UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

on behalf of itself and all others similarly situated,

Plaintiff,

v.

IRHYTHM TECHNOLOGIES, INC., QUENTIN BLACKFORD, BRICE BOBZIEN, and DOUGLAS DEVINE,

Defendants.

Case No.

COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

CLASS ACTION

DEMAND FOR JURY TRIAL

Plaintiff

, by and through its counsel, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief are based upon, inter alia, counsel's investigation, which included review and analysis of: (a) regulatory filings made by iRhythm Technologies, Inc. ("iRhythm" or the "Company") with the United States Securities and Exchange Commission ("SEC"); (b) press releases, presentations, and media reports issued by and disseminated by the Company; (c) analyst and media reports concerning iRhythm; and (d) other public information regarding the Company.

I. INTRODUCTION

1. Plaintiff brings this securities class action on behalf of all persons or entities that purchased or otherwise acquired iRhythm common stock between January 11, 2022, and May 30, 2023, inclusive (the "Class Period").

2. The claims asserted herein are alleged against iRhythm and certain of the Company's former and current senior officers (collectively, "Defendants") and arise under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5, promulgated thereunder.

3. iRhythm is a digital healthcare company that develops and manufactures heart monitoring devices designed to diagnose arrhythmias. One of the Company's main products, Zio AT, is a heart monitor patch with a transmittal device that reports arrhythmic events to iRhythm's monitoring labs, which then notify the prescribing physician of the arrhythmic event. According to the Company, this allows physicians to diagnose high-risk arrhythmic events in "near real-time." These types of heart monitors that are approved for high-risk patients and provide near real-time alerts are called mobile cardiac telemetry monitors, also referred to as "real-time" monitors. Real-time monitors sell for a premium over monitors that do not provide real-time notifications of arrhythmic events.

4. Throughout the Class Period, iRhythm represented to investors that the Zio AT monitor was a real-time monitor intended for a target audience of high-risk patients. The Company's legacy monitor and main product, Zio XT, is a heart monitor intended for non-critical patients, as it does not provide real-time reporting. The Company touted the potential growth for the Zio AT as an innovative product that had only just begun to penetrate the market for real-time monitoring, which investors looked upon favorably given the premium selling price associated with devices approved for high-risk patients. As a result of these representations, the price of iRhythm common stock traded at artificially inflated prices throughout the Class Period.

5. The truth began to emerge on November 1, 2022, after the market closed, when the Company reported revised fourth quarter and full-year guidance, in part due to "Zio AT utilization." The Company's Chief Executive Officer, Defendant Blackford, explained during a conference call with investors that "coming into the fourth quarter, [iRhythm] voluntarily issued a Customer Advisory Notice to [its] Zio AT customers." Consequently, the Company lowered its Zio AT forecast for the quarter from the 40% growth target it had provided through the past three quarters to just 20%. As a result of these disclosures, the price of iRhythm common stock declined by $5.60 per share, or 4.4%, 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 $14.07 per share, or 11.6%, on November 3, 2023.

6. Then, on Friday, November 4, 2022, after the market closed, the Company revealed that on September 28, 2022, it initiated the Customer Advisory Notice as a result of its "assessment of topics raised in an FDA inspection focused on Zio AT," after which the FDA issued an inspection observation report on Form 483. Notably, a Form 483 is issued in cases where an FDA investigator observes conditions that constitute violations of the Food Drug and Cosmetic Act and related Acts. Although iRhythm did not expand on the concerns the FDA raised, it did assure investors that the Company did "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 [its] business

at this time[.]" As a result of these disclosures, the price of iRhythm common stock declined by $2.43 per share, or 2.4%.

7. Then, on May 4, 2023, after the market closed, iRhythm announced that a month earlier, it had received a subpoena from the Civil Division of the U.S. Department of Justice (the "DOJ"), requesting the production of documents related to certain of its products and services. Although the Company did not reveal the scope of the DOJ's requests, analysts noted that one of iRhythm's competitors also received a subpoena from the DOJ regarding its wearable real-time monitoring product, and thus presumed that the DOJ inquiry was likely related to Zio AT. Analysts additionally noted "uncertainty" and cited to "an overhang" on iRhythm in light of the DOJ inquiry. As a result of these disclosures, the price of iRhythm common stock declined by $9.25 per share, or 6.9%.

