the-market defense at this stage and does not deny their motion on this ground.

2. Near Real Time / Timely Transmission

Plaintiff alleges Defendants misrepresented the timeliness of arrhythmia data transmissions to physicians when they represented the Zio AT provided "timely transmission" and "near real-time" notifications of arrhythmia events "during the wear period." (Dkt. No. 43 ¶¶ 179-202.) The Court refers collectively to these statements as the "timing" statements.

The timing statements are plausibly pled to be false or misleading. Plaintiff alleges these statements were false because: (1) after the transmission limit, events were no longer reported; and (2) there was a lag time between when the arrhythmia data was collected by the Zio AT and when it was reviewed by CCTs. (*Id.* ¶ 200.)[6] As discussed above, Plaintiff provides ample specific and plausible factual allegations supporting these allegations.

Defendants insist "near real-time" and "timely" are too vague to be actionable. But if arrhythmia events are *never* reported, regardless of how one reads the statements, the transmissions are not timely. (Dkt. No. 43 ¶ 8 ("As the FDA made public at the end of the Class Period, iRhythm received 'critical customer complaints' beginning in 2019—or two years before the Class Period began—indicating that scores of patients suffered serious arrhythmias while wearing their Zio ATs but, having unknowingly hit the transmission limit, their doctors received zero notifications.").) And, again, the 2023 FDA Warning Letter states: "'Near real time cardiac event monitoring' implies that the device provides monitoring for high-risk patients that require clinically actionable, timely notification of life-threatening arrythmias to prevent serious injury or death." (Dkt. No. 43-2 at 4.) But owing to the transmission limit "the device is only able to transmit 100 patient-triggered and 500 automatically detected arrhythmia events. Once the transmission limit is hit, the device can no longer be used for its intended purpose." (*Id.* at 5; *see Oklahoma Police Pension and Ret. Sys. v. LifeLock, Inc.*, 780 F. App'x 480, 483 n.2 (9th Cir.

[6] Plaintiff alleges falsity because "iRhythm did not notify patients when their registration was incomplete, patients were often unaware that they had not completed iRhythm's registration requirements." (Dkt. No. 43 ¶ 202). But at oral argument, Plaintiff argued falsity arose by iRhythm hiding that patients needed to complete registration before any transmissions were made. The FDA Form 483 referencing the registration issue makes no mention of the registration requirement being hidden from users or doctors. (Dkt. No. 43-1 at 3-4.) So, this theory of falsity is not sufficiently pled and the Court does not consider it in its decision.

2019) (holding statements that the product offered "proactive, near real-time, actionable alerts" were "sufficient to allege violations of Section 10(b).")).

Defendants cite this Court's opinion in *Bhangal* for the proposition that the timeliness statements are not actionable because Defendants never represented "the Zio AT *always* provided 'timely' or 'near real-time' transmission." (Dkt. No. 51 at 17-18 (citing *Bhangal v. Hawaiian Elec. Indus., Inc.*, 23-cv-04332-JSC, 2024 WL 4505465, at *9 (N.D. Cal. Oct. 15, 2024).) And because the Zio AT was "capable" of timely transmissions, Defendants insist their statements about transmission timeliness could not be false. (Dkt. No. 51 at 17.) In *Bhangal*, however, the Court held the defendant's statement that it replaced traditional power lines in "targeted areas prone to vegetation-related outages" meant the statement could only be false if the defendant had not replaced powerlines in "targeted areas prone to vegetation-related outages." *Bhangal*, 2024 WL 4505465, at *9. Because the plaintiffs had not alleged powerlines had not been replaced in these targeted areas, and had not even identified the "targeted areas prone to vegetation-related outages," the allegations "[fell] short of a plausible inference of falsity." *Id.* at *10. Here, by contrast, and drawing inferences in Plaintiff's favor, iRhythm did not represent the Zio AT would only sometimes or in certain specific circumstances function to provide timely notifications; so, *Bhangal* is inapposite.

