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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

GLAZING EMPLOYERS AND GLAZIERS' UNION LOCAL #27 PENSION AND RETIREMENT FUND, on behalf of itself and all others similarly situated, Plaintiff, v. IRHYTHM TECHNOLOGIES, INC., et al., Defendants.	Case No. 3:24-cv-706-JSC **SECOND AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS** DEMAND FOR JURY TRIAL CLASS ACTION Assigned to: Honorable Jacqueline Scott Corley

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Lead Plaintiff Oklahoma Firefighters Pension and Retirement System ("Lead Plaintiff"), by and through its counsel ("Lead Counsel"), brings this action individually and on behalf of all persons and entities who purchased the publicly traded common stock of iRhythm Technologies, Inc. ("iRhythm" or the "Company") between November 5, 2021, and August 9, 2024, inclusive (the "Class Period") and were damaged thereby, arising from false and misleading statements by Defendants iRhythm; its Chief Executive Officer ("CEO") Quentin Blackford ("Blackford"); its Chief Financial Officer Brice Bobzien ("Bobzien"); its former interim CEO, Chief Financial Officer, and Chief Operating Officer Douglas Devine ("Devine"); its Chief Commercial Officer Chad Patterson ("Patterson"), its former Chief Technology Officer Mark Day ("Day"), and its Chief Medical Officer, Chief Scientific Officer, and Executive Vice President, Product Innovation, Mintu Turakhia ("Turakhia") (Blackford, Bobzien, Devine, Patterson, Day, and Turakhia are collectively referred to as the "Executive Defendants" in this Complaint, and with iRhythm, the "Defendants").

Lead Plaintiff alleges the following upon information and belief, except as to those allegations concerning Lead Plaintiff, which Lead Plaintiff alleges upon personal knowledge. Lead Plaintiff's information and belief are based upon Lead Counsel's investigation, which included review and analysis of, *inter alia*: (i) iRhythm's filings with the United States Securities and Exchange Commission ("SEC"); (ii) Defendants' additional public statements, including those made in press releases, at investor conferences, marketing presentations, and on earnings calls; (iii) correspondence between the United States Food and Drug Administration ("FDA") and iRhythm obtained by Lead Counsel pursuant to a Freedom of Information Act ("FOIA") request; (iv) analyst reports concerning iRhythm; (v) interviews with former employees of iRhythm; and (vi) other publicly available information regarding the Company. Lead Counsel's investigation into the factual allegations contained in this Complaint is continuing, and many of the relevant facts are known only by Defendants or are exclusively within their custody or control. Lead Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth in this Complaint after a reasonable opportunity for further investigation or discovery.

I. INTRODUCTION

1. This case arises from Defendants' materially false and misleading statements concerning iRhythm's premium wearable heart monitoring device: the Zio AT. According to repeated public statements by iRhythm and the Executive Defendants, the Zio AT supposedly would provide "near real-time" and "continuous" transmissions of significant arrhythmias to a patient's doctor and was thus expressly marketed to "high-risk" patients. These claims allowed iRhythm to expand into the lucrative Mobile Cardiac Telemetry ("MCT") space and to bill Medicare and Medicaid for millions more in reimbursement than it otherwise could. However, as investors—and doctors and patients—eventually learned when the FDA issued a public "warning letter" to iRhythm at the end of the Class Period (the "Warning Letter"), the device was "mislabeled" and these statements were all false: iRhythm had secretly designed the Zio AT to have a "transmission limit" so that, at a certain point, the device simply stopped transmitting data, without notice to the patient or their doctor. Far from being appropriate for a "high-risk" patient pool, the FDA concluded that, when used with a high-risk patient population, "the Zio AT System ***may cause or contribute to serious injury or death***."[1] The United States Department of Justice ("DOJ") has launched an ongoing investigation into these same issues with the marketing of the Zio AT. Finally, the FDA has recently warned iRhythm that the data provided by its Zio AT was not only dangerously untimely, but often inaccurate. As the impact of the truth emerged to the public, iRhythm's stock price declined and investors suffered material losses.

2. Defendants' misrepresentations must be understood by reference to iRhythm's other product, the Zio XT. For years, iRhythm only marketed the Zio XT, a cardiac monitoring patch that continuously records cardiac activity over a 14-day wear period. At the end of that wear period, iRhythm could generate a report and analysis of the patient's historic cardiac activity to be reviewed by a healthcare provider. As Defendant Patterson put it, the "Zio XT is retrospective."

3. In 2017, iRhythm revealed the Zio AT, touting its "real time continuous monitoring" for patients with "more critical symptoms." Unlike the Zio XT, the Zio AT

[1] Throughout this Complaint, emphasis is added to quotations unless otherwise noted.

supposedly continuously transmitted cardiac activity for ongoing real-time surveillance—rather than just providing historic data for analysis after the patient removed the device. From the time iRhythm commercially launched the Zio AT in October 2019, and throughout much of the Class Period beginning on November 5, 2021, iRhythm sold investors on the Zio AT's near real-time transmission capabilities for "high-risk" patients, who needed the kind of "timely data transmission capabilities" that the Zio AT supposedly provided in order to detect life-threatening heart conditions in time for treatment. These "real-time monitoring" representations also allowed iRhythm to claim that the Zio AT was an MCT, unlike the Zio XT, which was an "electrocardiogram monitor" for "low-risk" patients. iRhythm could bill Medicaid and Medicare for its supposed MCT at ***four times*** the rate that it billed for an electrocardiogram monitor.

4. Throughout the Class Period, Defendants also promoted the algorithm and clinical technicians that process data from the Zio AT device, stating they "provide[] accurate analytics and clinical results," and "ensure quality" in those results. Based on this supposedly sophisticated algorithm, iRhythm claimed that the Zio AT "has arrhythmia auto-detection capabilities that produce actionable event data for physician review."

5. These representations were important to investors and market analysts. For example, Morgan Stanley cited the Zio AT as driving iRhythm's expansion into the MCT market as part of the analyst's "overweight thesis" on iRhythm stock. J.P. Morgan noted that the Zio AT's "comprehensive reporting" will give "iRhythm a competitive advantage." iRhythm's stock price soared to a high of $168.01 (a ***65% increase*** from the $104 price on the first day of the Class Period) as Defendants continually touted these key characteristics of the Zio AT.

6. Unbeknownst to investors, Defendants' statements about the Zio AT were false. The Zio AT could not consistently provide "near real-time" notifications to healthcare providers, was not appropriate for "high-risk" patients, and was not properly marketed as an MCT. In fact, the Zio AT was secretly designed with a fatal mechanism that rendered it particularly ***dangerous*** for high-risk patients suffering from life-threatening arrhythmias. After transmitting an undisclosed number of arrhythmia events, the monitor stopped transmitting ***any data at all***. Similarly, without any notice to providers, iRhythm had imposed a requirement that all technical

patient registration details must be completed before the Zio AT would transmit any information. iRhythm did not notify the patient or the provider that these limitations existed, that the patient was nearing any sort of limit, or that the limit had been reached. The device simply silently stopped transmitting.

7. Indeed, in part because of these undisclosed limitations, iRhythm did not have FDA clearance to market the Zio AT as an MCT or to "high-risk" or "critical care" patients. Rather, the FDA later made clear in its Warning Letter that iRhythm's FDA clearance was limited to "long-term monitoring of arrhythmia events for ***non-critical care patients where real-time monitoring is not needed***." Although iRhythm could have sought additional clearance from the FDA to market the Zio AT as an MCT for "high-risk" patients, it did not do so.

8. These hidden limitations had serious, and even deadly, consequences. 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. Tragically, just one month before the Class Period began, iRhythm received notification that, after experiencing serious arrhythmias, two individuals had died of heart attacks while wearing the device. But because of the undisclosed transmission limit, the device failed to transmit the arrhythmia notifications to the patients' doctors, even though the doctors had requested such notification "to prevent serious injury or death."

9. In addition to these significant customer complaints, the FDA expressly placed Defendants on notice during the Class Period that iRhythm was making false and misleading statements about the Zio AT. The FDA conducted a (non-public) 12-day site inspection of an iRhythm facility over July and August 2022, culminating in the FDA issuing a "Form 483" Letter to iRhythm. The letter warned iRhythm of these exact issues concerning its marketing of the Zio AT, focusing largely on the device's transmission limit and associated patient arrhythmias and deaths that went un-transmitted by the Zio AT. The Form 483 noted that "your firm has ***yet to implement corrective actions*** to address this device limitation that ***your firm has been aware of***

since 2019 that can contribute to failure to notify clinicians of severe patient episodes, including life-threatening arrhythmias[.]"

10. In response, in September 2022, Defendant Blackford submitted responses to the warnings issued by the FDA in this Form 483 Letter. Notably, he did not deny the FDA's claims with regard to the Zio AT's undisclosed limitations; nor did he claim that they were unknown to him and other senior iRhythm leadership. Rather, he admitted that the transmission limit was a "***known design limitation***" that was "***crucial***" and "***essential***" to the functioning of the device. Therein, Blackford also admitted that iRhythm "conducted a risk assessment" and found that ***"[t]he hazardous situation of a max transmission design constraint potentially leads to a delayed notification of ECG findings until the final report is posted with all findings from the wear period."*** Incredibly, despite these admissions, Defendant Blackford blamed ***doctors*** for their failures to detect the (undisclosed) limitations on the device.

11. On November 1, 2022, the market began to get some inkling of the impact from iRhythm's misrepresentations concerning the Zio AT's capabilities. That day, after the market closed, iRhythm issued a press release stating that it had reduced the revenue outlook for the full year in part because it had "voluntarily issued a Customer Advisory Notice to [its] Zio AT customers," and thus had "seen reduced growth with Zio AT within the fourth quarter-to-date." Investors and analysts were surprised by this news, with some analysts expressing confusion about why iRhythm had not disclosed this expected problem earlier. But Defendants attempted to mitigate the blowback, claiming that this was merely a "near-term" headwind. The stock price fell 4.4% on November 2, 2022, and an additional 11.6% on November 3, 2022.

12. Then, on November 4, 2022, after market hours, Defendants filed their third quarter report with the SEC which disclosed additional details about the Customer Advisory Notice, including that it was in response to a Form 483 from the FDA and that the Notice warned patients of a labeling correction related to a transmission limit. The report further disclosed that iRhythm and the FDA were in "ongoing communication[s]" concerning the FDA's warnings. Once again, Defendants attempted to soften the blow of these revelations, stating that they did not expect them

to "present a material risk to our business at this time." iRhythm's stock price fell an additional 2.4% between Friday, November 4 and Monday, November 7, 2022.

13. On May 4, 2023, in iRhythm's first quarter report, Defendants revealed that iRhythm had received a subpoena from the Civil Division of the DOJ. As was only revealed later, the subpoena "sought communications and other documents concerning potential issues related to the Company's Zio Systems, including that the Zio Systems were failing to timely transmit patient cardiac data to physicians for review after the occurrence of a cardiac event." The news of the subpoena shocked analysts, noting that the disclosure was a "big surprise" and "unsettling." iRhythm's stock price fell 6.9% the next day.

14. The Company disclosed a bombshell later that month on May 30, 2023, when investors learned far more regarding the full extent of iRhythm's stunning failure to properly market and warn of the dangers of the Zio AT. That day, iRhythm disclosed it had received a Warning Letter from the FDA, which "alleges non-conformities to regulations for medical devices, including medical device reporting requirements, relating to the Company's Zio AT System and medical device quality system requirements."

15. The Warning Letter also stated, among other things, that iRhythm had falsely marketed the Zio AT as approved for use in "high-risk" patients that require "real-time cardiac monitoring," when, in truth, the Zio AT is approved only for "long-term monitoring of arrhythmia events for ***non-critical care patients where real-time monitoring is not needed***." Accordingly, the Warning Letter required iRhythm to submit a new 510(k) because iRhythm's "labeling describes a new patient population" which "affect[s] the safety or effectiveness of the device."

16. The Warning Letter also publicly disclosed, for the first time, the myriad customer complaints (including the instances of patient deaths that went unreported) associated with the Zio AT since 2019. Astonishingly, the Warning Letter stated that "***your firm has been aware of customer complaints related to this [transmission limit] issue since at least 2019***" and "***[s]ince at least 2017, your firm has been aware of this [registration] issue where your clinical care team cannot access the patient's data***."

17. Investors were stunned by the news of the FDA's Warning Letter. Analysts reported that they expected these revelations to have a large impact on the Company's stock price and that the full scale of the ramifications of the Warning Letter would continue to unfold. Analysts at Truist observed that the Warning Letter "could very well serve as an extended overhang on shares" and "full ramifications of potential remediation are unknown." The stock price again plummeted, this time by 6.1%.

18. But iRhythm had still not disclosed the full scope and impact of its fraud regarding the Zio AT. On July 1, 2024, investors were surprised to learn that the DOJ was ramping up its investigation of iRhythm: explicitly focusing on problems with the Zio AT. Specifically, the DOJ filed an extensive evidentiary petition to enforce its subpoena seeking documents from iRhythm (attaching multiple internal documents from iRhythm). The agency explained to the court that "the Subpoena sought communications and other documents concerning potential issues related to the Company's Zio Systems, including that the Zio Systems were ***failing to timely transmit patient cardiac data to physicians*** for review after the occurrence of a cardiac event." In response, the stock price fell by 7.3% on July 2, 2024.

19. In August 2024, investors learned of a whole new dimension of the Company's misconduct, ultimately leading investors to question iRhythm's value proposition entirely. On August 1, 2024, the Company disclosed that the FDA had issued new Form 483s to iRhythm in July 2024. As revealed by the FDA in those then-confidential reports, the Company received ***over 4,000 complaints*** since May 2022 that the Zio AT was providing inaccurate information to patients and doctors. Specifically, contrary to Defendants' representations throughout the Class Period about the "accuracy" of the data transmitted by the Zio AT, iRhythm's technicians were routinely misreading patients' arrhythmia data. Rather than quickly investigating complaints of such widespread (and undisclosed) problems, the FDA found that iRhythm swept them under the rug—the Company did not analyze the complaints; the Company did not "initiate[] ***any*** corrective and preventive actions to investigate the cause or identify the action(s) needed to correct and prevent recurrence" of the problems; and the Company "routinely [did] not report complaints and events" to the FDA as required after becoming aware that the Company's devices have "malfunctioned

and ***would be likely to cause or contribute to a death of serious injury*** if the malfunction were to recur." Even worse, according to the FDA, iRhythm actively manipulated its internal data analysis to exclude false positives or other data that would make its product appear less accurate.

20. Thus, over the course of multiple disclosures, investors learned that the Zio AT's two main purported benefits—its speedy notifications and its superior accuracy—were seriously in question.

21. In the Company's August 1 disclosure, iRhythm omitted many of the most damning details of the Form 483s and attempted to deny that this renewed scrutiny from the FDA involved issues of patient safety. Even so, investors were troubled that the Company's problems with the Zio AT persisted enough for the FDA to conduct new inspections and document these violations. Analysts at J.P. Morgan noted that, contrary to the Company's characterization, the problems observed in the Form 483s "should be recognized as a safety concern given the chance for misdiagnosis." Analysts at William Blair noted that the new Form 483, combined with the ongoing DOJ inquiry and the Zio AT warning letter, "could take several quarters to resolve." The Company's stock price dropped by 12.2% on August 2, 2024.

22. On August 9, 2024, the Capitol Forum reported that it had obtained the new Form 483s pursuant to a FOIA request and publicly revealed the startling details—including that iRhythm received ***over 4,000 complaints*** since May 2022 that the Zio AT was providing inaccurate information to patients and doctors. The Capitol Forum also reported that, despite Defendant Blackford's August 1, 2024 claim that the FDA was not concerned with "the overall safety or efficacy of" the Zio AT, "FDA inspectors highlighted the risks of iRhythm not reporting these errors to doctors and the FDA." The Company's stock price dropped by 8.94% on August 12, 2024.

23. All told, Defendants' materially false and misleading statements concealing the fatal flaws of the Zio AT—and the market's realization of the truth—led iRhythm's stock to fall 62% from its Class Period high of $169.54. In the process, investors lost hundreds of millions of dollars.

II. JURISDICTION AND VENUE

24. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

25. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

26. Venue is proper in this District under 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act, 15 U.S.C. §78aa(b), because iRhythm maintains its headquarters in this District and many of the acts giving rise to the violations complained of in this action, including the preparation and dissemination of materially false and misleading statements, occurred in substantial part in this District.

27. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

A. Lead Plaintiff

28. Lead Plaintiff Oklahoma Firefighters is a public pension fund that provides retirement allowances and other benefits to firefighters in Oklahoma. Currently, Lead Plaintiff manages over $3.5 billion in assets on behalf of over 26,000 members. Plan members and their families rely on the retirement benefits offered by Oklahoma Firefighters, and in order to grow and provide those benefits, the retirement system trades in public securities. During the Class Period, Lead Plaintiff purchased iRhythm common stock at inflated prices due to the misrepresentations alleged in this Complaint, then saw the value of that stock fall when the truth emerged. As reflected in the previously filed certification (ECF No. 15-2), Oklahoma Firefighters suffered substantial losses as a result of its investments in iRhythm common stock during the Class Period.

B. Defendants

29. Defendant iRhythm is a digital healthcare company that manufactured during the Class Period just two heart monitoring devices—the Zio XT and Zio AT—designed to diagnose arrhythmia. The Company maintains its headquarters at 699 8th Street, Suite 600, San Francisco, California. iRhythm common stock trades on NASDAQ under the ticker symbol "IRTC." As of October 23, 2023, iRhythm had over 30 million shares of common stock outstanding, owned by hundreds or thousands of investors.

30. Defendant Quentin Blackford ("Blackford") is, and was at all relevant times, iRhythm's Chief Executive Officer and a Director of the Company. Defendant Blackford has worked in the medical device industry for over 25 years. Before joining iRhythm, Defendant Blackford served as Chief Financial Officer and then as Chief Operating Officer at Dexcom, Inc. from 2017 to 2021. Prior to that, from 2009 to 2017, he served as Chief Financial Officer and then as Head of Strategy and Corporate Integrity at NuVasive Inc. From 1999 to 2009, Defendant Blackford held several senior financial leadership positions at Zimmer Biomet, Inc.

31. Defendant Blackford was well aware of the importance of complying with FDA labeling regulations and the dangers of misbranding a medical device. While at NuVasive, Blackford encountered these same warnings regarding marketing and labeling from the FDA. In March 2013, when Blackford was Executive Vice President of Finance and Investor Relations, the FDA issued a warning letter to NuVasive based on misbranding a medical device. The warning letter stemmed from an FDA inspection which found that NuVasive was selling its spinal fixation devices for uses not approved by the FDA. Additionally, during Blackford's tenure as Executive Vice President of Finance and Investor Relations at NuVasive, NuVasive faced a *qui tam* lawsuit brought by the DOJ for "caus[ing] health care providers to submit false claims to Medicare and other federal health care programs for spine surgeries by marketing the company's [medical device] for surgical uses that were not approved by the [FDA]." *United States ex rel. Kevin Ryan v. NuVasive, Inc.*, No. 12–cv–2683 (D. Md.). Ultimately, the DOJ and NuVasive reached a multimillion-dollar settlement to resolve the matter, which was finalized while Blackford was the CFO.