8. Weeks later, on May 30, 2023, after the market closed, iRhythm disclosed the receipt of a warning letter from the FDA that detailed several serious issues with the Zio AT device (the "Warning Letter"). Among other things, the Warning Letter criticized iRhythm's marketing of the Zio AT as a "mobile cardiac telemetry monitor" that provides "near real-time monitoring" and is approved for use in "high-risk patients" as false. In truth, the Zio AT device was only approved for non-critical patients and suffered from critical flaws that imperiled high-risk patients. For example, iRhythm imposed an arbitrary transmission limit on the number of times the Zio AT can transmit data and failed to communicate this to providers and end-users. Critically, once the transmission limit is reached, the patient's data stops being transmitted, and the device can no longer be used for its intended purpose and cannot be relied upon by high-risk patients, as iRhythm stated. The Warning Letter also outlined other serious issues with the Zio AT device that iRhythm had known of since at least 2017 yet failed to disclose to the FDA, patients, or investors. These disclosures caused the price of iRhythm common stock to decline by $7.41 per share, or 6.1%.

9. As a result of Defendants' actions detailed herein, and the precipitous decline in the market value of the Company's common stock, Plaintiff and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

10. 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.

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

12. Venue is proper in this District under Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b), because iRhythm's principal executive office is located in San Francisco, California, which is situated 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.

13. In connection with the acts alleged in this Complaint, 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. Plaintiff

14. As indicated in the certification submitted herewith, Plaintiff purchased shares of iRhythm common stock at artificially inflated prices during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

B. Defendants

15. Defendant iRhythm is a digital healthcare company that develops and manufactures heart monitoring devices 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.

16. Defendant Quentin Blackford ("Blackford") is, and was at all relevant times, iRhythm's Chief Executive Officer and a Director of the Company.

17. Defendant Brice Bobzien ("Bobzien") has served as iRhythm's Chief Financial Officer since August 8, 2022.

18. Defendant Douglas Devine ("Devine") served as iRhythm's Chief Financial Officer from June 22, 2020, to August 8, 2022, and as Chief Operating Officer from December 1, 2021, to March 10, 2023.

19. Defendants Blackford, Bobzien, and Devine are collectively referred to herein as the "Officer Defendants." The Officer Defendants, because of their positions with iRhythm, possessed the power and authority to control the contents of iRhythm's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors. Each of the Officer Defendants was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information, each of the Officer Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading.

IV. BACKGROUND

20. iRhythm develops and manufactures heart monitoring devices designed to diagnose arrythmias. The Company's principal product—which until recent years made up over 90% of its revenue—is a monitoring patch that provides electrocardiogram ("ECG") monitoring for up to 14 days, called Zio XT. iRhythm developed Zio XT in 2009 and has gained a significant foothold in the ECG market as one of the first extended-wear wireless monitors in the market.

21. In 2017, iRhythm developed 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 troubling symptoms and serious medical complications, including blood clots that can lead to stroke and heart failure. The Zio AT comes with a cellular transmittal device that provides connectivity between the Zio AT and the proprietary algorithmic software that analyzes the ECG data and detects arrhythmic events for the 14-day wear period. Importantly, given its purported capabilities to provide "real-time" notifications of arrhythmic events, the Zio AT device is marketed to high-risk patients as a mobile cardiac telemetry device.

22. As a medical device provider, iRhythm is reimbursed for its services by third-party payors, including commercial insurers and government agencies such as the Centers for Medicare and Medicaid Services. Insurance companies require the Company to report the service for which it seeks reimbursement using the Current Procedural Terminology codes, a unified reporting and classification system maintained by the American Medical Association. Each calendar year, the Centers for Medicare and Medicaid Services sets the rates it will pay for medical devices and other products. In 2021, the reimbursement rates for Zio XT were reduced in some cases by hundreds of dollars from the historical average of $311. This reimbursement rate reduction significantly negatively impacted the Company's bottom line.

23. As a mobile cardiac telemetry device, Zio AT was not subject to the reimbursement rate reduction imposed on Zio XT—a 14-day ambulatory cardiac monitoring device that does not provide real-time notification and is intended for non-critical patients. The price premium on real-time monitors is significant. 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.