Defendants further argue the transmission limit issue is immaterial because Plaintiff does not plead details showing the transmission limit materially interfered with the Zio AT's ability to provide near-real-time transmissions. (Dkt. No. 51 at 18.) Specifically, Defendants identify iRhythm's September 2022 response to the 2022 FDA Form 483, (Dkt. No. 51-3), where Mr. Blackford addressed the transmission limit issue: "The Zio AT design is constrained due to finite battery capacity available on the patch's lithium coin cell batteries [] and the lithium-ion battery pack [] in the gateway." (*Id.* at 38.) So, "[t]o ensure the battery can last the wear period, the design entails setting maximum thresholds for transmissions (the asymptomatic transmissions are limited to 500; and the symptomatic transmissions are limited to 100)." (*Id.*) According to iRyhym's response, it conducted an analysis of data from June 2019 to August 2022 and found 2,955 devices reached the asymptomatic transmission limit (2.46% of devices) and 1,046 devices

reached the symptomatic transmission limit (0.87% of devices). (*Id.* at 41.)

But, drawing all reasonable inferences in Plaintiff's favor, the Court cannot conclude, as a matter of law, that these numbers mean the Zio AT "rarely" hit the transmission limit in a way that did not affect the truthfulness of its statements. Indeed, the FDA's Warning Letter—sent eight months after receiving iRhythm's response—found: "[T]he customer complaints reviewed during the inspection reveal that the device was hitting the transmission limit *more often than expected*. When the transmission limit is reached more often than expected, it introduces a nonconformance." (Dkt. No. 43-2 at 6 (emphasis added).) And the Company's responses to the FDA also indicate "[then-]current procedures followed by Customer Care do not ensure the healthcare providers who receive the calls from Customer Care are aware of the consequences of a device reaching the maximum transmission limits and the impact to the patients." (Dkt. No. 51-3 at 42.) The Court must "interpret the allegations and factual disputes in favor of the plaintiff at the pleading stage." *Khoja*, 898 F.3d at 1014 (citations omitted). So, Defendants' evidence does not defeat materiality or falsity as pled in the SAC.[7]

Finally, Defendants argue Former Employee 3's statements about lag time are insufficiently credible to support a PSLRA claim. "If a plaintiff relies upon a [Confidential Witness,] CW[,] to show the falsity of the statements alleged, the CW must be described with sufficient particularity to establish his reliability and personal knowledge, and the statements reported by the CW must be indicative of scienter." *Scheller v. Nutanix, Inc.*, 450 F. Supp. 3d 1024, 1031 (N.D. Cal. 2020) (citing *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 995 (9th Cir. 2009)). So, courts look to the particularity of the pleadings to determine the likelihood "a person in the position occupied by the source would possess the information alleged" and that the

[7] Defendants also argue in a footnote that all statements to the effect that the Zio AT made "transmissions during the wear period," provided "more continuous communication of results back to the physician," and transmits arrhythmia events "to a monitoring center for review and reporting according to physician-selected notification criteria," are not false or misleading because Plaintiff does not allege the Zio AT does not do these things. (Dkt. No. 51 at 17 n.9.) This argument fails, however, because Plaintiff's allegations regarding the transmission limit are that "at a certain point, the device simply stopped transmitting data." (Dkt. No. 43 ¶ 1.) Plaintiff alleges the above statements are misleading because there are instances when no transmissions at all are made during the period, specifically, when the transmission limit is reached.

alleged witness "ha[d] personal knowledge of the events they report." *Zucco*, 552 F.3d at 995 (citations omitted). Here, Plaintiff alleges Former Employee 3 was "a former iRhythm Zio AT [CCT] technician from before the Class Period through November 2022." (Dkt. No. 43 ¶ 73.) And Former Employee 3 spoke from personal knowledge about the lag time he witnessed while working for iRhythm. (*Id.*) Plaintiff alleges with specificity Former Employee 3's personal observations as a CCT reviewing incoming Zio AT data. (*Id.* ¶ 76.) As alleged, CCTs such as Former Employee 3 "conduct[ed] 'a final quality assessment review of the data,' and reports [were then] issued to doctors 'following observations by' these technicians." (*Id.* ¶ 44.) Accordingly, Plaintiff adequately alleges Former Employee 3 both "ha[d] personal knowledge" of the lag time issue, and that Former Employee 3 was in a position where he "would possess the information alleged." *Zucco*, 552 F.3d at 995 (citations omitted).