32. Defendant Blackford's base salary rate when he joined iRhythm in 2021 was $650,000 per year, and he was eligible to earn a target bonus of 100% of his base salary each year. He received a $675,000 signing bonus as well. In addition, Blackford stood to receive equity awards worth $14,000,000. Along with the other Executive Defendants, part of Blackford's bonus compensation could be increased or decreased based on Medicare reimbursement rates. For example, with regard to iRhythm's 2021 annual bonus plan, "the Compensation Committee also reserved the right to adjust the corporate performance measures based on final 2021 regional Medicare reimbursement adjustments, if any, for the year, whether positive or negative."

33. Defendant Brice Bobzien ("Bobzien") served as iRhythm's Chief Financial Officer from August 8, 2022 through August 31, 2024. Like Defendant Blackford, he has years of experience working at medical device companies. Before joining iRhythm, he worked with Defendant Blackford at Dexcom, Inc., where Defendant Bobzien worked from 2018 to 2022 in various roles, including Senior Vice President, Global FP&A, Investor Relations and Strategic Pricing. From 2013 through 2017, Bobzien again worked with Defendant Blackford, this time at NuVasive, Inc.—a medical device company that faced an FDA warning letter during his tenure. Previously, from 2005 to 2010, Bobzien worked at medical device company Zimmer Inc. in various roles, including Associate Director of Finance/Controller.

34. Defendant Bobzien's base salary rate when he was appointed iRhythm's Chief Financial Officer during the Class Period was $400,000 per year. Bobzien was eligible to earn a target bonus of 60% of his base salary each year. In addition, Bobzien stood to receive equity awards worth $1,800,000. As with the other Executive Defendants, part of Bobzien's incentive-based compensation could be increased or decreased based on Medicare reimbursement rates.

35. Defendant Douglas Devine ("Devine") served as iRhythm's Chief Financial Officer from June 22, 2020, to August 8, 2022, and as Chief Operating Officer ("COO") from December 1, 2021, to March 10, 2023. Beginning on June 1, 2021, Devine acted as iRhythm's Interim CEO after prior CEO Mike Coyle resigned. Defendant Devine served as Interim CEO until Defendant Blackford joined the Company on October 4, 2021. On March 10, 2023, the Company announced that Devine resigned from his position as COO.

36. Defendant Devine's base salary rate when he joined iRhythm in 2020 was $450,000 per year. Devine was eligible to earn a target bonus of 60% of his base salary each year. Devine also received a signing bonus of $150,000. In addition, Devine stood to receive equity awards worth $2,000,000. As with the other Executive Defendants, part of Devine's incentive-based compensation could be increased or decreased based on Medicare reimbursement rates.

37. Defendant Mark Day ("Day" and collectively with Blackford, Bobzien, Devine, and Patterson, "Executive Defendants") served as iRhythm's Chief Technology Officer from March 2022 to April 2024 and was formerly the Executive Vice President of Research & Development. Since joining iRhythm in 2007, he has held other leadership roles in Research & Development and Systems Development. He previously worked in Medtronic's Cardiac Rhythm Disease Management division. He holds a PhD in Computation Flow Physics from Stanford University.

38. Defendant Day's base salary rate at the start of the Class Period was $388,053 per year. Day was eligible to earn a target bonus of 40% of his base salary each year. Defendant Day received a stock award worth $2,745,572 in 2021. As with the other Executive Defendants, part of Day's incentive-based compensation could be increased or decreased based on Medicare reimbursement rates.

39. Defendant Chad Patterson ("Patterson") has served as iRhythm's Chief Commercial Officer since July 2022. Before joining iRhythm, he worked with Defendants Blackford and Bobzien at DexCom, Inc., where he served as Executive Vice President, Chief Marketing Officer at DexCom, Inc. from January 2021 to July 2022 and held roles of increasing seniority since 2015.

40. Defendant Patterson's base salary rate during 2022 was $450,000 per year. Patterson was eligible to earn a target bonus of 60% of his base salary in 2022, rising to 70% in 2023. Patterson received a stock award of $6,215,223 in 2022. As with the other Executive Defendants, part of Patterson's incentive-based compensation could be increased or decreased based on Medicare reimbursement rates.

41. Defendant Mintu Turakhia ("Turakhia") served as iRhythm's Chief Medical Officer and Chief Scientific Officer since June 2022. He has also served as the Company's Executive Vice President, Product Innovation since April 2023. Turakhia received his M.D. from the University of California, San Francisco, where he also received an M.S. in Clinical Research.

42. Defendant Turakhia's base salary rate when he joined iRhythm in 2022 was $425,000 per year, and he received a $500,000 signing bonus. Turakhia was eligible to earn a target bonus of 50% of his base salary in 2022, rising to 60% in 2023. Turakhia received a stock award of 4,566,853 in 2023. As with the other Executive Defendants, part of Turakhia's incentive-based compensation could be increased or decreased based on Medicare reimbursement rates.

IV. SUMMARY OF THE FRAUD

A. The Original Zio XT And The Purportedly Advanced Zio AT

43. During the Class Period, iRhythm manufactured two wearable heart monitoring devices designed to diagnose arrhythmias. The Company's principal product was a monitoring patch called the Zio XT, which provides doctors with a patient's arrhythmia and electrocardiogram ("ECG") information following a 14-day wear period. iRhythm 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.

44. 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***." Actionable arrhythmic events include atrial fibrillation, a condition that can cause serious medical complications, including blood clots that can lead to stroke and heart failure. 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." As part of that process, iRhythm's Certified Cardiographic Technicians ("CCTs") conduct "a final quality assessment review of the data," and reports are issued to doctors "following observations by" these technicians.

45. Importantly, given the Zio AT's purported capabilities to provide "real-time" notifications of arrhythmic events, iRhythm explicitly marketed the Zio AT device to "high-risk" patients as a "mobile cardiac telemetry" ("MCT") device.[2] According to the Mayo Clinic, an MCT is "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."

46. By contrast, the Zio XT was not considered an MCT and was instead marketed as a continuous electrocardiography (ECG) device, because it did not transmit real or near-real-time cardiac activity data for analysis.

47. Analysts immediately lauded the Zio AT's purported "real time" transmission as a boon for iRhythm. In August 2017, Morgan Stanley listed "Real time ZIO" as one of a series of product "catalysts leading to inflection" and resulting in an increase in its estimates for iRhythm. On December 1, 2017, Dougherty & Company LLC noted that iRhythm was "disrupting conventional cardiac arrhythmia detection" with its "near real-time continuous transmission patch called Zio AT." In August 2017, J.P. Morgan noted the Zio AT's purported "real-time" capabilities that would give iRhythm "a competitive advantage when engaging with accounts and securing coverage."

48. The supposed differences between the Zio XT and the Zio AT were well-understood by physicians and the marketplace. For example, in a December 3, 2017 analyst report, RBC noted that the Zio AT "is designed to provide real-time transferrable data during the wear period by utilizing Bluetooth connectivity. . . . ***The product is a premium device compared to the Zio XT, which does not provide real-time reporting***."

49. Similarly, in a piece published by Stanford Medicine Children's Health titled "Diagnosing Your Child's Arrhythmia," the pediatric healthcare network advised caregivers that the Zio AT:

[2] "Telemetry" is the process of collecting data from remote locations and automatically transmitting them to a central location for monitoring and analysis.

> [D]elivers comprehensive, precise, ***real-time data*** on your child's heart rhythms. The AT version notifies EKG technicians standing by of the most significant heart events, complete with full analysis of the data, ***more quickly than other monitoring devices***. . . . The patch boasts ***earlier detection*** compared with other telemetry monitors, which is ***important for detecting more serious arrhythmias***.

50. By contrast, the network advised parents that the Zio XT "can be a more affordable option" and that it "records electrical activity of the heart for up to two weeks, but it doesn't provide real-time feedback; rather, the device is mailed to the manufacturer, where trained EKG technicians review the data and send a report to your doctor. It is typically used to monitor less serious arrhythmias."

B. Regulatory Oversight Concerning The Zio AT

51. The FDA reviewed the Zio AT for marketing pursuant to a Premarket Notification (510(k)) application. The 510(k) pathway allows medical device manufacturers to market a proposed new device if they can demonstrate that the device is substantially equivalent to a legally marketed predicate device—here, the Zio XT. This abbreviated process allows the manufacturer to avoid the much lengthier "Premarket Approval" process for new devices. As part of the application, iRhythm demonstrated substantial equivalence within similar patient populations as the predicate device (the Zio XT).

52. iRhythm received a majority of its revenue—nearly 82% by the end of 2021—through third-party payors, including government agencies such as the Centers for Medicare and Medicaid Services ("CMS"). CMS annually sets the rates the agencies will pay for medical devices and other products each calendar year. Private insurers often use CMS rates as a benchmark when setting their own reimbursement rates for medical services and procedures.

53. On June 2, 2017, iRhythm received clearance to market the Zio AT pursuant to the Company's Section 510(k) premarket notification of intent to market the Zio AT. By August 2021, the "Zio AT had a record quarter, reaching approximately 10% of overall company revenue for the first time."

C. Throughout The Class Period, The Company Trumpets The Zio AT's "Real-Time" "Accurate" Notifications For "High-Risk" Patients As a Supposed MCT

54. From the start of the Class Period on November 5, 2021, through the end of the Class Period in August 2024, iRhythm touted to customers and investors alike that the Zio AT had the benefits of the Zio XT and provided accurate data to patients and doctors, but also (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. These statements about the Zio AT's "accurate" and "real-time" data, use for "high-risk" patients who needed "timely" data, and position as an MCT monitor were fundamental to the Company's pitch (to investors and customers) for the product.

55. ***"Timely" and "near real-time" transmissions of actionable data.*** Throughout the Class Period, Defendants made statements to investors about the near-instant transmission of cardiac telemetry data from the Zio AT to patients' physicians. For example, iRhythm's 2021 Form 10-K, filed on February 28, 2022, extensively discussed the Zio AT's "timely transmissions" of "notifications" of "significant events" "during the wear period" of arrhythmia to physicians. There, Defendants stated that "timely alerts" are sent from the Zio AT monitor to a "wireless gateway" provided to a patient via Bluetooth. From there, data would be transferred to a physician over the LTE network. Defendants explained that "[t]he Zio AT monitor, in conjunction with the wireless gateway and the unique Zio arrythmia detection algorithm, has arrhythmia auto-detection capabilities that produce actionable event data for physician review."

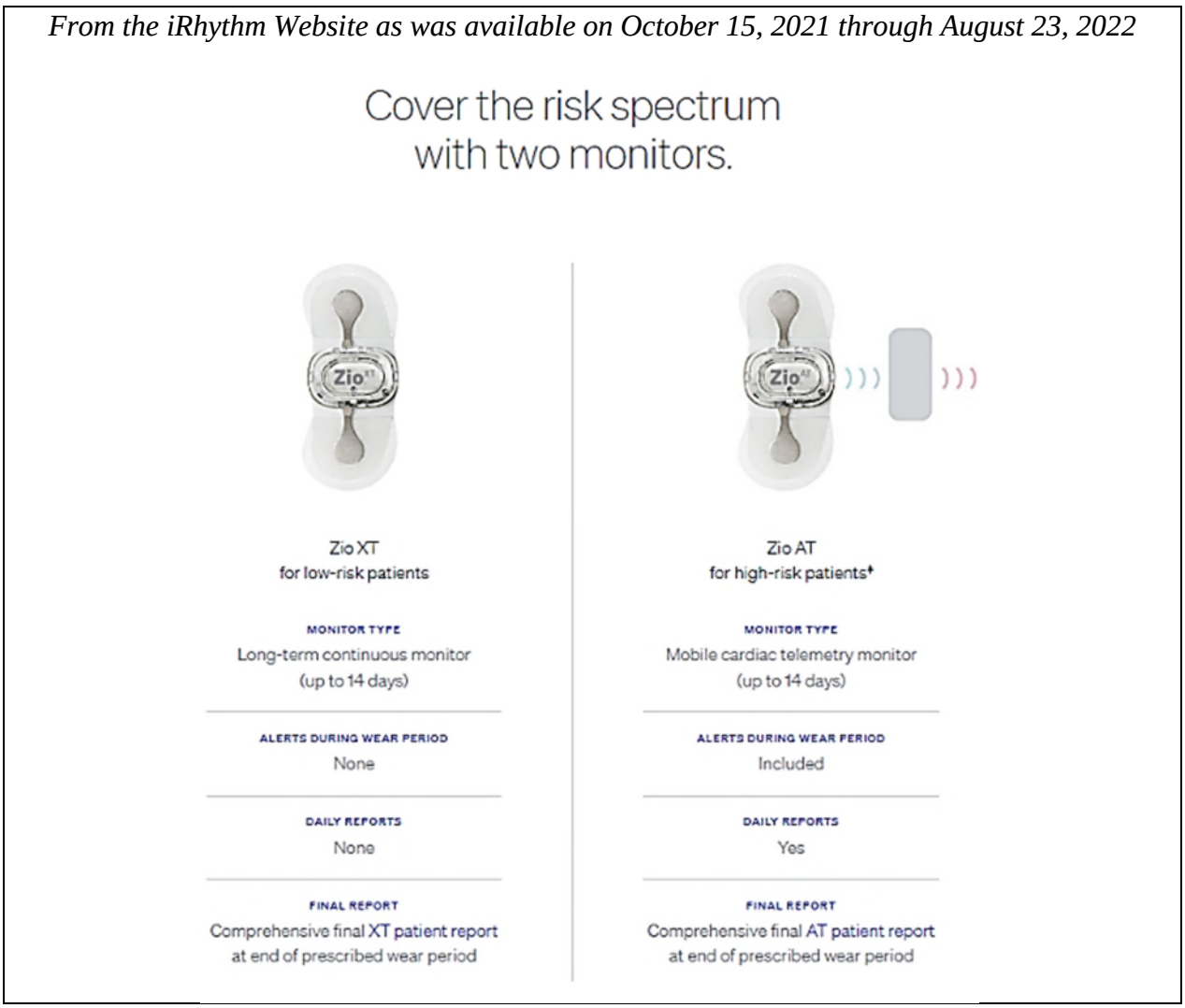
56. Defendants also touted the purported "near real-time" transmission capabilities of the Zio AT, alongside the repeated refrain that it would provide "timely transmissions." Specifically, Defendant Blackford told investors in September 2022 that iRhythm had "a perfect product to address, putting information into the hands of the patient on a near real-time basis." Less than two months later, during a November 14, 2022 Nasdaq interview, Defendant Blackford stated that the AT "provides near real-time capability and can put that information right at [the treating physician's] fingertips." From as early as February 19, 2023, iRhythm's website touted the Zio AT as "offer[ing] near real time cardiac event monitoring," and by February 23, 2023,

Defendants were touting the Zio AT's alleged "near real-time" monitoring throughout iRhythm's 2022 10-K filing.

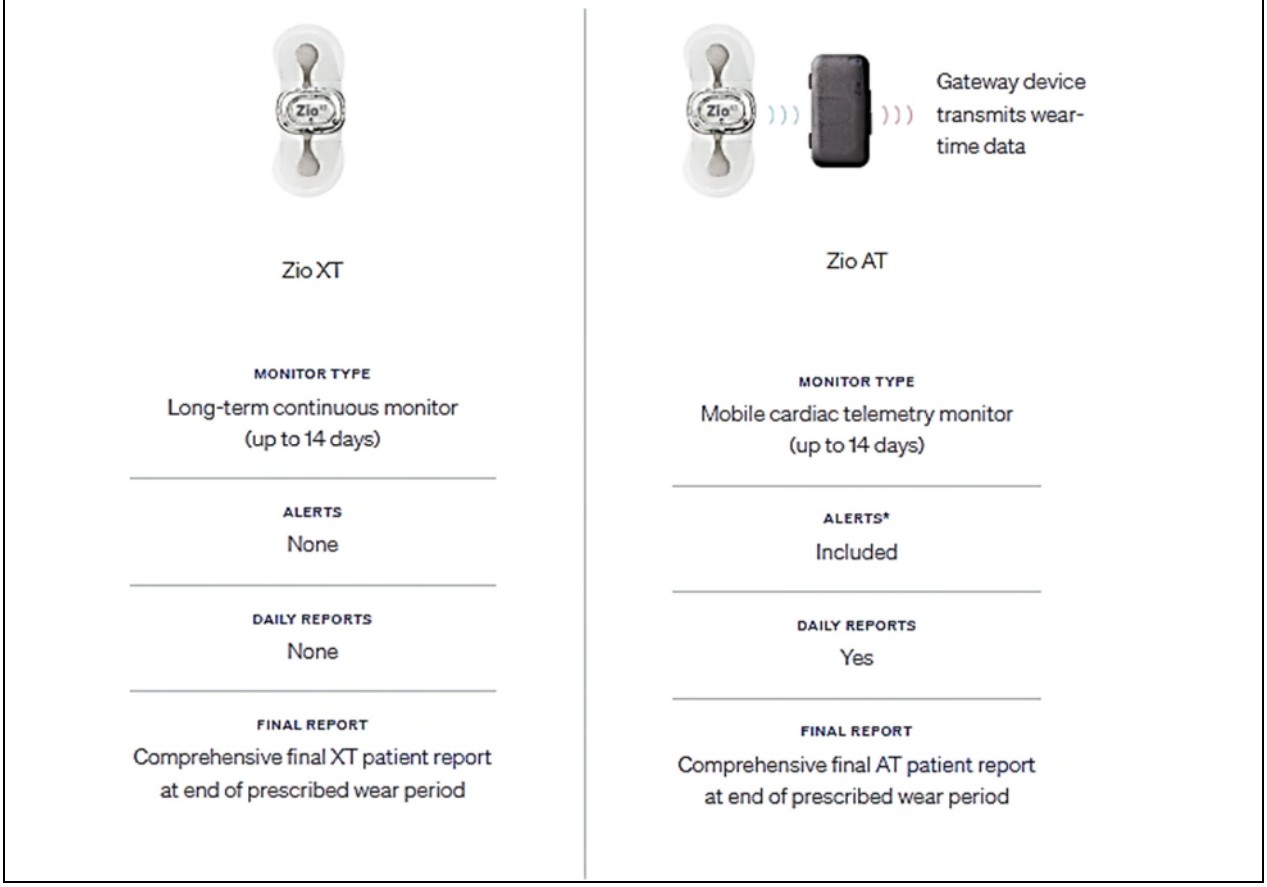
57. ***Pitching the Zio AT for "high-risk" patients.*** Based on these purportedly timely notifications, Defendants asserted to investors that the Zio AT was appropriate for "high-risk" patients. Specifically, in iRhythm's 2021 10-K filed on February 28, 2022, Defendants stated that the "Zio AT is appropriate for the smaller percentage of the population that requires timely notification" because of the "additional capability of transmissions," as opposed to the absence of such capabilities in the Zio XT. In investor presentations dated June 8, 2022 and August 11, 2022, iRhythm made the distinction between the XT's "low-risk" patient base and the AT's "high-risk" patient base in the following illustration:

58. A similar chart was published throughout the Class Period on iRhythm's website. As with the iRhythm investor presentations, the website originally touted the XT and the AT as being for "low-risk" and "high-risk" patients, respectively. However, in late August 2022 (after the Company received the non-public criticism from the FDA discussed below), such references to "high-risk" patients were scrubbed from the chart without explanation:

From the iRhythm Website as was available on October 15, 2021 through August 23, 2022



From the iRhythm Website as was available on August 30, 2022 through August 23, 2023[3]



59. Nonetheless, Defendants continued making these statements in other forums into 2023. Defendant Blackford told investors at the January 10, 2023 JP Morgan Healthcare Conference that the Zio AT was marketed to "some of the most at-risk patients." Then, just over a month later in iRhythm's 2022 Form 10-K filed on February 23, 2023, Defendants represented that Zio AT was "appropriate for more acute patients that require timely notification."

60. ***Characterizing the Zio AT as a "mobile cardiac telemetry" monitor.*** Throughout the Class Period, Defendants repeatedly represented to investors that the Zio AT was a "mobile cardiac telemetry" monitor, or an MCT. For example, Defendant Blackford repeatedly referred to the Zio AT's position in the "MCT space." iRhythm's 2021 annual filing and 2022 Q1 filing

[3] Both charts obtained by Lead Counsel as part of its investigation using The Wayback Machine Internet Archive.

referred to the Zio AT as a "mobile cardiac telemetry monitor." The diagrams published in June and August 2022 (*see* ¶57) described the Zio AT as the "clinically superior MCT."

61. The characterization of the Zio AT as an MCT had significant implications for iRhythm's reimbursement by CMS and reported revenue. The Zio AT, based on its claims of purported "real time continuous monitoring," utilized CMS billing codes unique to MCTs. The CMS reimbursement rates for the Zio XT, on the other hand, utilized CMS billing codes related to ECG (continuous electrocardiography) monitoring. Generally, CMS pays for MCT monitoring at a rate of about ***four times*** that of an ECG. iRhythm reported that for the year 2022, it billed the Zio AT device at an average rate of $1,150, whereas it billed the Zio XT device at an average rate of $250.

62. Given this significantly higher reimbursement rate as a supposed MCT, iRhythm focused heavily on promoting the Zio AT. Former Employee ("FE") 1, who worked at iRhythm from prior to the Class Period until 2024 as a territory manager responsible for selling both the Zio XT and the Zio AT and training newer sales representatives, recalled that under iRhythm's sales bonus plan, selling the Zio AT earned a sales employee twice as many points towards their bonus goal numbers as selling a Zio XT.

63. Defendants' statements regarding "real time" or "continuous" transmission and the Zio AT's status as a supposed MCT were credited by the market. Analysts repeatedly parroted iRhythm's claims about the Zio AT's "real-time" or continuous transmission of data. For example, on January 12, 2022, BTIG noted in upgrading iRhythm from "Neutral" to "Buy" that iRhythm had "unveiled a patch monitoring device called the Zio AT, which adds real-time functionality." On April 4, 2022, JP Morgan wrote in an analyst report touting its "bullish thesis on durable near- and long-term growth" for iRhythm that the Zio AT was "used to give you real-time feedback on the patient's condition and any adverse events post-procedure," and that this functionality would help "iRhythm to improve the marketability of its MCT device in this significantly underpenetrated market."

64. Analysts also relied heavily on iRhythm's characterization of the Zio AT as an MCT in recommending iRhythm's stock to investors. For example, Morgan Stanley cited the Zio

AT "driving TAM ["total addressable market"] expansion into the MCOT ["mobile cardiac outpatient telemetry"]" market as part of what the analyst's "overweight thesis" of iRhythm "rests on." On November 6, 2019, Morgan Stanley noted iRhythm's having "highlighted earlier this year case study examples of how an MCOT + extended holter offering increases physician/hospital willingness to adopt the ZIO platform." During the Class Period, on February 23, 2023, Canaccord Genuity referred to the Zio AT business as iRhythm's "MCT service" and reaffirmed its "BUY" rating for iRhythm. Analysts also discussed at length the preferential MCT billing rate in the context of the Zio AT's commercial success—including that, for example, per Wolfe Research on February 23, 2023, the MCT rate increased by "mid-20%" between 2021 and 2022.

65. ***Trumpeting the "incredible accuracy" of the data provided by the Zio AT to patients and doctors.*** Throughout the Class Period, Defendants repeatedly told investors that the Zio AT provided accurate data to patients and doctors. For example, in iRhythm's annual report on Form 10-K for the year 2021, filed on February 28, 2022, iRhythm stated that the Zio service "help[s] physicians monitor patients and diagnose arrhythmias with a high degree of accuracy and confidence," that the Zio AT "improves the speed and accuracy of diagnosis relative to traditional mobile cardiac telemetry ('MCT') devices and services." iRhythm explained that it was able to provide such accurate data thanks to its cardiographic technicians, who review the data generated by iRhythm's devices and "help ensure high accuracy and quality of reports before delivering them to the prescribing physician."

66. The Company used the supposed "accuracy" of the Zio AT to pitch to investors the idea that the Company's market will "expand dramatically." For example, on a February 23, 2023 earnings call for the fourth quarter of 2022, Defendant Blackford stated about the Zio, "I remain convinced that you're going to see this market expand dramatically as we continue to push into the primary care setting, just given how easy it is to use the product, how accurate it is[.]" Similarly, on a May 2, 2024 earnings call for the first quarter of 2024, Defendant Blackford again stated about the Zio, "[P]rimary care is absolutely the place that this device is ultimately going to get applied into the future, just with its ease of use, its high diagnostic yield, ***its incredible accuracy***."

D. In Reality, The Zio AT Did Not Provide "Near Real-Time" Warnings, Was Not Appropriate For "High-Risk" Patients, Was Not Appropriately Marketed As An MCT, And Was Not Accurate

67. Unbeknownst to investors, and in stark contrast to Defendants' repeated statements to investors throughout the Class Period, the Zio AT (i) did not reliably provide real-time data transmission to patient providers, (ii) was not designed for "high-risk" patients; (iii) was not appropriately marketed and billed as an MCT; and (iv) had routine errors and inaccuracies in the reports sent to patients and doctors due to technicians' regular misreading of arrhythmia data. In reality, as the FDA later made public, the marketing of the Zio AT as an MCT or to high-risk patients was inappropriate and dangerous, as the device was not designed to transmit real-time cardiac telemetry data to patient providers. Indeed, when used with a high-risk patient population, the FDA concluded that "the Zio AT System ***may cause or contribute to serious injury or death***." And as revealed by the next round of Form 483s issued in July 2024, during the Class Period, iRhythm received ***over 4,000*** complaints about its technicians' misreading of arrhythmia data that resulted in inaccurate reports sent to patients and doctors.

68. ***First***, in June 2023, the FDA publicly revealed for the first time—following extensive undisclosed back-and-forth with iRhythm during the Class Period discussed further below—that iRhythm had knowingly implemented an undisclosed "transmission limit" on the Zio AT's transmission of patient data. According to the Warning Letter, as a result of this transmission limit,

> [T]he device is only able to transmit 100 patient-triggered and 500 automatically detected arrhythmia events. Once the transmission limit is reached, the patient's data stops being transmitted for review/reporting. Thus, when the transmission limit is hit, the device can no longer be used for its intended purpose of transmitting patient ECG for reporting. Further, when the transmission limit is hit, the device can no longer provide near real time monitoring for high-risk patients.

69. In other words, once the device hit its transmission limit, the Zio AT functioned the same as the lesser Zio XT—providing historical data after the end of the wear period, but not transmitting any further actionable data ***during*** the wear period.

70. The FDA made it clear that this critical transmission limit was undisclosed to physicians and their patients, who continued to expect the Zio AT to provide actionable real-time data in case the patient suffered a serious arrhythmia. Specifically, in the Warning Letter, the FDA revealed that iRhythm did not provide any information to physicians regarding "the existence of a transmission limit, when the transmission limit is reached, or include any information about the action a physician should take if the device reaches the transmission limit." Further, with respect to patients, "there is no information provided to the patient that a transmission limit exists, no notification to the patient when the transmission limit is reached, and no information provided to the patient about what to do when the transmission limit is reached." As a result of these undisclosed limitations, as discussed further below, serious arrhythmic events (including those resulting in two patient ***deaths***) occurred while wearing the device, without being reported to their provider for timely treatment.

71. For these reasons, the Warning Letter concluded that the Zio AT was "misbranded," because the labeling for the device—claiming to provide "near-real time monitoring for high-risk patients"—was untrue. The FDA further stated that iRhythm's claims that the Zio AT was an MCT "implies this device is intended for high-risk patients and near real-time monitoring"—which was not true.

72. Additionally, according to current and former employees who spoke with The Capitol Forum, a subscriber-based investigative news organization and industry watchdog, iRhythm did not inform its sales employees about the Zio AT's transmission limit. Instead, according to The Capitol Forum, problems with the Zio AT "were kept from iRhythm's sales force so that they could keep selling the Zio AT as an MCT to cardiologists." One former sales employee stated that he was "completely unaware" of these problems with the Zio AT, adding "I would have stopped trying to sell the Zio AT as an MCT if I knew it could harm patients." A then-current sales employee told The Capitol Forum, "Here's the deal. We were never told it was not an MCT. We were never told to not call it an MCT, and we are 100% still selling it as an MCT."

73. ***Second***, the Zio AT failed to consistently provide "near real-time" notifications because—unbeknownst to physicians and patients—iRhythm's patient registration policy limited

transmissions if a physician did not technically complete the patient registration. In the Form 483, the FDA identified that when a patient's registration was incomplete, "the patient data was not reported to the physician during wear due to the incomplete registration, and [Company] records do not show follow up on the patient status to determine the impact of any delayed MD notifications." The FDA further warned that this limitation "can contribute to failure to notify clinicians of severe patient episodes, including life-threatening arrhythmias such as Ventricular Fibrillation." This policy was unknown to patients using the Zio AT and their physicians.

74. Ultimately, the FDA determined that although iRhythm's "marketing materials, website, and other documentation" state that "the Zio AT system is intended for 'near real-time monitoring' and 'high-risk patients,' . . . the Zio AT System is not cleared for these indications. When used in this patient population, the Zio AT System may cause or contribute to serious injury or death because life-threatening arrhythmias may not receive timely treatment."

75. ***Third***, further unknown to physicians and patients, the Zio AT failed to consistently provide "near real-time" notifications because it regularly had a "lag time" of around ***four hours*** or more. FE 3—a former iRhythm Zio AT technician from before the Class Period through November 2022—explained that because of this lag time, the Zio AT was not live and did not notify physicians of arrhythmias right away. According to FE 3, it took four hours for any arrhythmia events transmitted from the Zio AT to show up in a "queue" for technicians' review. Then, the technicians had to work their way down this queue to analyze the events one by one, which added on additional "lag time" to the four hours it took just for events to make it into the queue. Worse, on weekends and overnight, the queue built up even more because there were not as many technicians during those shifts. FE 3 further explained that it sometimes took more than four hours to even receive the arrhythmia data in the queue. The queue would suddenly be bombarded with new arrhythmias, and FE 3 could never figure out why this happened.

76. These failures of the Zio AT had serious consequences. Troublingly, FE 3 stated that technicians could see patients dying while wearing the Zio AT monitor. FE 3 stated that many patients should not have been wearing the Zio AT device and should have been monitored live instead. FE 3 wanted to look at critical and end-of-life arrhythmias first in the queue, but there was

no way to prioritize review of those arrhythmia events. FE 3 stated that the technicians were always concerned about the additional "lag time" that it took to work through the queue and analyze arrhythmia events. It was a constant discussion among the technicians, but these concerns were never addressed during FE 3's tenure. At the same time, in stark contrast to the Company's statements throughout the Class Period, FE 3's managers consistently told technicians that the Zio AT was "not an emergency service" and that they were not here for "the critical arrhythmias."

77. ***Fourth***, in its July 2024 inspection, the FDA exposed an additional major problem with the Zio AT: iRhythm's technicians were routinely misreading patients' arrhythmia data, leading to the regular transmission of inaccurate arrhythmia reports to patients and doctors. On August 1, 2024, iRhythm disclosed that the FDA had issued new Form 483s regarding these issues. Significantly, the FDA found that since May 2, 2022 through July 19, 2024—when the FDA inspected iRhythm's facilities once again—the Company received (and did not disclose) ***over 4,000 complaints*** about its technicians' misreading of patients' arrhythmia data.

78. The FDA detailed examples of complaints the Company had received regarding technicians' misinterpretation of data. For example, in one complaint, notification to a patient's doctor of a serious arrhythmia was delayed "as a result of a CCT misread/misinterpretation of cardiographic arrythmia event data." The technician misinterpreted a Complete Heart Block (a condition that, according to the Cleveland Clinic, "can be serious" and can in serious cases "cause sudden cardiac arrest" without treatment), as a mere Sinus, Ventricular Trigeminy (a common arrhythmia that often resolves on its own). The patient's providers stated "they would have brought the patient in sooner for pacemaker placement had they been notified sooner" of the Complete Heart Block.

79. The FDA also detailed examples of the Company sending inaccurate reports to patients and doctors because of failures by the algorithm (rather than the technicians). For example, in one complaint, the algorithm missed two serious arrhythmias, noting that "the arrythmia event data indicated two, separate Complete Heart Block events, although these cardiac events were not transmitted during wear, as intended." The patient's providers stated that "they would have brought the patient in sooner for pacemaker placement had they been notified sooner." As another example,

a separate complaint documents delayed doctor notification "as a result of an algorithm miss of arrythmia data" in which the patient had a ventricular tachycardia event that "was not transmitted during wear, as intended." According to the Cleveland Clinic, a ventricular tachycardia is "serious and requires urgent treatment."

80. Former iRhythm technicians confirmed that these routine errors were the result of both the Zio AT's technical limitations and iRhythm's training. In an August 9, 2024 report, The Capitol Forum reported that iRhythm CCTs recalled that reports to patients using the Zio AT were inaccurate and failed to report a number of arrhythmias to patients. One of these former CCTs "found missed arrythmias that were not reported to cardiologists in ***100% of final reports they analyzed***, which they blamed on the technical limitations of the Zio AT and iRhythm's processes for classifying arrhythmias."

81. The iRhythm CCTs attributed the errors to the Zio AT's technical limitations. One of the CCTs, who had worked at other cardiology imaging companies before, recalled that the "Zio AT has only a single lead, meaning you only get a very narrow view of the heart," whereas many fellow iRhythm CCTs with previous experience "found that questionable when a regular Holter monitor was six leads and gives a much better read of cardiac activity." In talking with other CCTs, the CCT stated "we felt we couldn't get accurate readings. We were told we had to do it the iRhythm way, that iRhythm has all this AI and algorithms to make up for the narrow view the Zio AT gets. They trained us to read these rhythms through the program they use and do it the iRhythm way, but it did not feel accurate." Thus, the "initial reports could be inaccurate and require massaging before being submitted to cardiologists." This CCT stated, "I found the reports to be inaccurate and alarming as a technician."

82. Alarmingly, the Capitol Forum's interviews with former iRhythm CCTs revealed that the Company was directing and training CCTs to provide inaccurate reports to patients and doctors in order to make the final report "match" the reporting transmitted during the wear period. The report stated, "Both former iRhythm CCTs said that they were often countermanded by iRhythm when they identified cardiac events that would [have] been classified as arrhythmias at other companies and tried to include them in final reports." These final reports were issued to

doctors once the patient's wear period had ended. One of the CCTs observed that "we were told that ***it is 'important that the final report match what the patient experienced during wear time***.'" Thus, if the CCT found "a life-threatening arrhythmia while doing the final report, and said life-threatening arrhythmia was not found during the wear time . . . I do not mention the life threatening arrhythmia I found on the final report the doctor sees."

83. One of the CCTs further explained,

> There would be times when during the final report, myself or others would find what we consider to be 3rd degree or complete heart block (for example). We would include it in the final report only for QA leadership to downplay it and say, "That is not complete heart block. That is only first degree with non-conducted pvc," a much less non-life threatening rhythm.

84. One of the CCTs believes that the reason for this downplaying was to "sell the narrative that the Zio is intended for 'long term life threatening arrhythmia monitoring' when it clearly isn't."

85. Similarly, FE 3 also had concerns about getting accurate reads from the Zio AT and about misreading data. According to FE 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. 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. Whenever FE 3 asked about a questionable arrhythmia, FE 3 was told not to "post" it for the physician's review. FE 3 stated that providing "cleaner" reports to physicians was prioritized over simply providing the information to the physician for the physician's evaluation. FE 3 explained that this was clear from the training FE 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.

86. Despite the technicians' integral involvement in the analysis and processing of arrhythmia data from the Zio AT, iRhythm formally excluded technicians from the Company's risk analyses. Defendant Blackford admitted once iRhythm disclosed that it received new Form

483s that iRhythm treated the technicians as if they were not "part of the product." This means Defendants did not include any issues arising from technicians' involvement in their risk analyses, as the FDA ultimately revealed in the new Form 483s. Thus, contrary to Defendants' repeated assurances about the accuracy of the Zio AT, the technicians responsible for analyzing arrhythmia data were formally excluded from Defendants' risk analyses—measures that are supposed to ensure accuracy and quality when properly applied.

E. Since Well Before The Class Period, Defendants Were Aware Of The Zio AT's "Essential" Limitations And The "Negative Trend" And "Critical Customer Complaints" Concerning These Limitations

1. Defendants Knew That The Zio AT Failed To Transmit Significant Arrhythmias And Patient Deaths

87. The FDA explicitly found that the Zio AT's timing limitations—and their negative impact on patient health—were known to iRhythm. As discussed below, patients and physicians complained to iRhythm ***for years*** that Zio AT was not reporting serious arrhythmias and patient deaths. iRhythm knew that the cause of these serious failures was the "essential" limitations discussed above—but it continued to withhold these facts from the public.

88. ***First***, with respect to the transmission limits, iRhythm "knew that the device's transmission limit . . . was resulting in data not being transmitted." Indeed, the FDA concluded in the Warning Letter that, based on "records reviewed during [the FDA's] inspection," "your firm has been aware of customer complaints related to this issue since ***at least 2019***. Specifically, our inspection found a significant number of complaints regarding this issue, which revealed two deaths as well as significant arrythmias that were not reported to physicians."

89. Specifically, the FDA noted in the Form 483 that beginning in 2019, iRhythm received ***twenty-eight*** complaints in which patients had severe episodes that were not reported to their doctors during the wear-period—all due to the undisclosed transmission limit on the Zio AT device.

90. Directly before the Class Period began, the Company received two shocking new complaints related to the same issue with the transmission limit. On October 25, 2021, the Company learned of two complaints in which "a patient ***passed away*** while using the Zio AT" but

prescribing doctors were not notified of the significant arrhythmias because the Zio AT's transmission limit had been reached. Instead of receiving a "near real-time" notification and obtaining treatment for the patients, these doctors did not find out about their patients' significant arrhythmias—which caused their deaths—until after the wear period, when a final report was generated.

91. In one such instance, a patient suffered a Ventricular Fibrillation—a symptom that results in the heart failing to pump blood to the rest of the body due to rapid and uncoordinated contractions—while using the Zio AT monitor. This serious arrhythmia caused the patient's death. However, because the patient had hit the transmission limit prior to this deadly cardiac event, their doctor was not notified in "real-time" or even "near real-time." Rather, the patient's cardiac telemetry did not become available to their doctor until the final report at the end of the 14-day wear period was generated.

92. These reports continued into the Class Period. For example, in a complaint dated April 27, 2022, the FDA quoted a Zio AT customer's report of having "32 minutes of sustained ventricular tachycardia with loss of consciousness. Device designed to report daily events remotely and failed to report this life-threatening arrhythmia until 1 week later."