So, for these reasons, Plaintiff plausibly pleads with particularity Defendants' timing statements were false or misleading.

3. MCT Device

Plaintiff alleges statements that the Zio AT is an MCT device were false or misleading because the statements implied "this device is intended for high-risk patients and near real-time monitoring." (Dkt. No. 43 ¶ 223.) But Plaintiff fails to provide a definition for an MCT device supported by well-pleaded, particular factual allegations. *See In re Cloudera*, 121 F.4th at 1188. The SAC alleges a definition of MCT device derived from the Mayo Clinic's website: "'a continuous cardiac monitoring test that uses the mobile device to monitor cardiac activity,' the key characteristics of which are that the device 'provides near-real-time data, the ability to analyze the patient's heart rhythm, and overview monitoring by certified technicians 24/7 in order to alert a patient's care team of critical events as they are observed.'" (Dkt. No. 43 ¶ 45.) But the SAC does not include any factual allegations that support an inference MCT meant a device with the particular characteristics the Mayo Clinic identifies, or that investors would have understood MCT to mean the Mayo Clinic's definition. And Plaintiff does not allege MCT has a plain meaning or that the term's meaning is well-understood or established so that the Company's statements are provably false. *See In re Cloudera*, 121 F.4th at 1188-89. Plaintiff fails to substantiate its

definition of MCT as including the "near-real-time" and "continuous" requirements, but Plaintiff "must plead facts that will support this crucial premise in order to satisfy the PSLRA[]." *Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1193 (9th Cir. 2021).

So, the Court GRANTS Defendants' motion as to Defendants' MCT statements.

4. Accuracy

Finally, Plaintiff alleges statements that the Zio AT was "highly accurate," "[a]ble to diagnose heart rate arrhythmias with the accuracy of a panelist of cardiologists," and delivered "superior clinical accuracy" were false or misleading. (Dkt. No. 43 ¶¶ 224-226.) As support, Plaintiff relies on FDA documents about customer complaints, confidential witness statements, and a news article. The FDA's July 2024 Form 483 observed iRhythm had received "approximately 4,014 complaints related to" the CCTs from May 2022 through July 2024, "including issues/events related to CCT personnel misreading arrhythmia data and providing such misclassified data to end users for diagnosis purposes." (Dkt. No. 43-3 at 2.) And the FDA also found "iRhythm failed to include appropriate 'data input sources'—including false positive arrhythmia events and 'duplicated algorithm miss events'—in the process iRhythm uses 'for algorithm functionality monitoring.'" (Dkt. No. 43 ¶ 171.) This included instances when the Zio AT's algorithm "misinterpreted/misread" arrhythmia events. (Dkt. No. 43-3 at 5.) Plaintiff also highlights a Capitol Forum article interviewing anonymous CCTs who attested they "'were told it is "important that the final report match what the patient experienced during wear time"'—even if it required that the final report omit lift[*sic*]-threatening arrhythmias." (Dkt. No. 43 ¶ 232.) Finally, Plaintiff cites Former Employee 3, who explained "the Company wanted to show doctors very 'clean' reports instead of 'ugly' reports, and when a report was 'ugly,' technicians were sometimes instructed to 'artifact' the data in question—which resulted in deletion of the data, and it would never be seen by the patient's physician in the final report." (*Id.*) These allegations plausibly allege the falsity of the Company's accuracy statements.