93. The Company failed to timely report many of these serious events to the FDA, as required by FDA regulations on medical device reporting ("MDR"). The FDA noted that, based on its investigation, the Company had failed to report multiple serious events to the FDA, including two "MDR reportable events where a patient passed away [in or before October 2021] while using the Zio AT system," notification of which the Company withheld from the FDA for ***a year***; an incident where a patient was hospitalized due to serious cardiac events in or before April 2022, which the Company withheld from the FDA for five months; and three instances where patients suffered "significant arrhythmias" that were not caught because the transmission limit had been reached, which the FDA noted was a "reportable malfunction" because it was "likely to cause or contribute to death or serious injury"—the Company did not report these instances at all and instead termed them "unreportable malfunctions."

94. ***Second***, with respect to the registration limitations, iRhythm "has known ***since 2017*** that patient data is held inaccessible . . . thereby not allowing it to be properly analyzed for potential corrective action" when registration was technically incomplete, but made no effort to notify physicians and patients of this limitation. The FDA noted that, through its inspection, it was able to readily identify dozens of such incidents. These serious incidents included significant arrhythmias required physician notification, such as atrial fibrillation and bradycardia.

95. The FDA reviewed 39 "Ztickets" during its inspection, in which "clinicians had requested immediate notification of critical and life-threatening arrhythmias" but "the patient data was not reported" during the wear period "due to the incomplete registration." Critically, the FDA found that reports to clinicians were withheld due to missing technical patient registration information that was "not necessary to allow matching of data to a specific patient"—including such information as "pending billing or insurance information."

2. The Executive Defendants Were On Notice Of This Trend Of "Critical Customer Complaints" Regarding The Transmission And Registration Limitations With The Zio AT

96. This serious trend of "critical customer complaints" would have been well-known at the highest levels of iRhythm, including by the Executive Defendants. FE 2, a former senior compliance officer at iRhythm during the Class Period,[4] recalled that Blackford and Devine served on iRhythm's Compliance Committee. FE 2 said that iRhythm had a compliance reporting line that tracked all the complaints and assigned each one a severity ranking of either low, medium, or high. The Compliance Committee received reports on these complaints on a quarterly basis, including from FE 2. Indeed, iRhythm publicly stated in its SEC filings that quarterly reports by iRhythm's Ethics and Compliance department concerning iRhythm's interactions with healthcare providers were provided to the Compliance Committee. Complaints from doctors who were never notified of severe arrhythmias due to the Zio AT's transmission limit, particularly those that

[4] Because the seniority of this Former Employee makes them easily identifiable by their formal title, Lead Counsel has provided the role and responsibilities for this senior executive rather than their title.

resulted in the patient's death, would likely qualify as high-grade complaints that would be reported both to the Compliance Committee and to the Board of Directors.

97. Additionally, Blackford specifically claimed that he paid close attention to regulatory compliance. Blackford highlighted this focus at the Morgan Stanley Global Healthcare Conference on September 13, 2022, stating, "We began in 2021 to really invest into the whole quality regulatory organization of the company." Here, where there is no question that the customer complaints were readily identifiable—as demonstrated by the FDA's ability to swiftly identify them during the inspection—Blackford and senior management would have known, or been severely reckless in not knowing, that the Zio AT customer complaints existed.

98. Indeed, federal regulations required iRhythm to have complaint review procedures that would ensure that the Company tracked complaints and reported them to management and the FDA. As required by Quality System regulations from 21 C.F.R. § 820.198(a), iRhythm would have "maintain[ed] complaint files" and "establish[ed] and maintain[ed] procedures for receiving, reviewing, and evaluating complaints ***by a formally designated unit***." These procedures ensure that "[a]ll complaints are processed in a uniform and timely manner." 21 C.F.R. § 820.198(a)(1). As described in the FDA's "Guidance for Industry" concerning medical device reporting, the Quality System regulation requires manufacturers "to have a formally designated unit to receive, review and evaluate complaints," and manufacturers "should ask all of their employees to forward device-related complaints to that unit in a timely manner."

99. Further, as required by Corrective and Preventive Action regulations from 21 C.F.R. § 820.100, iRhythm would have analyzed and investigated complaints, ensured that information related to problems "is ***disseminated to those directly responsible*** for assuring the quality of such product or the prevention of such problems," and submitted "relevant information on identified quality problems, as well as corrective and preventive actions, ***for management review***." 21 C.F.R. § 820.100(a)(6)-(7). Medical Device Reporting regulations from 21 C.F.R. § 803.50 further required that manufacturers like iRhythm are "responsible for conducting an investigation of each event and evaluating the cause of the event," when "[a]ny information in your possession" "reasonably suggests that a device that you market" may have "caused or

contributed to a death or serious injury." These MDR regulations further require such information to be reported to the FDA within 30 calendar days.

100. Additionally, as described in iRhythm's Code of Conduct dated April 15, 2022, iRhythm's Quality Policy included a commitment to "[r]eport potential complaints and adverse events as soon as you discover them to the Quality and Regulatory Assurance team." As noted in iRhythm's 2022 Environmental, Social and Governance Report:

- iRhythm has a "Quality Council" that "reviews matters quarterly," the Company "conduct[s] a management review annually," and [s]ubsystem metrics, such as Corrective and Preventive Actions (CAPA) and complaints are typically reviewed monthly"
- "iRhythm works cross-functionally with Medical Safety, Clinical Operations, R&D, Customer Care and Quality to identify the root cause of the reported complaints. The information is analyzed, trended, evaluated with available data of the same or similar devices, and then reported back to the appropriate functions to determine next steps."
- "Quality and Regulatory leaders meet at least quarterly to review, and where necessary, take action to address quality system performance indicators."
- "iRhythm's quality management system is certified to ISO 13485, an internationally recognized standard for medical device quality management system."

101. Similarly, while he was Chief Operating Officer, Devine stressed the Company's tracking related to manufacturing quality and customer complaints. At the September 21, 2022 Investor Day, he explained, "We're now tracking literally hundreds of different metrics on a ***weekly, sometimes on a daily basis***. I mean, these are ranging from ***manufacturing quality to customer service call metrics*** to clinical efficiency and accuracy to the initial quality of insurance claims when we submit them to payers." Devine also emphasized his own involvement in these metric-based operations, stating, "We've moved all the operations groups under me."

102. If any of Defendants' claims about regulatory focus were true, these highly material customer complaints—about one of the Company's two devices—would have been reported to Blackford and Devine, at minimum.

3. The FDA Privately Warned iRhythm During The Class Period That iRhythm Was Improperly Marketing The Zio AT As A "Near Real-Time" Device For "High-Risk" Patients

103. Defendants were aware that the FDA had discovered these critical limitations in the Zio AT and that it disapproved of iRhythm's marketing well before receiving the Warning Letter. On August 12, 2022, on the last day of a twelve-day inspection of iRhythm's manufacturing facility in Cypress, California starting on July 25, 2022, the FDA sent iRhythm a private, confidential inspection report (an FDA Form 483) outlining multiple issues with the labeling and marketing of the Zio AT as a "near real time" device for "high risk" patients. Indeed, the FDA concluded and conveyed to the Company that the "***Zio AT was a contributing factor [in a] patient's death***."

104. A Form 483 report is issued to management at the conclusion of an inspection when an FDA investigator has observed any conditions or practices indicating that an FDA-regulated product may be in violation of the FDA's requirements. The company is encouraged to respond in writing with its corrective action plan and implement that plan expeditiously.

105. ***First***, the FDA's Form 483 identified the Zio AT's transmission limit and warned iRhythm that because of this flaw, the Zio AT did not provide "near real-time" warnings and was inappropriate or even dangerous for use in "high-risk" patient populations.

106. The FDA further found that while iRhythm claims that the Zio AT provides "'timely detection of clinically actionable arrythmia during the wear period,' with immediate notification to clinicians (MD Notification)," the Company had, as discussed above, received dozens of complaints since June 2019 of severe cardiac events that were not reported to physicians as required.

107. ***Second***, the FDA also warned iRhythm that the Zio AT's technical registration requirement resulted in the device's failure to provide "near real-time" notifications. Furthermore, the FDA identified in this private inspection report that iRhythm knew about this limitation since 2017 and failed to remedy it or warn patients of it. The Form 483 described this as a "device limitation that can contribute to failure to notify clinicians of severe patient episodes, including

life-threatening arrhythmias such as Ventricular Fibrillation," and the FDA noted that iRhythm had not "implement[ed] corrective actions to address this device limitation."

4. The Company Privately Responded To The Form 483 Admitting That The Transmission Limit Posed A "Hazardous Situation," While Continuing To Make False Statements

108. On September 1, 2022, Defendant Blackford responded to the FDA on iRhythm's behalf. Blackford copied Patrick Murphy (Chief Legal Counsel and EVP of Quality & Regulatory, Market Access & Government Affairs), Mazi Kiani (SVP, Quality & Regulatory), and lawyers from Reed Smith LLP on the letter.[5]

109. Blackford did not deny the FDA's observations relating to the Zio AT transmission limit and registration requirements. Nor did Blackford claim that he and other senior management had not known about these limitations in the Zio AT. Instead, the response letter reflected Defendants' understanding that the transmission limit 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," because eliminating the need for recharging "necessarily places" limitations on the number of transmissions. Therein, Blackford also admitted that iRhythm had "conducted a risk assessment" and found that ***"[t]he hazardous situation of a max transmission design constraint potentially leads to a delayed notification of ECG findings until the final report is posted with all findings from the wear period.***"

110. Incredibly, despite these admissions, Blackford attempted to place blame on doctors and patients. For example, concerning one patient complaint of their Zio AT failing to notify their doctor of a severe arrhythmia, Blackford argued that because the doctor had received some "routine reports" possibly documenting episodes of ventricular fibrillation, the "obligation to review and treat" was "incumbent upon the treating clinician"—even though iRhythm failed to transmit the notifications that the doctor had requested and expected. Additionally, regarding similar patient complaints of failure to send near real-time notification of arrhythmic events, iRhythm argued that because doctors received "daily reports"—rather than the specific, immediate

[5] Lead Counsel was able to obtain this response letter via a FOIA request to the FDA.

notifications they had requested—the doctors "could have acted on" that information. Similarly, in claiming that their monitoring employees attempt to notify doctors when the transmission limit is approaching, iRhythm asserted that it "is the ordering physician's responsibility to determine if they have adequate amount of ECG information or would like an additional patch shipped to the patient."

111. The Company further told the FDA, "Although the Zio AT, as an ambulatory ECG monitor, ***is not intended to be an alert system***, the conclusion of this assessment is there are in fact process and labeling improvements which can be made to increase [health care provider] awareness and understanding of the purpose of the current process and the potential impact for the patient." This would, of course, be a surprise to the patients and providers who understood that the Zio AT was intended for "high-risk" patients who require "real time" notifications.

112. As a result of these warnings from the FDA, on September 1, 2022, iRhythm initiated a "voluntary recall" (that it only disclosed to investors later) that would notify doctors "that monitoring cannot begin until the patient registration is completed." On September 28, 2022, iRhythm initiated a Customer Advisory Notice to Zio AT customers regarding a Zio AT "labeling correction" that involved "additions and modifications to the Zio AT labeling precautions relating to the device's maximum transmission limits during wear, and also to the need for healthcare providers to complete registration to initiate monitoring services."

113. However, as The Capitol Forum reported on April 4, 2024, the Customer Advisory Notice was carefully worded to divulge little helpful information, and to help iRhythm "control the narrative." Specifically, The Capitol Forum reported that, per one iRhythm employee, the Customer Advisory Notice "appear[ed] to downplay the potential frequency of the problem and highlight the technical limitations as a benefit to patients," and that it "only had to be signed and returned by a member of a practices administrative staff rather than the prescribing cardiologist."

114. Despite the FDA's findings, iRhythm continued to market the Zio AT as a "near real-time" device designed for "at-risk" patients and took no steps to disclose the issues flagged in the inspection report to investors. Notably, on September 21, 2022—over one month after the Company received the Form 483, and weeks after the Company submitted its response to the FDA

privately admitting to the "hazardous situation" posed by the transmission limit—the Company held an Investor Day where Defendants repeatedly misrepresented the Zio AT as "putting information into the hands of the patient on a near real-time basis," "allow[ing] transmissions during the patient's wear time," enabling "timely monitoring," and providing an MCT with "[a]ctionable transmission reports" along the high risk end of the "spectrum of care." Defendants continued the same misrepresentations through the end of the Class Period.

F. The FDA Issued The Warning Letter To iRhythm

115. On May 25, 2023, the FDA issued the Warning Letter to iRhythm regarding the violations in labeling and marketing the Zio AT as a "near real-time" device for "high-risk" patients. Warning letters are issued by the FDA when it identifies significant violations of federal requirements. Significant violations are violations that may lead to enforcement action by the FDA if not promptly corrected. The FDA uses warning letters as its main method of achieving voluntary compliance with applicable laws.

116. As set forth above, the Warning Letter found that iRhythm was committing an unapproved device violation for the Zio AT for marketing the device to "high risk patients" as an MCT, and that iRhythm would have to submit a new 510(k) for the Zio AT. The FDA further found that iRhythm had been committing labeling violations, by making statements about the product (that it was for "high risk patients" and provided "near-real time continuous transmission") that were not true. Further, the FDA found quality system regulation violations, because iRhythm had known about these violations since 2017 (for the registration limitation) and 2019 (for the transmission limitation) and had done nothing about them. In addition, the FDA noted that the customer complaints revealed that ***the device was hitting the transmission limit more often than expected***," which "introduce[d] a nonconformance," and that the Zio AT was "***not remotely capable of delivering near-real time monitoring for high-risk patients***." Finally, the FDA found medical device reporting violations because the Company failed to report to the FDA when it became aware of information that reasonably suggested that the Zio AT may have caused or contributed to death or serious injury.

G. Early In the Class Period, Defendants Were Aware Of Numerous Complaints Concerning Technicians' Routine Misreading Of Zio AT Data And iRhythm Sought To Sweep The Complaints Under The Rug

117. At the same time that iRhythm was under an onslaught of FDA criticism for the material limitations in the Zio AT device, starting in at least May 2022, Defendants also received ***thousands*** of undisclosed complaints about the Company's inaccurate reporting. Specifically, the FDA explained in the 2024 Form 483, "[Y]our firm received approximately 4,014 complaints related to your Certified Cardiographic Technician (CCT) personnel operations from 05/02/2022 to 07/19/2024, including issues/events related to CCT personnel misreading arrythmia data and providing such misclassified data to end users for diagnosis purposes. However, your firm is not adequately analyzing these complaints, issues, or events to identify the rate of occurrence or detect recurring quality problems."

118. Having found thousands of patient complaints concerning the endemic inaccuracies of the Zio device, the FDA identified three separate ways the Company worked to conceal these complaints and the meaningful impact of these inaccuracies. ***First***, the FDA found that the Company simply refused to analyze the complaints or to take action to address them. Specifically, the FDA found that the Company failed to take action to "investigate the cause or identify the action(s) needed to correct and prevent recurrence of this quality problem." Even outside of receiving these thousands of patient complaints, the FDA found that iRhythm's risk analysis for the critical CCT function was inadequate or nonexistent, noting that "You have not evaluated the risk associated with your Certified Cardiographic Technician (CCT) personnel operations to ensure that your Zio AT, Zio XT, Zio Monitor, and Zeus System Software medical devices conform to defined user needs and intended uses."

119. ***Second***, knowing that these complaints would trigger FDA inquiry, iRhythm withheld these complaints from the FDA in direct violation of the FDA's MDR requirements. The Form 483 noted, "you ***routinely do not report*** required information after becoming aware of events that allege your Zio AT, Zio XT, Zio Monitor, and Zeus System Software medical devices have malfunctioned and would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." It is particularly remarkable that iRhythm withheld these serious

complaints in light of the FDA's earlier criticism of the Company for violations of MDR requirements, discussed above.

120. ***Third***, the Company manipulated its internal analysis of the accuracy of the Zio devices in a manner designed to make the device appear more accurate than it was. The FDA explained that 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." The FDA described an example of a "duplicated algorithm miss event": A certain type of arrhythmia was not detected during patient wear (and thus should have been included as an error in the analysis), but because other arrhythmias of the same kind were accurately reported, the misread was not included as an error. The FDA concluded that due to these missing inputs, "***it is not an accurate or all-inclusive quality metric***."

121. Finally, as explained above, the Company's technicians were trained and instructed to provide inaccurate final reports that matched the reports generated during the patients' wear time. Technicians were instructed to do this even when they believed an arrhythmia had occurred. As one technician explained to the Capitol 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."

H. The Truth Is Revealed

122. Investors learned the truth behind Defendants' fraudulent scheme over a series of partial corrective disclosures, each of which led to a significant stock price decline and caused investors losses. Each of these events disclosed a part of the relevant truth, but not the entire truth. As such, the full scope of the fraud was only revealed over the course of all of the disclosures discussed below.

1. November 1, 2022: iRhythm Disclosed Downgraded Revenue Guidance Due To A "Customer Advisory Notice" Issued In Connection With the Zio AT

123. The truth behind Defendants' false statements began to emerge on November 1, 2022, after the market closed, when iRhythm issued a press release announcing revised revenue

guidance for its fourth quarter and full year 2022. In the press release, the Company provided revised revenue guidance for 2022 of between $407 million and $411 million, a quarter after the Company had ***increased*** guidance to between $415 million and $420 million. The Company attributed the revision in part to "Zio AT utilization" as a challenge that will "persist[] into the fourth quarter" and "have led us to reduc[e] our full year revenue guidance."

124. Later that same day, iRhythm held a conference call with analysts and investors to discuss the Company's financial results. During that call, Blackford explained that the Company reduced the revenue outlook for the full year in part because it had "voluntarily issued a Customer Advisory Notice to [its] Zio AT customers" and thus "ha[s] seen reduced growth with Zio AT within the fourth quarter to-date." Blackford further announced that "[w]ith the Customer Advisory Notice" the Company "adjusted [its] Zio AT forecast for the quarter to grow closer to approximately 20%, which is a step down from the upper 40% growth [it] had seen through the first nine months of the year." Defendants did not disclose the FDA's findings from its August 2022 inspection or the cause or substance of the customer advisory notice that it had issued.

125. Investors were surprised by this news. In discussing the lowered guidance and its connection to the "lower AT utilization due to a voluntary customer advisory notice," analysts at William Blair remarked, "[t]he decrease is disappointing and naturally leads to questions around why management did not provide these updates at its mid-September analyst day," when the Company had reiterated its previously provided optimistic guidance for 2022. Similarly, analysts at Oppenheimer noted the link between the revenue miss and a slowdown in Zio AT growth "driven by Customer Advisory notice on managing event trigger limits." The Oppenheimer analysts commented, "Suffice it to say, given the short gap since the late-September Investor Day, the surprise shortfall in the quarter is a head scratcher."

126. These analysts were referring to iRhythm's Investor Day, held on September 21, 2022, in which Defendants made multiple false statements (as alleged herein) concerning the Zio AT's "near real-time" capabilities, "real time notification[s]," "timely monitoring," and status as a "mobile cardiac telemetry" device providing for patients on the high-risk end of the "spectrum of care." By the time of this Investor Day, unknown to these analysts, Defendants had already

received the FDA's Form 483 pointing out transmission and labeling issues, had responded to it admitting a "hazardous situation," and had indicated to the FDA then that iRhythm would be issuing the field advisory regarding the Zio AT.