Defendants' attack on Plaintiff's use of customer complaints and confidential witness statements as unreliable and non-probative is unavailing. In *In re Netflix*, the court held the plaintiffs' reliance on amorphous customer complaints did not demonstrate the falsity of

statements regarding "improved service." *In re Netflix, Inc. Sec. Litig.*, No. 04-cv-02978-FMS, 2005 WL 1562858, at *7 (N.D. Cal. June 28, 2005). Here, by contrast, the FDA found 4,014 complaints from May 2022 through July 2024 regarding the CCTs, including complaints about the technicians "misreading arrhythmia data and providing such misclassified data to end users." (Dkt. No. 43-3 at 5.) Further, the FDA observed the Zio AT Zeus System Software algorithm also misclassified or misread arrhythmia events. (*Id.*) These allegations are more than the vague allegations in *In re Netflix* when the plaintiffs merely alleged "the existence of several customer complaints" meant the company's service "was much worse than represented." *In re Netflix*, 1562858, at *7. And, together with Former Employee 3's allegations about CCTs altering data, these statements lend credence to the Capitol Forum article's confidential witness statements. Further, while Plaintiff does not allege which specific reports were "ugly" or "clean," Former Employee 3's allegations that "technicians were sometimes instructed to 'artifact' the data in question, which resulted in deletion of the data," sufficiently pleads that CCTs were not always providing accurate data to physicians. (Dkt. No. 43 ¶ 232.)

Plaintiff therefore plausibly pleads with particularity Defendants' accuracy statements were false or misleading.

B. Scienter

Defendants also argue Plaintiff does not plausibly allege each Individual Defendant knew of information contradicting the challenged statements and thus, Plaintiff fails to plead scienter.

"[A] securities fraud complaint must 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *New Mexico State Inv. Council v. Ernst & Young LLP*, 641 F.3d 1089, 1095 (9th Cir. 2011) (quoting 15 U.S.C. § 78u–4(b)(2)(A)). "A complaint can plead scienter by raising a strong inference that the defendant possessed actual knowledge or acted with deliberate recklessness." *Id.* The court first determines whether any allegations, standing alone, "are sufficient to create a strong inference of scienter." *Zucco*, 552 F.3d at 992. If no individual allegations are sufficient, the court "conduct[s] a 'holistic' review of the same allegations to determine whether the insufficient allegations combine to create a strong inference of intentional conduct or deliberate recklessness." *Id.* In reviewing

the sufficiency of a complaint's allegations, the court must "take into account plausible opposing inferences." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 323 (2007). "A complaint will survive… only if a reasonable person would deem the inference of scienter cogent and *at least as compelling as any opposing inference one could draw from the facts alleged*." *Id.* (emphasis added) "Where, as here, the plaintiffs seek to hold individuals and a company liable on a securities fraud theory," the plaintiff must "allege scienter with respect to each of the individual defendants." *Oregon Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 607 (9th Cir. 2014). "[T]he ultimate question is whether the defendant knew his or her statements were false, or was consciously reckless as to their truth or falsity." *Gebhart v. SEC*, 595 F.3d 1034, 1042 (9th Cir. 2010).

Plaintiff bases its scienter allegations on: (1) iRhythm's 2022 FDA response, authored and signed by Mr. Blackford; (2) Defendants' knowledge of and access to the FDA correspondence; (3) Mr. Blackford and Mr. Devine's membership on iRhythm's Compliance Committee; (4) the existence of numerous complaints; (5) identification of Mr. Day in DOJ-subpoenaed documents; and (6) the Zio AT being a core product for the Company. (Dkt. No. 66 at 26-29.)