127. As a result of these disclosures, the price of iRhythm common stock declined by $5.60 per share, or 4.4%, from a closing price of $126.77 on November 1, 2022, to a closing price of $121.17 on November 2, 2022. As the market digested this news and multiple analysts cut their price targets, the price of iRhythm common stock declined by an additional $14.07 per share, or 11.6%, to a closing price of $107.10 on November 3, 2022.

128. The Company tried to quiet investor concerns. During the November 1, 2022 conference call, Defendant Blackford assured investors that the slower growth was only "more of a near-term impact . . . on the Zio AT side," because "once we get the [Zio AT] packaging updated, the labeling updated, the field action notice starts to subside, I don't think it becomes nearly as big of a headwind." This statement was materially false and misleading because the Company knew that the issues it faced with Zio AT's transmission limit were not a "near-term" headwind that merely involved updates to "packaging" and "labeling." From its receipt of the FDA's Form 483, the Company knew that it faced severe scrutiny from the FDA regarding the transmission limit and its failure to disclose the limit to end users and physicians. Moreover, since the device was never approved as an MCT for real-time reporting on a high-risk or "at-risk" patient population, the Company knew it was continuing to promote the product for unapproved and off-label uses.

2. November 4, 2022: iRhythm Discloses FDA "Labeling Correction"

129. On November 4, 2022, after the market closed, the Company filed with the SEC its quarterly report on Form 10-Q for the third quarter of 2022. In the 10-Q, the Company revealed additional details regarding the Customer Advisory Notice. Specifically, iRhythm disclosed that the Company initiated the Customer Advisory Notice on September 28, 2022, following issues raised by the FDA during an inspection that culminated in an inspection observation report on Form 483 (without describing the inspection report), and that the Customer Advisory Notice warned patients of a "labeling correction" related to "the device's maximum transmission limits during wear, and also to the need for HCPs to complete registration to initiate monitoring services."

iRhythm stated that it "reported this Customer Advisory Notice and related information to the FDA under 21 C.F.R., Part 806, and are in ongoing communication with the FDA on this matter."

130. As a result of these disclosures, the price of iRhythm common stock declined by $2.43 per share, or nearly 2.4%, from a closing price of $102.87 on November 4, 2022, to a closing price of $100.44 on November 7, 2022.

131. However, in its Form 10-Q for the third quarter of 2022, the Company tried to assuage investor concerns by adding, "we do not expect this Zio AT labeling correction or the activities associated with the topics raised in the FDA inspection to present a material risk to our business at this time."

132. On February 23, 2023, after the market closed, iRhythm announced its financial results for the fourth quarter and full year 2022. Later that evening, iRhythm held a conference call with analysts and investors to discuss the Company's financial results. During the conference call, in response to an analyst question regarding the growth of Zio AT in view of the Customer Advisory Notice, Blackford responded, "that business is going to grow right around 30% for us . . . we certainly have seen a difference in that growth profile coming out of that field advisory notice. Now we've made all the updates in the labeling that we need to do and in the packaging that we need to do." This statement was materially false and misleading because the Company had failed to take sufficient measures to remediate the concerns the FDA raised in the Form 483, and failed to remedy the "hazardous situation" Defendants admitted to in their response. Far from having done all "that we need to do" in response to the FDA's findings, the Company was continuing to market the Zio AT for an unapproved patient population by describing it as an MCT providing "near real-time" information. Since the Zio AT device was never approved as an MCT for real-time reporting on a high-risk patient population, the Company falsely represented to investors that it had done "all that we need to do" through its updated labeling and packaging—which, as confirmed by the FDA's Warning Letter issued months later, was insufficient.

133. On March 10, 2023, iRhythm announced that Defendant Devine resigned from his position as COO of the Company.

3. May 4, 2023: iRhythm Disclosed DOJ Subpoena

134. Then, on May 4, 2023, the Company filed with the SEC its quarterly report on Form 10-Q for the first quarter of 2023. In the Form 10-Q, iRhythm announced that "on April 4, 2023, [it] received a Subpoena Duces Tecum from the Consumer Protection Branch, Civil Division of the U.S. Department of Justice, requesting production of various documents regarding [its] products and services." As disclosed by the DOJ after the Class Period, this subpoena sought "sought communications and other documents concerning potential issues related to the Company's Zio Systems, including that the Zio Systems were failing to timely transmit patient cardiac data to physicians for review after the occurrence of a cardiac event."

135. This news surprised investors, with analysts at BTIG noting that the disclosure of the subpoena was "[t]he big surprise on the call" and was "unsettling." William Blair analysts observed that "the DOJ investigation adds a new risk to the story," "adds a new wrinkle to the story/market," and "is likely to remain an overhang." Analysts at J.P. Morgan commented that "news of a DOJ subpoena shows that once again, iRhythm's rose comes with a thorn."

136. This news caused the price of iRhythm common stock to decline by $9.25 per share, or 6.9%, from a closing price of $134.04 on May 4, 2023, to a closing price of $124.79 on May 5, 2023.

4. May 30, 2023: iRhythm Discloses The Warning Letter

137. On May 30, 2023, after the market closed, iRhythm filed with the SEC a Current Report on Form 8-K, disclosing that it had received a Warning Letter from the FDA, which "resulted from the inspection of the Company's facility located in Cypress, California that concluded in August 2022" and "alleges non-conformities to regulations for medical devices, including medical device reporting requirements, relating to the Company's Zio AT System and medical device quality system requirements." While iRhythm did not disclose the full contents of the Warning Letter on May 30, 2023, it did share certain details about the Warning Letter's contents with analysts behind the scenes. For example, Oppenheimer wrote in a June 1, 2023 Company Update that the Warning Letter identified issues concerning "untimely patient registration," "trigger warning limits, traditional MCOT definition" and "device changes."

Oppenheimer further noted that the "Zio AT has patient and device trigger event limits (100 and 500, respectively)," and that once "wearers hit these limit[s] . . . [the] patch becomes a passive monitor." As explained in ¶¶115-16 above, when the Warning Letter was published, it confirmed that iRhythm had falsely marketed the Zio AT as approved for use in high-risk patients that require real-time cardiac monitoring, when in truth, the Zio AT is only approved for "long-term monitoring of arrhythmia events for non-critical care patients ***where real-time monitoring is not needed***." Accordingly, the Warning Letter required iRhythm to submit a new 510(k) because iRhythm's "labeling describes a new patient population" which "affect[s] the safety or effectiveness of the device."

138. Investors were stunned by these revelations. J.P. Morgan analysts remarked that they "understand investor frustration with what feels like a never-ending series of external pressures," including the "DOJ investigation and Zio AT warning letter." These analysts "expect[ed] to see these challenges pressuring the stock given how difficult it is to risk-adjust for these types of binary events." Similarly, analysts at Truist observed that the Warning Letter joins "a now growing list of regulatory considerations," and the Warning Letter "could very well serve as an extended overhang on shares." The Truist analysts further noted that "ultimately it seems like this all took mgmt. by surprise and full ramifications of potential remediation are unknown."

139. These disclosures caused the price of iRhythm common stock to decline by $7.41 per share, or 6.1%, from a closing price of $121.68 on May 30, 2023, to a closing price of $114.27 on May 31, 2023. As the market digested the disclosure of the Warning Letter and the additional details shared with analysts, it fell an additional 7% over June 1-2, 2023, to a closing price of $105.66 on June 2, 2023.

140. In April and May of 2024, Capitol Forum published articles quoting several current and former sales representatives that maintain they were instructed to market the Zio AT as an MCT, and that "the [C]ompany misled both them and customers about the short-comings of the Zio AT." The Capitol Forum also reported that iRhythm submitted 93 medical device reports ("MDR") to the FDA's MAUDE database for manufacturer and user complaints regarding medical devices between September and December of 2023, ***over 15x more MDRs*** than iRhythm had

submitted in the previous 4 months. The Capitol Forum also reviewed all 48 reports submitted in April 2024 on the Zio AT. Forty of those reports noted that "patient experienced an arrythmia that met Medical Doctor Notification (MDN) requirements that was not transmitted during the wear period," and several others concluded that arrhythmias were "only detected when the device was sent back to iRhythm for analysis, often weeks after the event occurred." Finally, The Capitol Forum analyzed data of FDA reported deaths while using the Zio AT as well as MCTs sold by other companies, and they found that reports of patient deaths were far higher with the Zio AT.

5. July 1, 2024: The DOJ Files Suit To Enforce Its Subpoena, Revealing The Tie To The Zio AT And The Seriousness Of The Investigation

141. On July 1, 2024, the DOJ revealed in court filings that iRhythm had refused to produce certain relevant documents regarding the Zio AT, in response to the same DOJ subpoena that the Company previously disclosed on May 4, 2023. This revealed that the DOJ inquiry was in fact about the Zio AT's failure to timely transmit patient data to doctors, which had not been previously confirmed. This event further revealed to investors the seriousness with which the DOJ was pursuing its investigation, given that it was now seeking court intervention to obtain these documents about the Zio AT over a year after the DOJ inquiry had been disclosed. Specifically, the DOJ was forced to move for enforcement of the subpoena because iRhythm has withheld relevant documents—"over 1,000 documents" concerning "third-party consultant reports"—over the course of months of negotiations. The DOJ filed its motion in the U.S. District Court for the Northern District of California before Judge Martínez-Olguín. In its petition, the DOJ explained that "the Subpoena sought communications and other documents concerning potential issues related to the Company's Zio Systems, including that the Zio Systems were ***failing to timely transmit patient cardiac data to physicians*** for review after the occurrence of a cardiac event."

142. The DOJ's petition specified that the Company "has refused to produce three third-party consultant reports assessing the design history of their devices, as well as hundreds of related communications that do not involve an attorney." DOJ's Petition for Order to Show Cause and Application for Enforcement of Administrative Subpoena, ECF No. 1, 3:24-cv-03967 (N.D. Cal. July 1, 2024). These third-party reports and related communications assess "whether the

Company's cardiac monitoring devices were developed in accordance with the approved design plan," which the Company is required by federal regulation to maintain.

143. This news caused the price of iRhythm common stock to decline by $10.88 per share, or 10.1%, from a closing price of $107.64 on June 28, 2024, to a closing price of $96.76 on July 3, 2024 as investors digested the news.

144. Investors were extremely troubled by this news. In later investor calls in August and September 2024, analysts asked repeatedly about the progress, scope, and impact of the DOJ's enforcement action. Several analysts included the schedule of the briefing of the DOJ's motions in subsequent analyst reports as value-relevant information. Indeed, no doubt due to investor concerns, during the Company's second quarter 2024 earnings call on August 1, 2024, Defendant Blackford affirmatively addressed at length the DOJ's motion, the advice the Company had received from outside counsel regarding the motion, and next steps in the litigation.

145. iRhythm itself has acknowledged the material impact of the DOJ's filing and the information contained in it on its stock price. The Company moved to seal documents associated with the DOJ's motion from public view. iRhythm's Administrative Motion to File Under Seal, ECF No. 4, 3:24-cv-03967 (N.D. Cal. July 3, 2024). In iRhythm's reply brief in support of that motion to seal, it noted "the immediate negative impact the disclosure of the investigation [the DOJ's administrative motion] may have had on its stock price." ECF No. 6 at 4, 3:24-cv-03967 (N.D. Cal. July 7, 2024). In a more recent Administrative Motion to Seal, the Company noted that "when the information was published in the Government's Petition to Enforce, iRhythm's stock dropped over 10% in just two days." ECF No. 22 at 4, 3:24-cv-03967 (N.D. Cal. Sept. 13, 2024); *see also* ECF No. 17 at 4, 3:24-cv-03967 (N.D. Cal. Aug. 16, 2024) (same).

6. August 1, 2024: iRhythm Discloses Its Receipt of Form 483s Regarding Inspections Of Cypress And San Francisco Facilities

146. On August 1, 2024, iRhythm disclosed that the FDA had issued new Form 483s involving the Zio AT. The Form 10-Q filed on August 1, 2024, stated,

> On July 15, 2024, FDA initiated inspections of our Cypress and San Francisco FDA-registered facilities. We received Form 483 observations at the close of the inspections of our Cypress and San Francisco facilities. . . . These inspections broadly evaluated

> medical device quality system requirements and other medical device regulatory topics, and the observations generally centered on complaint handling and medical device reporting, risk analysis regarding the involvement of the technicians to prepare the Zio ECG reports, the corrective and preventive action process, process controls and statistical techniques.
>
> As we are already subject to an FDA warning letter associated with our Cypress facility, the inspection results may contribute to greater risk of potential escalation, which could involve issuance of additional warning letters, or there is a possibility that FDA could initiate consent decree discussions.

147. The Company also disclosed in a Form 8-K filed the same day that Defendant "Brice Bobzien resigned from his position as Chief Financial Officer of the Company, and his employment with the Company, effective August 31, 2024."

148. During an earnings call that day, Defendant Blackford downplayed the significance of the Form 483s, stating, "At a high level, the observations were primarily focused on our quality system and regulatory compliance, including complaint handling and medical device reporting, risk analysis regarding the involvement of the company's certified technicians to prepare the ECG reports and the CAPA process." In response to numerous analyst questions regarding the Company's latest regulatory issues, Defendant Blackford stated, "At the end of the day, I think the fundamental issue sort of comes down to whether the IDTF, the CCTs, if you will, the clinical technicians, are they part of the product, or are they not? And I think from the beginning of time, we've viewed those as separate items. And I think the FDA has a bit of a different perspective right now that we're working through."

149. On the same earnings call, Defendant Blackford falsely claimed that,

> [T]here is no conversations in here with the FDA in the course of these inspections around the overall safety or efficacy of our product. That's not being discussed. . . . This is really about how we go about identifying what complaints to report or not to report, how we document those things and the processes set around it. So, ***nothing specific to safety or efficacy of the product whatsoever***. It's more about how we continue to build and make our quality systems more robust.

150. Investors were stunned by the revelations about the Zio AT. On August 2, 2024, analysts at William Blair noted that the new Form 483, combined with the ongoing DOJ inquiry

and the Zio AT warning letter, "could take several quarters to resolve and delay next-gen product launches." Analysts at J.P, Morgan noted that, contrary to the Company's characterization, the problems observed in the Form 483s "should be recognized as a safety concern given the chance for misdiagnosis."

151. Notwithstanding the fact that the Company had otherwise disclosed positive financial news, the Company's disclosure of its receipt of new Form 483s caused the price of iRhythm common stock to decline by $10.34 per share, or 12.2%, from a closing price of $84.22 on August 1, 2024, to a closing price of $73.88 on August 2, 2024.

7. August 9, 2024: Capitol Forum Reveals The Substance Of The Latest Form 483 Reports, Including 4,000 Patient Complaints Regarding The Devices' Accuracy

152. On the evening of August 9, 2024, the Capitol Forum published an article revealing the substance of the new Form 483s, which the Capitol Forum obtained through a FOIA request. The article was titled, "iRhythm: Recent FDA Inspection Reports Obtained by Capitol Forum Detail Significant Problems with Company's Technicians and Operations; Company Received Over 4,000 Complaints Regarding Technicians Misreading Data Yet Did Nothing." Unlike the Company's disclosure on August 1, 2024, this article publicly disclosed specific details of the FDA's findings in the Form 483s. Notably, the article revealed the FDA findings explained above, including the 4,014 complaints that iRhythm received related to technicians' misreading of arrhythmia data and providing that misclassified data to patients and doctors, and the Company's failure to analyze these complaints and report them to the FDA.

153. This news caused the price of iRhythm common stock to decline by $6.35 per share, or 8.9%, from a closing price of $70.99 on August 9, 2024, to a closing price of $64.64 on the next business day, August 12, 2024.

V. POST-CLASS PERIOD DEVELOPMENTS

154. An August 13, 2024 Capitol Forum article relayed commentary from an FDA expert, highlighting the seriousness of the FDA's repeated findings against iRhythm. The FDA expert, Marc Sanchez, explained that the FDA's new Form 483s could indicate that the government is preparing to take significant regulatory action. He explained, "It's impressive that

following the Warning Letter and what appears to be ongoing communication of corrective actions, the FDA conducted simultaneous, multi-day inspections at two facilities. The result is incredibly detailed Observations." Sanchez emphasized "how little it appears the Agency trusts this company." According to Sanchez, the new inspections show that the FDA wanted to verify whether iRhythm had actually implemented the corrective actions the FDA requested relating to the Company's previous violations. Sanchez observed that "[i]t does not seem to have gone well," as the new Form 483s found that corrective actions were inadequate and several standard operating procedures were not followed. He explained, "These 483s set the foundation for future litigation by the FDA because it shows that the agency has provided ample opportunity for self-correction, but the company seems incapable of doing so. I wouldn't be surprised to learn that the company voluntarily enters into a Consent Decree or that the DOJ/FDA files for a permanent injunction." Regarding the 483 observations related to CCTs' misinterpretation of arrhythmia data, Sanchez observed that "ultimately what the FDA is saying through these two inspections is that the procedures related to this question, like complaint tracking, are so deficient that there's no ability to complete a proper assessment."

155. On August 15, 2024, analysts at Wells Fargo reported their FDA consultant's evaluation that in light of these Form 483 observations, "there is risk that IRTC receives another warning letter" from the FDA. The analyst report further observed that while the Company "made the case that CCT's are separate from its Zio product, our consultant and we believe that they are an integral part of IRTCs product/service. Our expert believes remediation will require IRTC to revamp training and risk controls for its CCT's."

156. On September 16, 2024, investment analyst firm CFRA published a report detailing its significant concerns about iRhythm. Noting the Company's regulatory issues, CFRA predicted that "if the company continues to face regulatory pressure following new 483s the stock will likely decline." CFRA rated its "concern level" about iRhythm as "significant."

VI. ADDITIONAL SCIENTER ALLEGATIONS

157. Numerous allegations set forth above and summarized below give rise to the strong inference that Defendants intentionally or recklessly misled investors about the function of the Zio AT. These allegations include, but are not limited to, the following:

158. ***First***, iRhythm 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." Two such complaints concerned instances where the patient was killed by the arrhythmia that went un-notified. Furthermore, iRhythm has known ***since 2017*** that the registration requirement and policy caused the same serious failure to transmit arrhythmia data. 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. In the Warning Letter, the FDA reiterated the conclusion that iRhythm knew ***since 2019*** that the transmission limit was resulting in data not being transmitted. As the Warning Letter explained, "Records reviewed during our inspection indicate that ***your firm has been aware of customer complaints related to this issue since at least 2019***. Specifically, our inspection found a significant number of complaints regarding this issue, which revealed two deaths as well as significant arrythmias that were not reported to physicians." iRhythm had information relevant to these patient complaints readily available to investigators thanks, in part, to internal investigations iRhythm had already conducted. As to the registration requirement failure, the Warning Letter stated, "***Since at least 2017, your firm has been aware of this issue where your clinical care team cannot access the patient's data***. Our inspection confirmed 39 examples from a list of over [redacted by FDA] Z tickets where this problem occurred." On top of this prior knowledge from customer complaints, the Company and Blackford admitted in the 483 response letter that 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," because

eliminating the need for recharging "necessarily places" limitations on the number of transmissions.

159. Weeks before the beginning of the Class Period, iRhythm received reports of two deaths that had occurred while the patient was wearing the Zio AT, suffered serious arrhythmias, and the Zio AT failed to notify their doctor as required because of the transmission limits. Even if the "negative trend [of] critical customer complaints" up until this point did not put the Executive Defendants on notice of the truth behind iRhythm's false and misleading marketing—which it should have—these two tragic deaths undoubtedly would have.