1. Mr. Blackford

Plaintiff plausibly alleges Mr. Blackford's scienter. He signed iRhythm's responses to the FDA's 2022 Form 483 in which he attested "the wireless transmission limit is an essential design constraint." (Dkt. No. 51-4 at 33.) Further, the 2023 Warning Letter that followed was addressed to him. (Dkt. No. 43-2.) And Mr. Blackford signed the SEC Forms 8-K and 10-Q which reported on FDA correspondence, including the 2024 Form 483. (Dkt. No. 43 ¶ 146.) Given Mr. Blackford's admitted involvement in the internal investigation into the FDA's Form 483 claims, and his knowledge of the transmission limit issues, Plaintiff plausibly alleges "specific information [was] conveyed to [him] and related to the fraud," at least as of the date of the FDA investigations in July of 2022. (Dkt. No. 43-1); *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1068 (9th Cir. 2008).[8]

[8] Plaintiff does not sufficiently allege Mr. Blackford had scienter prior to this date. Indeed, Plaintiff's scienter allegations do not predate the July 2022 investigation. Mr. Blackford did not

And Plaintiff's allegations lead to a "strong inference" of culpability which is "cogent and compelling in light of other explanations." *Tellabs*, 551 U.S. at 324. When "compar[ing] the malicious and innocent inferences cognizable from the facts pled in the complaint," "the malicious inference is at least as compelling as any opposing innocent inference." *Zucco*, 552 F.3d at 991. Specifically, Plaintiff alleges the FDA, in its Forms 483 and Warning Letter, notified iRhythm and Mr. Blackford of issues which contradicted his assertions about the Zio AT's capabilities. (Dkt. No. 43 ¶ 158.) The FDA found iRhythm knew of the transmission limit issue since at least 2019, and accuracy-related issues since at least 2017. (*Id.*) Further, the SAC alleges iRhythm removed reference to Zio AT's appropriateness for "high-risk" patients on its website, (*id.*) but thereafter continued to make statements suggesting the Zio AT was appropriate for high risk patients, contradicting the FDA's findings. (*Id.* ¶¶ 168, 209, 210.) Plaintiff also alleges the FDA found in 2024 that iRhythm "routinely do[es] not report complaints and events alleging that [its] [CCT] personnel have misread or misinterpreted cardio-graphic arrhythmia event data." (*Id.* ¶ 169.) Taken together, these and other allegations lead the Court to conclude "the malicious inference is at least as compelling as any opposing innocent inference." *Zucco*, 552 F.3d at 991.

Defendants insist these and other allegations simply show "an innocent lack of clarity in iRhythm's marketing that was quickly, and publicly, remedied." (Dkt. No. 51 at 25.) As support, they cite *Aramic*, when the court held the plaintiffs failed to adequately allege scienter when they identified a Form 483 and subsequent response to allege scienter. *Aramic*, 2024 WL 1354503, at *14 ("Indeed, the Form 483 is not a final determination by the FDA, and although evidently [the defendant's] Form 483 Response did not satisfactorily address the FDA's concerns, [the defendants'] misreading of what the FDA required does not show conscious intent to deceive or an

become the CEO of iRhythm until 2021 and he was not at the Company prior to becoming CEO. (Dkt. No. 43 ¶ 30.) Plaintiff does not provide any allegations of *when* he would have become aware of the transmission limit issue prior to this date. Indeed, Plaintiff acknowledges the timing issue in its opposition brief: "[a]t minimum, Defendants gained actual knowledge of these issues upon receipt of the 2022 Form 483 on August 12, 2022." (Dkt. No. 66 at 26.) And while Mr. Blackford was on the Company's Compliance Committee, as is explained *infra*, Plaintiff fails to allege membership in the Committee would have actually given Mr. Blackford knowledge of particular customer complaints. Further, Plaintiff does not allege when Mr. Blackford first joined the Committee.