160. When Blackford responded to the FDA's Form 483, he did not deny knowledge of these events or of the Company's internal investigation into these events. Instead, as noted above, he admitted prior knowledge of the transmission limit as a "crucial," "essential," and "known design constraint," and admitted that the issue identified by the FDA posed a "hazardous situation."

161. ***Second***, during the Class Period, the FDA issued private findings to iRhythm that the same issues outlined in the eventual warning letter—including the Zio AT's transmission limit and marketing—needed "corrective action." The FDA delivered these findings to the Company in its Form 483 inspectional findings on August 12, 2022, following the FDA's inspection of iRhythm's manufacturing facility.

162. ***Third***, the severe incidents resulting in customer complaints relating to the transmission limit of the Zio AT would have been well-known at the highest levels of iRhythm, including by the Executive Defendants. FE 2, a former senior compliance officer at iRhythm during the Class Period, recalled that Blackford and Devine served on iRhythm's Compliance Committee. FE 2 said that iRhythm had a compliance reporting line that tracked all the complaints and assigned each one a severity ranking of either low, medium, or high. The Compliance Committee received reports on these complaints on a quarterly basis, including from FE 2. Indeed, iRhythm publicly stated in its SEC filings that quarterly reports by iRhythm's Ethics and Compliance department concerning iRhythm's interactions with healthcare providers were provided to the Compliance Committee. Complaints from doctors who were never notified of

severe arrhythmias due to the Zio AT's transmission limit, particularly those that resulted in the patient's death, would likely qualify as high-grade complaints that would be reported both to the Compliance Committee and to the Board of Directors. Indeed, analysts such as William Blair noted that iRhythm purportedly "elevated its focus on regulatory and compliance" after Blackford was hired. Blackford and Devine, through their membership on the Compliance Committee (and, in Blackford's case, the Board of Directors) knew, or at least were severely reckless in disregarding, the serious failings of the Zio AT that physicians reported.

163. Indeed, federal regulations required iRhythm to have complaint review procedures that would ensure that the Company tracked complaints and reported them to management and the FDA. As required by Quality System regulations from 21 C.F.R. § 820.198(a), iRhythm would have "maintain[ed] complaint files" and "establish[ed] and maintain[ed] procedures for receiving, reviewing, and evaluating complaints ***by a formally designated unit***." Further, as required by Corrective and Preventive Action regulations from 21 C.F.R. § 820.100, iRhythm would have analyzed and investigated complaints, ensured that information related to problems "is ***disseminated to those directly responsible*** for assuring the quality of such product or the prevention of such problems," and submitted "relevant information on identified quality problems, as well as corrective and preventive actions, ***for management review***." 21 C.F.R. § 820.100(a)(1)-(7). Medical Device Reporting regulations from 21 C.F.R. § 803.50 further required manufacturers like iRhythm to report to the FDA within 30 days of receiving any information that "reasonably suggest[s]" that a device it markets may have "caused or contributed to a death or serious injury." Additionally, iRhythm's Code of Conduct required reporting "potential complaints and adverse events as soon as you discover them to the Quality and Regulatory Assurance team," and iRhythm's 2022 Environmental, Social and Governance Report described several processes demonstrating management's regular review of complaints and product quality matters, including: a Quality Council that "reviews matters quarterly," an annual "management review," meetings of "Quality and Regulatory leaders" at least quarterly to review and address "quality system performance indicators," and a "quality management system" that is certified to "ISO 13485, an internationally recognized standard for medical device quality management system."

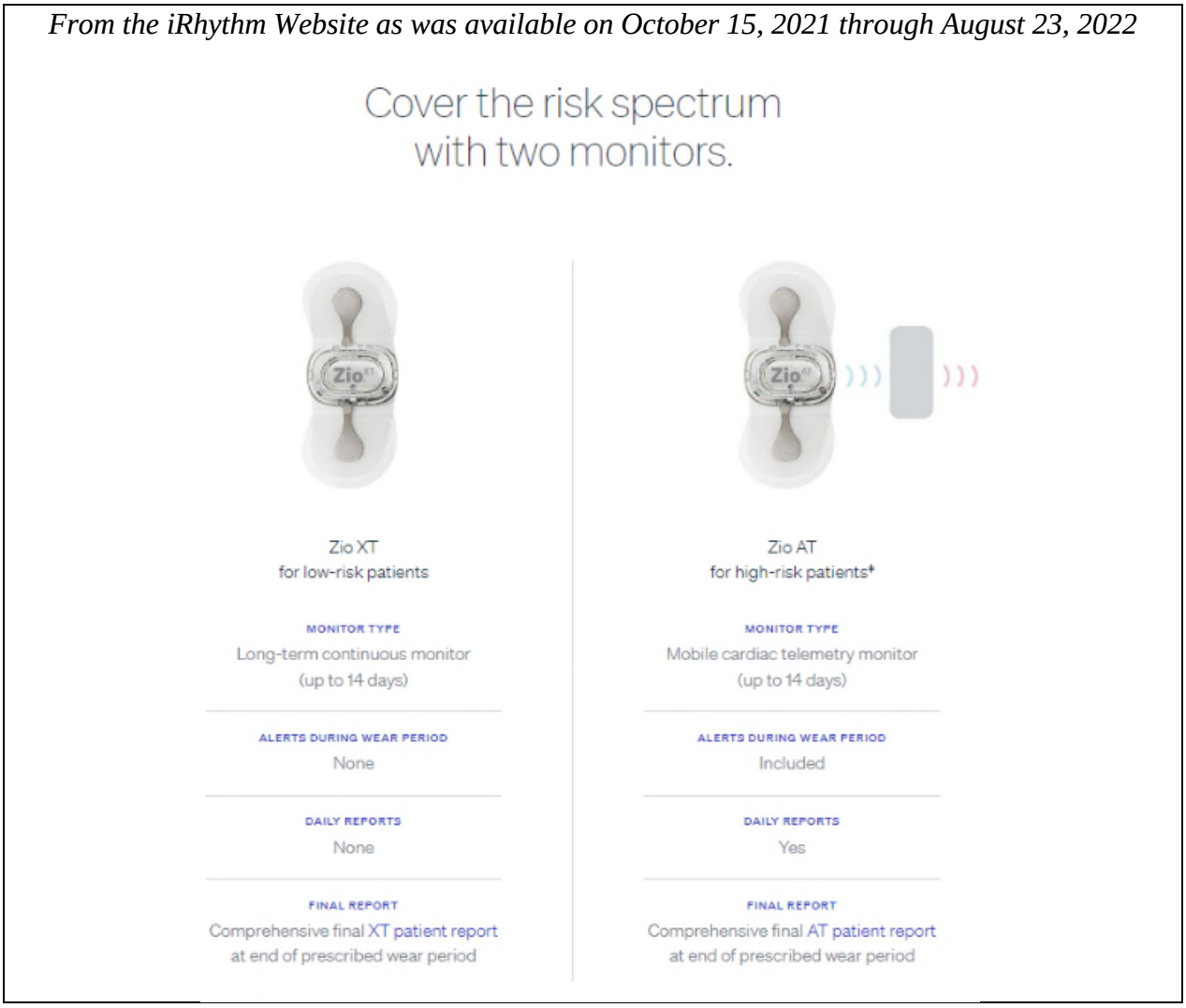
164. Additionally, Blackford specifically told investors that he put extraordinary focus on regulatory compliance in 2021 and paid close attention to it. Blackford highlighted this focus at the Morgan Stanley Global Healthcare Conference on September 13, 2022, stating, "We began in 2021 to really invest into the whole quality regulatory organization of the company." Here, where there is no question that the customer complaints were readily identifiable—as demonstrated by the FDA's ability to find them in a few days during the inspection—Blackford and senior management would have known, or been severely reckless in not knowing, that the Zio AT customer complaints existed.

165. ***Fourth***, the Warning Letter explained that iRhythm knew that the Zio AT was cleared by the FDA for a purpose that was ***not*** mobile cardiac telemetry. Rather, the "device was cleared under K163512 for long-term monitoring of arrhythmia events for non-critical care patients where real-time monitoring is not needed as reporting timeliness is not consistent with life-threatening arrhythmias." It was therefore, at minimum, reckless for the Company to market the Zio AT as providing "near real-time" notifications for "high-risk" patients. As the FDA noted, "The claim that the device is intended as a mobile cardiac telemetry monitor implies this device is intended for high-risk patients and near real-time monitoring."

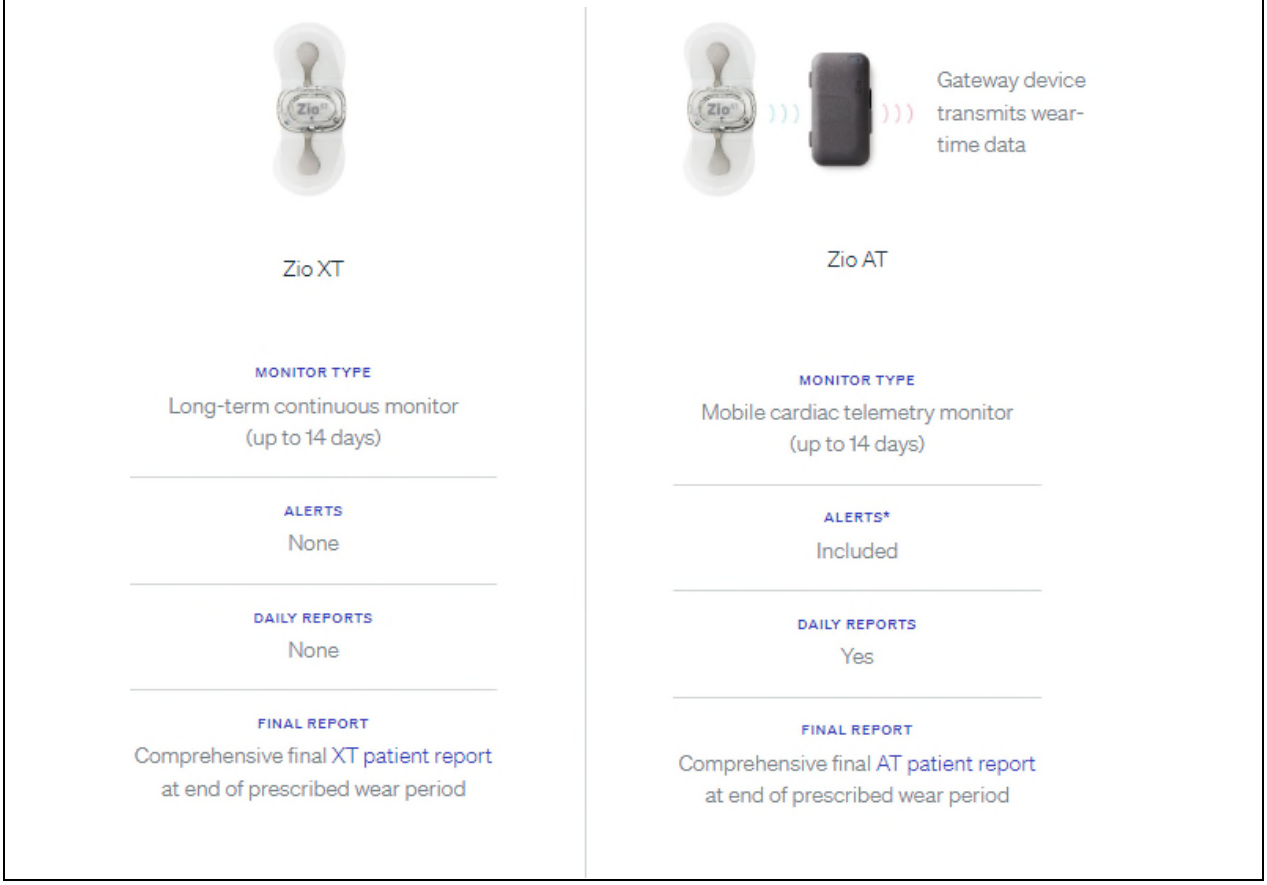
166. ***Fifth***, the undisclosed transmission limit of the Zio AT was a calculated design component that iRhythm described as "crucial" and "essential" to the functioning of the device. Defendants forcefully stressed in their defense of the Zio AT to the FDA in light of the FDA's Form 483 that the transmission limit was "necessary to ensure patient compliance … and continuous data capture during the wear period," was "crucial for the Zio AT system," and was "an essential design constraint that is necessary to effectuate the intended use of the device." Defendants specifically described the limit as a "***known design constraint*** . . . [for] the purpose of conserving power consumption to allow for continuity of wear and data capture," because eliminating the need for recharging "necessarily places" limitations on the number of transmissions. The transmission limit was not some undetectable flaw that Defendants could chalk up to a quality control issue—iRhythm ***hard coded*** the transmission limit into the Zio AT because ***it could not function without it***.

167. ***Sixth***, just days after receiving the FDA's 483 Letter that warned, among other things, that the Zio AT 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. Specifically, in a chart that iRhythm had published consistently on its website with only slight variations from before the Class Period began through the end of the Class Period comparing the relative capabilities of the Zio XT and Zio AT, iRhythm removed the references to "high-risk patients" entirely at some point between August 23, 2022 and August 30, 2022:

From the iRhythm Website as was available on October 15, 2021 through August 23, 2022



From the iRhythm Website as was available on August 30, 2022 through August 23, 2023



168. Notably, Defendants' silent acknowledgement that the Zio AT was, indeed, not for high-risk patients came just days after iRhythm received the FDA's 483 Letter on August 12, 2022, and immediately before its response to the FDA on September 1, 2022. Despite the fact that Defendants knew that the Zio AT was inappropriate for high-risk patients thanks, in part, to the FDA's warning, and modified their website to avoid further FDA scrutiny on the subject, Defendants did not disclose this limitation until the end of the Class Period and, in fact, continued to make similar claims to investors.

169. ***Seventh***, Defendants would have been well aware of the over 4,000 complaints received by iRhythm between May 2, 2022 and July 2024, given the sheer volume of complaints, the importance of CCTs' interpretation of data in iRhythm's Zio service, and regulatory requirements for reporting complaints of this nature as medical device reporting ("MDR") to the FDA. Defendants would have been especially alert to correcting iRhythm's complaint reporting

following the regulatory scrutiny from the initial round of Form 483s. Indeed, during that initial round of Form 483s, Defendants promised the FDA that it would ameliorate its complaint and MDR reporting. Instead, the FDA found additional MDR violations by iRhythm in the second round of Form 483s, noting, "You routinely do not report complaints and events alleging that your [CCT] personnel have misread or misinterpreted cardio-graphic arrythmia event data . . . and provided such misinformation to clinical end users for diagnostic purposes," and "You routinely do not report complaints and events alleging algorithm misinterpretations/misreads of cardio-graphic arrythmia event data, as malfunctions of your medical devices' intended uses."

170. Further, as the Capitol Forum reported in August 2024, the Company—including "QA leadership"—directed CCTs to provide inaccurate reports to patients and doctors, in order to downplay the severity of arrhythmias so that the final reports sent to doctors would match any "near real-time" reporting that occurred during the wear period. The report stated, "Both former iRhythm CCTs said that they were often countermanded by iRhythm when they identified cardiac events that would [have] been classified as arrhythmias at other companies and tried to include them in final reports." One of the CCTs explained, "[A]s scanners we were told that it is 'important that the final report match what the patient experienced during wear time.' 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." This was "the iRhythm way" that CCTs were instructed to use. In other words, the Company directed CCTs to conform final reports to the wear-time reporting, in order to prevent concerns and complaints from doctors who would likely take notice of discrepancies between the two.

171. Additionally, the Company manipulated its internal analysis of the accuracy of the devices in a manner designed to make the device appear more accurate than it was. Specifically, the FDA explained in a July 2024 Form 483 that 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." In other words, iRhythm's

analysis was structured to exclude certain key errors. The FDA concluded that due to these missing inputs, "***it is not an accurate or all-inclusive quality metric***."

172. ***Eighth***, Defendants had a substantial economic motivation to market the Zio AT as an MCT even though it was inappropriate for "high-risk" patients and could not provide "near real-time" detection. Specifically, the CMS reimbursement rate for MCTs was several times higher than the reimbursement rate applicable to traditional electrocardiograph event monitors. According to The Capitol Forum, in 2021 alone, iRhythm billed Medicare $8.2 million using an MCT billing code for the Zio AT. Had iRhythm used a code applicable to a traditional monitor, it would only have been paid $1.7 million for those same claims. The reimbursement rate for MCTs increased by approximately 25% between 2021 and 2022, so iRhythm stood to make even more money by improperly marketing the Zio AT as an MCT. Indeed, as one former iRhythm employee who worked as a territory manager responsible for selling both the Zio XT and the Zio AT and training newer sales representatives FE 2 recalled, under iRhythm's sales bonus plan, a sales employee earned twice as many points towards their bonus goal targets by selling Zio AT rather than a Zio XT. In its August 4, 2023 Form 10-Q, Defendants admitted for the first time the risk that being barred from using MCT-specific codes for the Zio AT would pose to iRhythm's business:

> Regulators or other third parties could assert that our technology does not support certain diagnostic procedures described by the CPT codes that we currently use to report our Zio Services. For example, a regulator or other third party could assert that the Zio AT System cannot support MCT services, which could jeopardize our ability to submit claims for reimbursement for services utilizing our Zio AT System . . . . Certain language in the [May 25, 2023 FDA] warning letter could increase the risk of inquiries regarding our historical or current use of CPT code 93229.

173. Each of the Executive Defendants were individually motivated by their compensation plan to increase Medicare compensation rates.

174. ***Ninth***, given the Executive Defendants' extensive experience in the medical device industry (¶¶30-42), they knew the importance of complying with FDA regulations and the significance of customer complaints in detecting regulatory issues. Blackford specifically had prior experience with an FDA warning letter concerning misbranding of a medical device while he held a senior role at NuVasive, Inc. While Blackford was an executive at NuVasive, in March 2013,

that company received a warning letter from the FDA regarding its marketing of a medical device for uses that were not approved by the FDA. Additionally, NuVasive faced a *qui tam* lawsuit by the DOJ for "caus[ing] health care providers to submit false claims to Medicare and other federal health care programs for spine surgeries by marketing the company's CoRoent System for surgical uses that were not approved by the [FDA]." *United States ex rel. Kevin Ryan v. NuVasive, Inc.*, No. 12–cv–2683 (D. Md.). When Defendant Blackford was NuVasive's CFO, the DOJ and NuVasive ultimately finalized a settlement to resolve the lawsuit.

175. ***Tenth***, that Defendants' misstatements concerned the most critical aspects of one of iRhythm's most significant products supports a strong inference of scienter, particularly as iRhythm was a relatively small company with management focused on the Zio AT's success during the Class Period. During the Class Period, iRhythm's portfolio included just two products: the Zio XT and the Zio AT. As alleged above, Defendants spoke (and investors asked) about the Zio AT consistently during Class Period investor calls. Analysts cited the Zio AT and its ability to catapult iRhythm into an entirely new and lucrative market as a reason why iRhythm was a good stock for investors to buy. And by marketing the Zio AT as an MCT, iRhythm was able to collect four times as much revenue from CMS reimbursement as it would otherwise. Thus, the Zio AT and its new patient population were particularly important to the Company.