'extreme departure from the standards of ordinary care.'") But here, Plaintiff's factual allegations support an inference that after Mr. Blackford was aware of the transmission and inaccuracy issues and the resulting inappropriateness of the Zio AT for patients requiring near-real time transmission, he and iRhythm continued to tout the device as appropriate for such patients. (*See e.g.* Dkt. No. 43 ¶¶ 184-199.) Further drawing inferences in Plaintiff's favor, iRhythm's public disclosures of FDA correspondence were not made "quickly," and even as iRhythm took corrective measures to change its labeling regarding the transmission limits, public statements about the transmission limit issue were vague at best. (*See, e.g.* Dkt No. 43 ¶¶ 12-114, 124-25, 137.) That iRhythm responded swiftly to the FDA does not undermine an inference of scienter when the FDA found, despite numerous responses, iRhythm had failed to take sufficient corrective action. (Dkt. No. 43-2 at 3.)[9]

Because of Mr. Blackford's involvement in iRhythm's Response to the first FDA Form 483, his knowledge of the Warning Letter, and his statements showing knowledge of the Forms 483, the Court, drawing all inferences in Plaintiff's favor, holds Plaintiff adequately alleges scienter as to him beginning in July 2022.

2. Remaining Individual Defendants

Plaintiff fails to sufficiently allege scienter as to any other Individual Defendant.

As to Mr. Devine, Plaintiff alleges Mr. Devine served on iRhythm's Compliance Committee, which "received reports on these complaints on a quarterly basis." (Dkt. No. 43 ¶ 162.) Notably, other than conclusory allegations that the number of complaints would have been escalated to all executives, membership in the Compliance Committee is the only allegation that could lead to an inference of Mr. Devine's knowledge of the complaints (outside the Forms 483). But Plaintiff does not allege what years Mr. Devine served on the Compliance Committee or what

[9] Defendants also argue that a scienter inference is undermined because they increased their iRhythm holdings during the Class Period. (Dkt. No. 51 at 25 (citing *Applestein v. Medivation, Inc.*, 861 F. Supp. 2d 1030, 1043 (N.D. Cal. 2012).) But Defendants do not respond to Plaintiff's counterargument that "nearly 98% of these shares were acquired through stock option grants as part of compensation packages—not through open-market purchases." (Dkt. No. 66 at 31.) Furthermore, "the lack of stock sales by a defendant is not dispositive as to scienter." *No. 84 Emp.-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 944 (9th Cir. 2003).

"reports on the complaints" looked like. Indeed, beyond alleging the reports were "on these complaints," (*id.*), Plaintiff does not allege any details about these supposed reports. *See Nguyen v. Endologix, Inc.*, 962 F.3d 405, 417 (9th Cir. 2020) (declining to credit confidential witness statement referencing "incident reports" when the complaint "d[id] not plead any details about these reports"); *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1063 (9th Cir. 2014) (declining to credit confidential witness statements that "d[id] not detail the actual contents of the reports the executives purportedly referenced or had access to").

Mr. Day was "Executive Vice President of Research and Development" and was identified in the Company's Form 10-K for 2021 as "critical for managing our research and development programs." (Dkt. No. 43 ¶ 177.) He was further identified as "an author and a writer on certain technical documents that show the limitations of [the Zio AT]." (Dkt. No. 76 at 34.) These documents lead to a plausible allegation Mr. Day was intimately involved in the development of the Zio AT, which, as noted above, was made with "the wireless transmission limit as an essential design constraint." (Dkt. No. 51-4 at 33.) But, the only statement Plaintiff alleges Mr. Day made does not plausibly demonstrate any falsity or misrepresentation. (Dkt. No. 43 ¶ 188 ("The Zio AT device has a Bluetooth capability that enables that kind of timely monitoring capability of the platform, the Zio XT does not.").) In other words, while the SAC adequately pleads Mr. Day's scienter, he only made one statement which itself is not actionable. *See Janus Cap. Grp., Inc. v. First Derivative Traders*, 564 U.S. 135, 141 (2011) ("To be liable [under Rule 10b-5], therefore, [a person] must have 'made' the material misstatements[.]").