176. Given the Zio AT's importance to iRhythm, Defendants discussed the Zio AT at ***every*** investor conference and on ***every*** earnings call during the Class Period. For instance, Defendant Blackford told investors in September 2022 that the Zio AT was the "perfect product to address, putting information into the hands of the patient on a near real-time basis." That Defendants were so focused on the Zio AT, and the Company was so financially motivated for the Zio AT—one of just two products in its portfolio—to be a success, indicates that the Executive Defendants would have known the truth about the Zio AT's well-documented flaws and the falsity of Defendants' statements concerning it.

177. ***Additional Facts Relating to Defendant Day.*** As iRhythm's Chief Technology Officer starting in April 2022—and before that, iRhythm's Executive Vice President of Research & Development—Defendant Day was well aware of the design and capabilities of the Zio AT, as

well as associated FDA requirements. A chief technology officer typically plays a key role in developing products and pursuing a company's technological vision, and oversees teams of engineers, scientists, and others in doing so. As he explained at the Company's September 21, 2022 Investor Day, Defendant Day worked extensively on the "product side" of iRhythm—including on the Zio AT, how it worked "underneath the hood," and how it was developed. Further, the Company's February 28, 2022 Form 10-K for 2021 noted that iRhythm's success depended in part on the services of Defendant Day—who was then Executive Vice President of Research and Development—as "critical for managing our research and development programs." [redacted]

VII. DEFENDANTS' MATERIALLY FALSE & MISLEADING STATEMENTS

178. Defendants made numerous materially false and misleading statements during the Class Period in violation of Sections 10(b) and 20(a) Exchange Act and Rule 10b-5 promulgated thereunder. Among other things:

(a) Defendants told patients and investors that the Zio AT monitor provided "near real-time" notifications of significant arrhythmias to the prescribing physician. In reality, as revealed by the FDA, when a patient reached an undisclosed transmission limit, the Zio AT would not transmit any additional data, and accordingly iRhythm would not inform a provider of even serious cardiac events until a report was generated at the end of the wear-period. Further, as reported by FE 3, the Zio AT was not "live" and instead had a lag time of about four hours before the arrhythmia data could reach the technicians' queue for review, plus the additional time it took for technicians to analyze the arrhythmia event.

(b) Defendants told patients and investors that the Zio AT is an arrhythmia monitor for "high risk" patients. In reality, as revealed by the FDA, the Zio AT was only cleared by the FDA for use in non-critical care patients. And as the FDA further revealed, the Zio AT's transmission limit—and thus failure to transmit arrhythmia data in "near real-time"—made it inappropriate and dangerous for use in high-risk patients.

(c) Defendants told patients and investors that the Zio AT was a "mobile cardiac telemetry" or "MCT" monitor. In reality, as revealed by the FDA in its May 2023 warning letter, "the claim that the device is intended as a mobile cardiac telemetry monitor implies this device is intended for high-risk patients and near real-time monitoring," which it was not.

(d) Defendants told patients and investors that the Zio AT provides accurate data. In reality, as revealed by the FDA, the Company's technicians routinely misinterpreted patients' arrhythmia data from the Zio AT, causing inaccurate reporting and failure to report arrhythmias.

A. False Statements Concerning The Zio AT's "Near Real-Time" Notifications And "Timely Transmission" Of Arrhythmia Data "During The Wear Period"

179. On November 5, 2021, iRhythm filed its quarterly report on Form 10-Q for the third quarter of 2022, signed by Defendants Blackford and Devine. In that report, iRhythm misrepresented the Zio AT as providing "timely transmission" of arrhythmia events:

- The Zio AT . . . offers what the Zio XT offers plus the additional capability of ***transmissions during the wear period*** to assist physicians in diagnosing and treating patients that require more ***timely action***. ***During the wear period, physicians will receive notifications*** if there are significant events that meet predetermined arrhythmia detection criteria.
- Zio AT offers the option of timely, detection- based transmission of data during the prescribed wear period
- [F]or the Zio AT monitor, we rely on the provision of cellular communication services for the ***timely transmission*** of patient information and reportable events.
- Zio AT . . . is designed to provide ***timely transmission*** of data during the wear period.

180. On February 28, 2022, iRhythm filed its annual report on Form 10-K for the year 2021, signed by Defendants Blackford and Devine. In that report, iRhythm repeatedly misrepresented the Zio AT as providing "timely transmissions" and "notifications" to doctors "if there are significant events" picked up by the Zio AT "during the wear period." The report stated:

- Zio AT offers the option of timely transmission of data during the prescribed wear period

- Zio AT offers the option of timely, detection based transmission of data during the prescribed wear period
- Zio AT ***offers*** the additional capability of ***actionable transmissions during the wear period*** to assist physicians in diagnosing and treating the small percentage of the population requiring more timely action. During the Zio AT wear period, physicians ***will receive notifications if there are significant events that meet pre-determined arrhythmia detection criteria***.
- Through the Zio AT offering, physicians can access the additional capability of timely transmissions during the wear period. During the wear period, physicians will receive notifications and reports if there are significant events that meet pre-determined arrhythmia detection criteria.
- Zio AT . . . is designed to provide ***timely transmission*** of data during the wear period
- [F]or the Zio AT monitor, we rely on the provision of cellular communication services for the ***timely transmission*** of patient information and reportable events.

181. In the same report, iRhythm gave further detail on how the Zio AT "transmit[s] data" during the wear period using a wireless gateway, and thus facilitates "timely medical action" and even allows patients to "initiate[] a wireless transfer" of ECG data by pressing a button:

- The Zio AT service delivers the same comprehensive final report, but also ***provides physicians with actionable notifications during the wear period***. These ***timely alerts*** are provided via a Bluetooth capability in the Zio AT monitor that sends data to a wireless gateway. The wireless gateway, slightly larger than a smart phone, is provided to the patient at the time of monitor application and ***will collect and transmit data from the monitor to the cloud*** via a long term evolution ("LTE") protocol.

Reporting Events During the Wear Period with Zio AT

- The Zio service with Zio AT includes a wireless gateway that provides connectivity between the Zio AT monitor and our monitoring center which enables symptomatic and asymptomatic ***data transmission during the prescribed wear period***. The Zio AT monitor, in conjunction with the wireless gateway and the unique Zio arrhythmia detection algorithm, has arrhythmia auto-detection capabilities that ***produce actionable event data for physician review***. The definition of an actionable arrhythmia event is customized by the physician to meet his or her needs, with the intent to reduce the number of over-notifications of data that do not require more ***timely medical action***. Additionally, patients have the option of pressing a trigger button which ***marks the continuous record and initiates a wireless transfer of a 90-second ECG strip to our monitoring center***.

182. The same report further stated, "Zio XT will be positioned as the workhorse service while Zio AT is appropriate for the smaller percentage of the population that requires ***timely notification***."

183. On May 6, 2022, iRhythm filed its quarterly report on Form 10-Q for the first quarter of 2022, signed by Defendants Blackford and Devine. In that report, iRhythm again misrepresented the Zio AT's provision of timely notifications to physicians during the wear period:

- The Zio AT . . . offers what the Zio XT offers plus the additional capability of ***transmissions during the wear period*** to assist physicians in diagnosing and treating patients that require more ***timely action***. ***During the wear period, physicians will receive notifications*** if there are significant events that meet predetermined arrhythmia detection criteria.
- Zio AT offers the option of timely, detection based transmission of data during the prescribed wear period
- [F]or the Zio AT monitor, we rely on the provision of cellular communication services for the ***timely transmission*** of patient information and reportable events.
- Zio AT . . . is designed to provide ***timely transmission*** of data during the wear period

184. On August 5, 2022, iRhythm filed its quarterly report on Form 10-Q for the second quarter of 2022, signed by Defendants Blackford and Devine. In that report, iRhythm repeatedly misrepresented the Zio AT as providing "timely transmission" of arrhythmia events during the wear period:

- [T]he Zio AT service offers the option of ***timely transmission*** of patient-triggered and automatically detected arrhythmia events data to a monitoring center for review and reporting according to physician-selected notification criteria
- Zio AT . . . is designed to provide timely transmission of data during the wear period
- [F]or the Zio AT monitor, we rely on the provision of cellular communication services for the ***timely transmission*** of patient information and reportable events.
- ***During the patient wear period***, the Zio AT monitoring system is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous ECG information. While continuously recording patient ECG data, both patient-triggered and automatically detected arrhythmia events are ***transmitted to a monitoring center for review and reporting according to physician-selected notification criteria***.

185. On August 11, 2022, at the Canaccord Growth Conference, Defendant Douglas Devine misrepresented the Zio AT as providing "more continuous communication of results back to the physician."

186. On September 21, 2022, iRhythm held its 2022 Analyst and Investor Day, during which Defendants further misrepresented the Zio AT's "real time" notifications. Defendants Blackford, Devine, Bobzien, Day, Patterson, and Turakhia all spoke at this Investor Day. By this time, the Company had received the FDA's Form 483 and Defendant Blackford had extensively responded in writing, including by acknowledging the "hazardous situation" posed by the undisclosed transmission limit in the Zio AT.

187. Nonetheless, at the Investor Day, Defendant Blackford stated, "We have a perfect product to address, ***putting information into the hands of the patient on a near real-time basis***." Defendant Chad Patterson, iRhythm's Chief Commercial Officer, stated, "Zio XT is retrospective and ***Zio AT allows transmissions during the patient's wear time*** based on criteria established by their physician." Next, Defendant Mintu Turakhia, iRhythm's Chief Medical Officer and Chief Scientific Officer, stated about the Zio AT that the "monitoring is continuous and uninterrupted" and "as a doctor . . . [m]y nurses or ***I could see the alerts that come in from AT if there was real time notification***."

188. At the same Investor Day, Defendant Mark Day, iRhythm's Chief Technology Officer, further highlighted the "timely monitoring capability" of the Zio AT that differentiates it from the Zio XT: "But underneath the hood, they're entirely different. The Zio AT device has a Bluetooth capability that ***enables that kind of timely monitoring capability*** of the platform, the Zio XT does not."

189. Defendants Blackford, Devine, and Bobzien were present during Defendants Day, Patterson, and Turakhia's statements as described above in ¶¶187-88, but did not correct them.

190. On November 4, 2022, iRhythm filed its quarterly report on Form 10-Q for the third quarter of 2022, signed by Defendants Blackford and Bobzien. In that report, iRhythm again misrepresented the Zio AT as providing "timely transmission" of arrhythmia events:

- [T]he Zio AT service offers the option of ***timely transmission*** of patient-triggered and automatically detected arrhythmia events data to a monitoring center for review

and reporting according to physician-selected notification criteria

- Zio AT . . . is designed to provide ***timely transmission*** of patient information and reportable events
- [F]or the Zio AT monitor, we rely on the provision of cellular communication services for the ***timely transmission*** of patient information and reportable events.
- ***During the patient wear period***, the Zio AT monitoring system is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous ECG information. While continuously recording patient ECG data, both patient-triggered and automatically detected arrhythmia events are ***transmitted to a monitoring center for review and reporting according to physician-selected notification criteria***.

191. On November 14, 2022, in a Nasdaq interview Behind the Bell: iRhythm, Defendant Blackford stated, "We have a device that ***provides near real-time capability*** and can put that information right at their fingertips."

192. On February 23, 2023, iRhythm filed its annual report on Form 10-K for the year 2022, signed by Defendants Blackford and Bobzien. In that report, iRhythm continued to misrepresent the Zio AT as providing "near real-time monitoring," "timely notification," "actionable transmissions during the wear period," "more immediate, clinically actionable information," "more immediate notifications . . . if there are significant events," and "timely transmission of . . . reportable events."

193. Specifically, in that report, iRhythm stated that the Zio AT "includes ***near real-time monitoring***, [and] is appropriate for more acute patients that require ***timely notification***." Similarly, iRhythm said that in connection with the Zio AT, "we rely on the provision of cellular communication services for the ***timely transmission of patient information and reportable events***."

194. In the same report, iRhythm further stated:

> For our MCT services, the Zio AT patch and wireless gateway also ***offer the additional capability of providing actionable transmissions during the wear period*** to assist physicians in diagnosing and treating patients in situations where their physician has determined that there is a ***medical need to receive more immediate, clinically actionable information***. For the MCT services, physicians will receive daily reports, routine reports, and ***more immediate notifications*** from CCTs [certified cardiographic technicians] if there are significant events that meet predetermined and physician-specified notification criteria.

195. On June 7, 2023, at the William Blair Growth Stock Conference, Defendant Blackford stated, "The XT product is sort of a blinded product where you return the device to us after 14 days. We download the data, do the interpretation. The AT product is more of a continuous monitoring, providing that information to the physicians on a ***near real time basis*** along the way."

196. On November 2, 2023, iRhythm filed its quarterly report on Form 10-Q for the third quarter of 2023, signed by Defendants Blackford and Bobzien. That report stated: "Further, for the MCT monitoring services utilizing our Zio AT System, we rely on the provision of cellular communication services for the ***timely transmission*** of patient information and reportable events."

197. On February 22, 2024, iRhythm filed its annual report on Form 10-K for the year 2023, signed by Defendants Blackford and Bobzien. In that report, iRhythm misrepresented the Zio AT as providing "timely notification" and "notifications" to doctors "if there are significant events" meeting the doctors' notification criteria. The report stated:

- The Zio Monitor System, which provides continuous long-term ECG monitoring, is designed to be appropriate for the majority of patients that require ambulatory cardiac monitoring while the Zio AT System, which ***includes near real-time monitoring***, is intended for more acute patients that require ***timely notification***.
- For our MCT services, the Zio AT patch and wireless gateway also offer the additional capability of providing ***actionable transmissions during the wear period*** to assist physicians in diagnosing and treating patients in situations where their physician has determined that there is a medical need to receive more ***timely, clinically actionable information***. For the MCT services, physicians will receive daily reports, routine reports, and ***notifications from CCTs if there are significant events*** that meet predetermined and physician-specified notification criteria.

198. On May 2, 2024, iRhythm filed its quarterly report on Form 10-Q for the first quarter of 2024, signed by Defendants Blackford and Bobzien. That report stated: "Further, for the MCT monitoring services utilizing our Zio AT System, we rely on the provision of cellular communication services for the ***timely transmission*** of patient information and reportable events."

199. On August 1, 2024, iRhythm filed its quarterly report on Form 10-Q for the second quarter of 2024, signed by Defendants Blackford and Bobzien. That report stated: "Further, for the MCT monitoring services utilizing our Zio AT System, we rely on the provision of cellular communication services for the ***timely transmission*** of patient information and reportable events."

200. The statements set forth above in ¶¶179-99 were materially false or misleading, and omitted facts necessary to make them not materially false and misleading. These statements were false and misleading given that, as set forth above in ¶¶67-74 and ¶¶87-114, as attested to by both former employees and the FDA after an investigation, the Zio AT could not provide "near real-time," "continuous," or "timely" transmission of arrhythmic events to patients' healthcare providers "during the wear period." Rather, 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. Defendants were aware of many instances where serious cardiac events, including cardiac events that caused the death of the patient, were not reported to providers during the wear period because the device exceeded the transmission limit unbeknownst to the patient or their provider.

201. The Zio AT additionally did not provide "near real-time" notifications because, according to FE 3, it had a lag time of about four hours or more before the arrhythmia data could even reach the technicians' queue for review. Then additional lag time occurred because it took time for technicians to analyze events in the queue. According to FE 3, technicians 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. The queue increased overnight and on weekends, when there were not as many technicians on those shifts. Sometimes, FE 3 reported, it took even longer than four hours for the arrhythmia data to show up in the queue.

202. Further, iRhythm repeatedly failed to properly inform patients and providers that the Zio AT's registration system required patients to fully register with iRhythm—including technical billing information—before any data could be transmitted from the monitor to a provider. Because iRhythm did not notify patients when their registration was incomplete, patients were often unaware that they had not completed iRhythm's registration requirements—an issue that persisted until iRhythm issued a voluntary recall in light of the FDA's private 2022 site inspection report.

B. False Statements Concerning The Zio AT's Use For A "High-Risk" and "At Risk" Patient Population

203. On November 5, 2021, iRhythm filed its quarterly report on Form 10-Q for the third quarter of 2022, signed by Defendants Blackford and Devine. In that report, iRhythm misrepresented the Zio AT as offering the "capability of transmissions during the wear period to assist physicians in diagnosing and ***treating patients that require more timely action***."

204. On February 28, 2022, iRhythm filed its annual report on Form 10-K for the year 2021, signed by Defendants Blackford and Devine. In that report, iRhythm misrepresented the Zio AT as "appropriate" for "the small percentage of the population" that "requires timely notification." The report stated, "Zio XT will be positioned as the workhorse service while ***Zio AT is appropriate for the smaller percentage of the population that requires timely notification***." The report further stated that the Zio AT offers "the additional capability of transmissions during the wear period to assist physicians in diagnosing and treating ***the small percentage of the population requiring more timely action***."

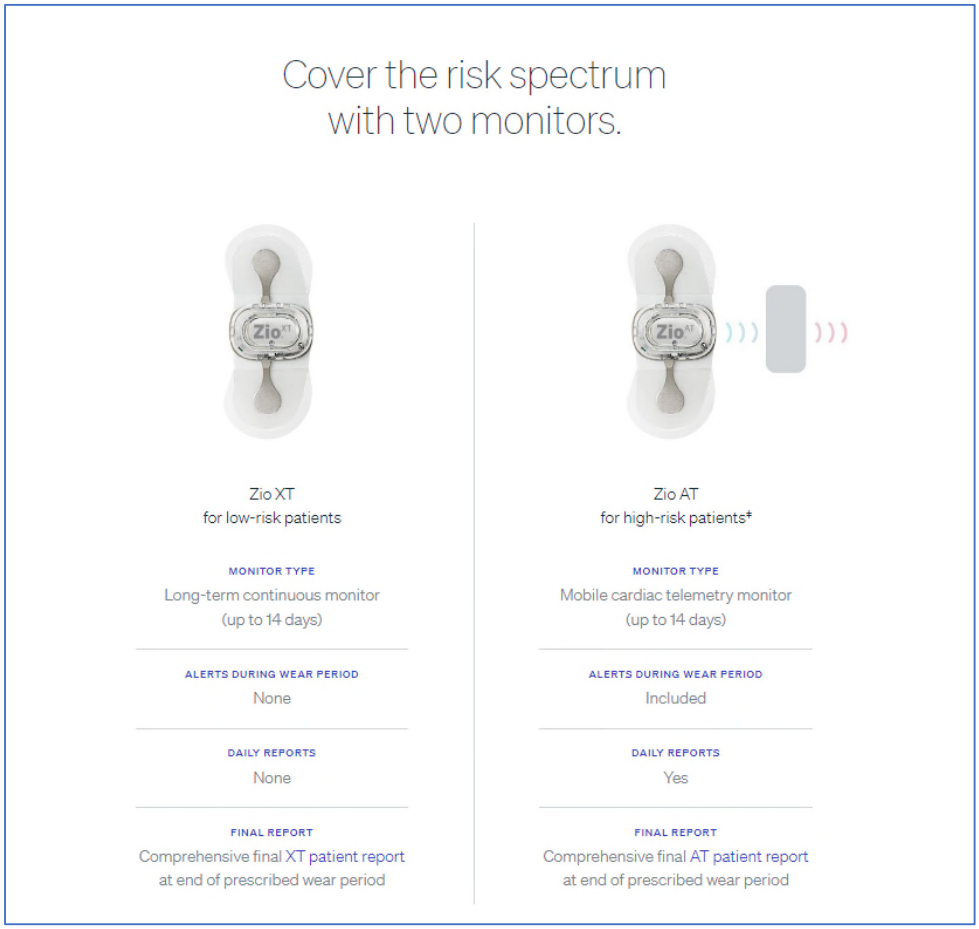
205. On May 6, 2022, iRhythm filed its quarterly report on Form 10-Q for the first quarter of 2022, signed by Defendants Blackford and Devine. In that report, iRhythm misrepresented the Zio AT as offering the "capability of transmissions ***during the wear period*** to assist physicians in diagnosing and ***treating patients that require more timely action***."