Plaintiff also intends to impute knowledge of all issues to the remaining Individual Defendants without alleging each Defendant actually knew of or accessed the FDA Forms 483 and Warning Letter. Plaintiff does not allege specific facts showing how these Defendants would have been aware of the FDA's findings. Plaintiff seemingly relies on the "core operations" theory to impute knowledge of this correspondence to all Defendants. Under this theory, "scienter may be imputed 'based on the inference that key officers have knowledge of the 'core operations' of the company." *Mulligan v. Impax Lab'ys, Inc.*, 36 F. Supp. 3d 942, 969 (N.D. Cal. 2014) (quoting *Reese v. Malone*, 747 F.3d 557, 575 (9th Cir. 2014) (overruled in part on other grounds by *City of*

Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., 856 F.3d 605 (9th Cir. 2017))). But the core operations theory also requires "[a]llegations regarding management's role in a corporate structure and the importance of the corporate information about which management made false or misleading statements may also create a strong inference of scienter when made in conjunction with detailed and specific allegations about management's exposure to factual information within the company." *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 785 (9th Cir. 2008). Plaintiff's allegations about each Individual Defendants' role in the Company is limited to their job titles, and as such is insufficient to impute scienter. *See Aramic*, 2024 WL 1354503, at *15 (finding the plaintiffs failed to make "detailed and specific allegations" supporting an inference that the defendants were intimately involved in the FDA's approval process for the product to impute knowledge under the core operations doctrine where they only alleged the defendants had "some meetings" about the approval process).

So, Plaintiff fails to allege, with particularity, scienter as to any other Individual Defendant.

* * *

Thus, even when "tak[ing] into account plausible opposing inferences[] … a reasonable person would deem the inference of scienter cogent" as to Mr. Blackford, and "at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 323.[10] But, because Plaintiff fails to allege scienter with respect to the remaining Individual Defendants, the Court DISMISSES without prejudice Plaintiff's claims as to Mr. Bobzien, Mr. Devine, Mr. Patterson, Mr. Day and Mr. Turakhia.

C. Whether Plaintiff Properly Pleads Loss Causation

"[T]he requirements for pleading loss causation are 'not meant to impose a great burden upon a plaintiff.'" *In re Zynga Inc. Sec. Litig.*, 12-cv-04007-JSW, 2015 WL 1382217, at *7 (N.D.

[10] The Court imputes Mr. Blackford's scienter on iRhythm. *See In re ChinaCast Educ. Corp. Sec. Litig.*, 809 F.3d 471, 476 (9th Cir. 2015) ("In the context of Rule 10b–5, we have adopted the general rule of imputation and held that a corporation is responsible for a corporate officer's fraud committed 'within the scope of his employment' or 'for a misleading statement made by an employee or other agent who has actual or apparent authority.'") (quoting *Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1577 n. 28 (9th Cir. 1990)).

Cal. Mar. 25, 2015) (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005)). To adequately plead loss causation a plaintiff need only plead "a causal connection between the material misrepresentation and the loss." *Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1211 (9th Cir. 2016) (quoting *Dura*, 544 U.S. at 342). And "'the ultimate issue is whether the defendant's misstatement, as opposed to some other fact, foreseeably caused the plaintiff's loss.'" *Mineworkers' Pension Scheme v. First Solar Inc.*, 881 F.3d 750, 753 (9th Cir. 2018) (quoting *Lloyd*, 811 F.3d at 1210).

Plaintiff meets its burden. Plaintiff's causation theory is that misleading statements and omissions "artificially inflated the price of iRhythm common stock" which then fell when the "conduct was disclosed to the market on November 1, 2022, November 4, 2022, May 4, 2023, May 30, 2023, July 1, 2024, August 1, 2024, and August 9, 2024." (Dkt. No. 43 ¶ 233.) Plaintiff alleges on these dates iRhythm disclosed that it "issued a Customer Advisory Notice to [its] Zio AT customers" regarding the transmission limit (*id.* ¶ 124), provided details about the FDA inspection leading to a label correction related to "the device's maximum transmission limits," (*Id.* ¶ 129), and that the DOJ Consumer Protection Branch was investigating "that the Zio Systems were failing to timely transmit patient cardiac data to physicians" (*id.* ¶ 134) among other disclosures. Plaintiff pleads that after each disclosure, iRhythm's common stock declined. (*Id.* ¶¶ 127, 130, 136, 139, 143, 145, 151, 153.) So, Plaintiff has plausibly alleged the loss is traced back to "'the very facts about which the defendant lied.'" *First Solar*, 881 F.3d at 753 (quoting *Nuveen Mun. High Income Opportunity Fund v. City of Alameda*, 730 F.3d 1111, 1120 (9th Cir. 2013)).

Defendants' arguments to the contrary are unavailing. Defendants contend (1) announcements of investigations are not corrective disclosures under the PSLRA, (2) Plaintiff does not substantiate how certain disclosures revealed new information to the market, (3) the 2023 FDA Warning Letter did not reveal new information to the market, and (4) the Capitol Forum article only disclosed risks of misconduct. But Plaintiff's allegations are specific and allege in detail what new information was disclosed to the market in each disclosure. (*See* Dkt. No. 43 ¶¶ 123-53.) And the Ninth Circuit has held that while simply announcing an investigation does not reveal any pertinent truths, an investigation announcement together with allegations of "a

subsequent corrective disclosure" *can* form the basis for a viable loss causation theory. *Lloyd*, 811 F.3d at 1210. Here, the investigation and subpoena announcements were soon followed by corrective disclosures. (Dkt. No. 43 at 134-40.) Additionally, the Capitol Forum article is alleged to contain detailed information about iRhythm's CCT issues, including, "the substance of the new Form 483s." (*Id.* ¶ 152-53.)

Given Plaintiff's specific and well-pleaded allegations, the Court holds Plaintiff, at this time, has adequately pled loss causation.

D. Whether Plaintiff's Section 20A Claim Should be Dismissed

Plaintiff also alleges Individual Defendants are liable under section 20(a) of the Exchange Act. (*Id.* ¶¶ 254-55.) To state a prima facie section 20(a) claim, a plaintiff must plead: (1) "a primary violation of federal securities laws"; and (2) "that the defendant exercised actual power or control over the primary violator." *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1065 (9th Cir. 2000).

Defendants only seek to dismiss the section 20A claims because they argue Plaintiff fails to plead a primary violation of section 10(b). "Because Plaintiff[] did not adequately allege violations of section 10(b), [against all Defendants] the Court dismisses the Section 20(a) claims [as to those Defendants]." *See Apollo Grp.*, 774 F.3d at 610; *see also Zucco*, 552 F.3d at 990 ("Section 20(a) claims may be dismissed summarily… if a plaintiff fails to adequately plead a primary violation of section 10(b)."). So, the Court does not dismiss claims against Mr. Blackford, for whom Plaintiff adequately pled section 10(b) violations.

CONCLUSION

For the reasons set forth above, the Court GRANTS Defendants' Request for Incorporation by Reference and Judicial Notice. The Court also GRANTS with leave to amend Defendants' motion to dismiss claims against Mr. Bobzien, Mr. Devine, Mr. Patterson, Mr. Day, and Mr. Turakhia, and further DISMISSES claims as to all Defendants regarding the "MCT" and "spectrum of care" statements. However, the Court DENIES the motion as to actionable statements made by Mr. Blackford regarding the Zio AT's timeliness, accuracy, and appropriateness for high-risk patients. Plaintiff shall file an amended complaint, if any, by July 1,

2025. Plaintiff may not add any new defendants or claims without further leave of court.

The Court schedules an initial case management conference for July 9, 2025 at 2:00 p.m. via Zoom video. A joint case management conference statement is due July 2, 2025.

This Order Disposes of Docket Nos. 51 and 52.

IT IS SO ORDERED.

Dated: June 3, 2025

JACQUELINE SCOTT CORLEY
United States District Judge

United States District Court
Northern District of California