206. On June 8, 2022, at the William Blair Growth Stock Conference where Defendant Blackford spoke, Defendants used a presentation stating that "Zio provides monitoring solutions across the risk spectrum," and specifically portrayed the Zio AT as appropriate for "high risk" use:

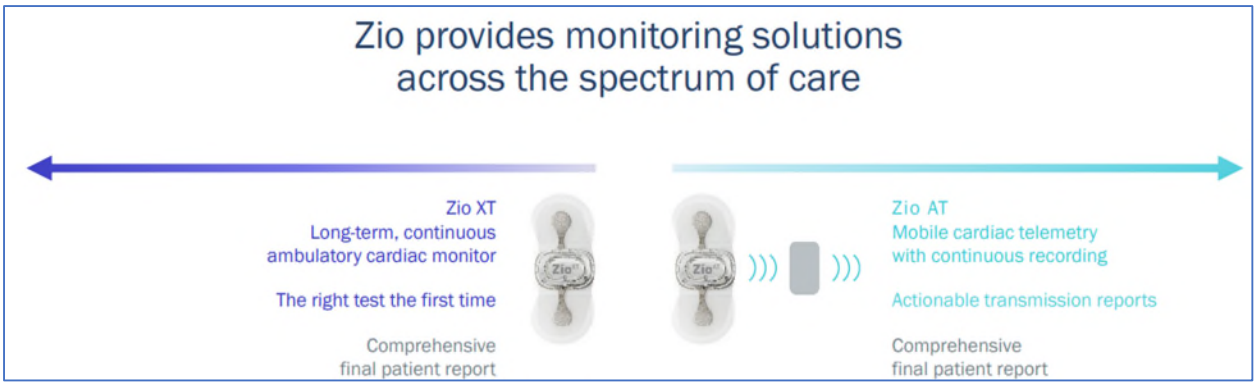
207. On August 11, 2022, at the Canaccord Growth Conference where Defendant Douglas Devine spoke, Defendants used a presentation that again showed investors the same false

and misleading slide depicted in ¶206 above, misrepresenting the Zio AT as appropriate for "high risk" use.

208. From before the Class Period through, at least, August 23, 2022, iRhythm published a chart similar to the slide depicted in ¶206 above on its website, misrepresenting the Zio AT as appropriate for use by "high-risk patients":



209. On September 21, 2022, at iRhythm's 2022 Analyst and Investor Day, where Defendants Blackford, Devine, Bobzien, Day, Patterson, and Turakhia all spoke (after the Company had received and responded to the FDA Form 483), Defendants showed investors a substantially similar slide, misrepresenting the Zio AT as providing continuous monitoring "across" the entire end of the depicted "spectrum of care":



210. On January 10, 2023, at the JP Morgan Healthcare Conference, Defendant Blackford misrepresented the Zio AT as appropriate for use in "some of the most at-risk patients." While discussing the "AT product" "in the MCT space," Defendant Blackford specified, "[w]ith respect to MCT, ***you're monitoring some of the most at-risk patients***."

211. On February 23, 2023, iRhythm filed its annual report on Form 10-K for the year 2022, signed by Defendants Blackford and Bobzien. In that report, iRhythm misrepresented the Zio AT as "appropriate ***for more acute patients that require timely notification***."

212. The statements set forth above in ¶¶203-11 were materially false or misleading, and omitted facts necessary to make them not materially false and misleading. These statements were false and misleading given that, as set forth above in ¶¶67-74 and ¶¶87-114, and per the May 25, 2023 warning letter issued by the FDA, iRhythm did not have FDA clearance to market the Zio AT as intended for "high-risk patients," or patients who "require timely notifications" and the device was indeed not appropriate for "high-risk patients." The FDA noted in its Form 483 that the Zio AT was inappropriate or even dangerous for use in high-risk patient populations. Defendants were aware of many instances where a serious cardiac event, in some cases including cardiac events that caused the death of the patient, were not reported to providers because the patient had unknowingly exceeded the transmission limit. Defendants also admitted to the FDA that based on their own risk assessment, the transmission-limit posed a "hazardous situation." Ultimately, the FDA determined that 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." For this reason, iRhythm had not sought—and the FDA had not granted—clearance to market to a high-risk patient population. As the FDA later said, the 510(k) clearance granted to iRhythm for the Zio AT only covered "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." The FDA found that the statements set forth above in ¶¶203-11 "describe[] a new patient population" other than the one iRhythm was cleared to market the Zio AT to, which "could significantly affect the safety or effectiveness of the device."

C. False Statements Concerning The Zio AT's Status As A "Mobile Cardiac Telemetry" Monitor

213. On November 5, 2021, iRhythm filed its quarterly report on Form 10-Q for the third quarter of 2021, signed by Defendants Blackford and Devine. In that report, iRhythm falsely and misleadingly stated that the Zio AT is a "mobile cardiac telemetry monitor."

214. On February 23, 2022, iRhythm held an earnings call for the fourth quarter of 2021, during which Defendants Blackford and Devine spoke. On that call, Defendant Blackford misrepresented the Zio AT as a mobile cardiac telemetry monitor, telling investors that "[t]he value of what you can get off of 14 days in that MCT space versus a traditional 30-day monitor, it's superior with our product [the Zio AT], even in a less number of days that we're . . . sensing for."

215. On February 28, 2022, iRhythm filed its annual report on Form 10-K for the year 2021, signed by Defendants Blackford and Devine. In that report, iRhythm misrepresented the Zio AT as a mobile cardiac telemetry monitor, stating that the "Zio AT improves the speed and accuracy of diagnosis relative to traditional mobile cardiac telemetry ('MCT') devices and services." The report further referred to the Zio AT as "[o]ur Zio AT mobile cardiac telemetry monitor."

216. On May 6, 2022, iRhythm filed its quarterly report on Form 10-Q for the first quarter of 2022, signed by Defendants Blackford and Devine. In that report, iRhythm falsely and misleadingly stated that the Zio AT is a "mobile cardiac telemetry monitor."

217. On June 8, 2022, at the William Blair Growth Stock Conference, Defendant Blackford stated that the Zio AT product "really plays in the MCT space." At the same conference,

Blackford used a presentation that again misrepresented the Zio AT as "mobile cardiac telemetry," describing it as "Mobile cardiac telemetry with continuous recording" and "[t]he clinically superior MCT."

218. On August 4, 2022, iRhythm held an earnings call for the second quarter of 2022, during which Defendants Blackford and Devine spoke. Defendant Blackford again misrepresented the Zio AT as an "MCT." Describing iRhythm's market share, he stated that "we're probably around 7% when we think about the MCT space or where Zio AT really can play."

219. On August 11, 2022, at the Canaccord Growth Conference where Defendant Douglas Devine spoke, Defendants used a presentation in which they misrepresented the Zio AT as "mobile cardiac telemetry," describing it as "Mobile cardiac telemetry with continuous recording" and "[t]he clinically superior MCT."

220. On November 1, 2022, iRhythm held an earnings call for the third quarter of 2022, during which Defendants Blackford, Bobzien, and Devine spoke. Defendant Blackford misrepresented the Zio AT as an MCT device again: "We look forward to enhancing our Zio AT product to grow our market share in the MCT space."

221. Similarly, on January 10, 2023, at the JP Morgan Healthcare Conference, Defendant Blackford said about the "Zio AT offering," "We have an offering in the ***MCT*** space today. . . . [T]hen you think about beyond international, the AT product, we have about 5% share ***in the MCT space with our AT product***. . . . With respect to MCT, you're monitoring some of the most at-risk patients."

222. Additionally, iRhythm's website also misrepresented the Zio AT as a "mobile cardiac telemetry monitor" throughout the Class Period.

223. The statements set forth above in ¶¶213-22 were materially false or misleading, and omitted facts necessary to make them not materially false and misleading. These statements were false and misleading given that, as set forth above in ¶¶67-74 and ¶¶87-114, and per the May 25, 2023 Warning Letter, marketing the Zio AT as an MCT "implies this device is intended for high-risk patients and near real-time monitoring"—which it was not. At minimum, Defendants' repeated statements that the Zio AT was an MCT, without disclosing that the device could not be

relied upon to provide near real-time monitoring and was not appropriate for high-risk patients, was materially misleading by omission of this highly material information.

D. False Statements Concerning The Accuracy Of The Zio AT

224. On February 28, 2022, iRhythm filed its annual report on Form 10-K for the year 2021, signed by Defendants Blackford and Devine. In that report, iRhythm repeatedly misrepresented the Zio AT's accuracy. The report stated:

- "We analyze and generate patient reports at our CMS-certified IDTFs staffed with our certified cardiographic technicians who specialize in advanced arrhythmia interpretation to help ensure ***high accuracy and quality of reports*** before delivering them to the prescribing physician."
- The "platform" of the "Zio service" includes "a deep-learned neural network algorithm that provides ***accurate analytics and clinical results***" and "skilled clinical and operational staff who utilize proprietary software to ensure quality in clinical results"
- "[U]p to 14 days of heartbeat data is uploaded to be processed through our cloud-based, FDA-cleared proprietary deep-learned algorithms for ***highly accurate*** ECG analysis"

225. On August 11, 2022, at the Canaccord Growth Conference, Defendant Douglas Devine misrepresented the Zio service, which includes the Zio AT, as "able to diagnose heart rate arrhythmias with the accuracy of a panelist of cardiologists."

226. On September 21, 2022, at iRhythm's 2022 Analyst and Investor Day where Defendants Blackford, Devine, Bobzien, Day, Patterson, and Turakhia all spoke, Defendants relied on a presentation that stated, "The Zio Service delivers superior clinical accuracy while reducing the cost of care."

227. On February 23, 2023, iRhythm held an earnings call for the fourth quarter of 2022, during which Defendants Blackford and Bobzien spoke. Defendant Blackford stated about the Zio, "I remain convinced that you're going to see this market expand dramatically as we continue to push into the primary care setting, just given how easy it is to use the product, ***how accurate it is*** and the downstream benefits that you get with monitoring these patients sooner."

228. On April 12, 2023, iRhythm issued a report titled 2022 Environmental, Social and Governance Report. The report stated, "Since the most common type of Afib occurs intermittently,

long-term continuous patch-based monitoring, such as that performed with our Zio Systems, ***more accurately measures Afib burden*** because heartbeats are continuously recorded without interruption during the entire monitoring period."

229. On May 4, 2023, iRhythm held an earnings call for the first quarter of 2023, during which Defendants Blackford and Bobzien spoke. Emphasizing the importance of accuracy to Zio's growth with primary care physicians, Defendant Blackford stated, "Our ability to deliver value across the continuum of care by quickly and ***accurately detecting arrhythmias*** for benefit of patients by enabling better clinical outcomes and even more important in today's environment."

230. On February 22, 2024, iRhythm held an earnings call for the fourth quarter of 2023, during which Defendants Blackford and Bobzien spoke. Defendant Blackford again falsely touted the accuracy of the Zio AT, stating, "Ease of use, ***accuracy***, and simple workflow of Zio Monitor and ZioSuite digital products is resonating within the primary care channel which represented approximately 21% of total US Zio XT registrations during 2023." Again, Defendant Blackford made this statement while emphasizing the importance of accuracy to Zio's growth with primary care physicians.

231. On May 2, 2024, iRhythm held an earnings call for the first quarter of 2024, during which Defendants Blackford and Bobzien spoke. Defendant Blackford stated about the Zio, "[P]rimary care is absolutely the place that this device is ultimately going to get applied into the future, just with its ease of use, its high diagnostic yield, ***its incredible accuracy***." Defendant Blackford further stated about the Zio, "it's natural to step into this and take advantage of what we've built to-date and the service offering that we've become known for, which is easy to use and ***highly predictable, highly accurate***."

232. The statements set forth above in ¶¶224-31 were materially false or misleading, and omitted facts necessary to make them not materially false and misleading. These statements were false and misleading given that, as set forth above in ¶¶77-86 and ¶¶117-21, and per the Form 483s issued by the FDA in July 2024 and Zio technicians, Defendants omitted the material facts that iRhythm received thousands of complaints regarding the accuracy of the Zio AT, because iRhythm's reports to patients and doctors routinely included inaccurate arrhythmia data or failed

to include arrhythmias altogether due to misinterpretation by the Company's technicians. The FDA's July 2024 Form 483s further explained that the Company failed to analyze these thousands of complaints, failed to take any action to investigate the cause of these complaint, 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—meaning that the Company had no reasonable basis to make these statements. Further, as reported by the Capitol Forum based on its interviews of former Zio AT CCTs, the CCTs observed that "we were told that 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-threatening arrhythmias. Similarly, FE 3, a former Zio AT technician, 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—which resulted in deletion of the data, and it would never be seen by the patient's physician in the final report.

VIII. LOSS CAUSATION

233. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and omissions, and engaged in a scheme to deceive the market. These misleading statements and omissions artificially inflated the price of iRhythm common stock and operated as a fraud or deceit on the Class (as defined below). Later, when the alleged misrepresentations and fraudulent conduct were 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, the price of iRhythm common stock fell precipitously as the prior artificial inflation came out of the price over time. As a result of their purchases of iRhythm common stock during the Class Period, Lead Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

IX. THE INAPPLICABILITY OF THE STATUTORY SAFE HARBOR

234. The false and misleading statements alleged above are all statements of purported present or historical fact, so none of the statements were forward-looking. Nonetheless, even if

they were found to be forward-looking (which they were not), iRhythm's "Safe Harbor" warnings accompanying those statements issued during the Class Period were ineffective to shield those statements from liability.

235. The Defendants are also liable for any false or misleading forward-looking statements pleaded herein because, at the time each such statement was made, the speaker knew the statement was false or misleading and the statement was authorized and/or approved by an executive officer of iRhythm who knew that the statement was false. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to, or stated to be dependent on, those historic or present tense statements when made.

X. THE PRESUMPTION OF RELIANCE

236. Lead Plaintiff and the Class are entitled to a presumption of reliance on Defendants' material misrepresentations and omissions pursuant to the fraud-on-the-market doctrine because, at all relevant times, the market for iRhythm securities was open, efficient, and well developed for the following reasons, among others:

a) iRhythm common stock met the requirements for listing, and was listed and actively traded on NASDAQ, a highly efficient and automated market;

b) As a regulated issuer, iRhythm filed periodic public reports with the SEC and NASDAQ;

c) iRhythm regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

d) iRhythm was followed by several securities analysts employed by major brokerage firm(s), such as J.P. Morgan, William Blair, and Canaccord Genuity, who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firm(s). Each of these reports was publicly available and entered the public marketplace.

237. As a result of the foregoing, the market for iRhythm common stock promptly digested current information regarding iRhythm from all publicly available sources and reflected such information in the price of iRhythm common stock. Under these circumstances, all purchasers of iRhythm common stock during the Class Period suffered similar injury through their purchase of iRhythm common stock at artificially inflated prices and the presumption of reliance applies.

238. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding iRhythm's device—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the significance of iRhythm's ability to provide high-quality products and reporting services that adequately meet the requirements set forth by the FDA and the needs and expectations of its customer base in the cardiac monitoring market, that requirement is satisfied here.

XI. CLASS ACTION ALLEGATIONS

239. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons or entities that purchased or otherwise acquired iRhythm common stock during the Class Period (collectively, the "Class"). Excluded from the Class are Defendants and their families, directors, and officers of iRhythm and their families and affiliates.

240. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. As of October 23, 2023, iRhythm had over 30 million shares of common stock outstanding, owned by hundreds or thousands of investors.

241. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

a) Whether Defendants violated the Exchange Act;

b) Whether Defendants omitted and/or misrepresented material facts;

c) Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

d) Whether the Executive Defendants are personally liable for the alleged misrepresentations and omissions described herein;

e) Whether the Defendants knew or recklessly disregarded that their statements and/or omissions were false and misleading;

f) Whether Defendants' conduct impacted the price of iRhythm common stock;

g) Whether Defendants' conduct caused the members of the Class to sustain damages; and

h) The extent of damage sustained by Class members and the appropriate measure of damages.

242. Lead Plaintiff's claims are typical of those of the Class because Lead Plaintiff and the Class sustained damages from Defendants' wrongful conduct.

243. Lead Plaintiff will adequately protect the interests of the Class and has retained counsel experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

244. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Joinder of all Class members is impracticable.

XII. CLAIMS FOR RELIEF

COUNT I

For Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 (Against All Defendants)

245. Plaintiff repeats, incorporates, and realleges each and every allegation contained above as if fully set forth herein.

246. During the Class Period, the Defendants carried out a plan, scheme, and course of conduct which intended to and, throughout the Class Period, did: (a) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (b) cause Plaintiff and other members of the Class to purchase iRhythm common stock at artificially inflated prices.

247. The Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

248. The Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the U.S. mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the Company's financial well-being, operations, and prospects.

249. During the Class Period, the Defendants made the false statements specified above, which they knew or recklessly disregarded to be false or misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

250. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or recklessly disregarded the true facts that were available to them. Defendants engaged in this misconduct to conceal the truth about one of its two products, the Zio AT, from the investing public and to support the artificially inflated prices of the Company's common stock.

251. Lead Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they purchased iRhythm common stock at artificially inflated prices and were harmed when the truth about iRhythm negatively impacted the price of the Company's common stock. Lead Plaintiff and the Class would not have purchased iRhythm common stock at the prices they paid, or at all, had they been aware that the market prices for iRhythm common stock had been artificially inflated by the Defendants' fraudulent course of conduct.

252. As a direct and proximate result of the Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their respective purchases of the Company's common stock during the Class Period.

253. By virtue of the foregoing, the Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

COUNT II

For Violations of Section 20(a) of the Exchange Act (Against the Officer Defendants)

254. Lead Plaintiff repeats, incorporates, and realleges each and every allegation contained above as if fully set forth herein.

255. The Executive Defendants acted as controlling persons of iRhythm within the meaning of Section 20(a) of the Exchange Act. By virtue of their high-level positions, participation in and awareness of the Company's operations, direct involvement in the day-to-day operations of the Company, and intimate knowledge of the Company's actual performance, and their power to control public statements about iRhythm, the Executive Defendants had the power and ability to control the actions of iRhythm and its employees. By reason of this conduct, the Executive Defendants are liable under Section 20(a) of the Exchange Act.

XIII. PRAYER FOR RELIEF

256. WHEREFORE, Lead Plaintiff prays for judgment as follows:

a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

b) Awarding compensation to Lead Plaintiff and other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

c) Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

d) Awarding such equitable/injunctive or other further relief as the Court may deem just and proper.

XIV. JURY DEMAND

257. Lead Plaintiff demands a trial by jury.

DATED: October 11, 2024

Respectfully submitted,

/s/ Katherine M. Sinderson

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