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS CAUSE SUBSTANTIAL LOSSES TO INVESTORS

24. The Class Period begins on January 11, 2022, when Defendant Blackford represented iRhythm at the J.P. Morgan Healthcare Conference. During the conference, Blackford touted iRhythm's "best-in-class ZIO platform," including the device's "digital platform," which "enables [patient data] to easily be shared and understood by our physicians, our patients, our payers all through desktop, mobile and [electronic health record] connectivity."

25. On February 23, 2022, iRhythm announced its financial results for the fourth quarter and full year 2021. That same day, iRhythm held a conference call with analysts and investors to discuss the Company's financial results. During that call, Defendant Blackford touted that "revenues from Zio AT doubled in 2021 versus 2020 and now represent approximately 10% of [iRhythm's] revenues," and attributed the growth to the product's expansion with use cases in higher risk patients. Blackford stated that iRhythm "continue[s] to believe [Zio AT will] grow at a faster rate than the XT business" because while "nearly 25% of the [ambulatory cardiac monitoring] market [is] utilizing Zio XT, maybe no more than 7% or so of market share [is] in the Zio AT opportunity." In response to an analyst question about how a 20% increase in reimbursement rates for mobile cardiac telemetry monitors would play into the pricing, margin, and volume ramp of Zio AT, Blackford stated that the increase "demonstrate[s] that the value of the product is being realized by" private health care insurers authorized to process Medicare claims. Later on the call, Blackford added "the value of what you can get off of 14 days in that [real-time monitoring] space versus a traditional 30-day monitor, it's superior with our product[.]"

26. On February 28, 2022, iRhythm filed with the SEC its 2021 annual report on Form 10-K for the year ended December 31, 2021. The Form 10-K was signed by Defendants Blackford and Devine and contained certifications by each that attested to the purported accuracy and completeness of the 10-K. In the 10-K, the Company stated that its "Zio AT mobile cardiac telemetry monitor . . . offers what our Zio XT offers plus 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." iRhythm further stated that its "Zio AT service delivers the same comprehensive final report [as Zio XT], but also provides physicians with actionable notifications" and highlighted that "Zio AT improves the speed and accuracy of diagnosis relative to traditional mobile cardiac telemetry . . . devices and services."

27. In the same 10-K, iRhythm announced that it had "received FDA clearance for [its] Zio AT ECG Monitoring System, which is designed to provide timely transmission of data during the wear period." Moreover, the Company acknowledged that "[t]he FDA and the Federal Trade

Commission ("FTC") . . . regulate the advertising and promotion of [its] products and services to ensure that the claims [iRhythm] make[s] are consistent with [its] regulatory clearances." According to the 10-K, iRhythm is required to follow the "labeling regulations and FDA prohibitions against the promotion of products for un-cleared, unapproved or off-label uses." Significantly, iRhythm acknowledged that "[m]aterial modifications to the Zio monitors, labelling of the Zio monitors, or Zio service," which include changing the products' addressable market "may require new [FDA] clearances" and may additionally require "premarket approvals or may require [iRhythm] to recall or cease marketing [its] products and services until clearances are obtained."

28. The same 10-K also included a statement from iRhythm that it followed "medical device reporting ("MDR") regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury[.]"

29. On June 8, 2022, Defendant Blackford participated in the William Blair Growth Stock Conference on behalf of iRhythm. During the conference, Blackford stated, "[T]here's really two products in the portfolio today. There's our Zio XT product, which is for a lower risk profile of a patient. . . . The other product that [iRhythm] launched just about a year and a half ago is our Zio AT product. This really plays in the [mobile cardiac telemetry monitor] space." Blackford noted that while Zio AT represented "less than 5% of the overall business," he believed "in time it'll represent a portion of the market that's very comparable to our XT product," which "represents 95% of the business today."

30. On August 4, 2022, iRhythm issued a press release announcing its financial results for the second quarter of 2022. In the press release, which was also filed with the SEC on Form 8-K, iRhythm raised its full year 2022 revenue guidance to between $415 million and $420 million, which represented between 29% and 30% growth over prior year results due to its top-line results in the second quarter. The Company stated that the increase in the second quarter was "primarily driven by Zio XT and AT volume growth and increases in Medicare pricing."

31. Later that same day, iRhythm held a conference call with analysts and investors to discuss the Company's financial results. During that call, Defendant Blackford, assured investors about the growth opportunity in the real-time monitoring space for Zio AT, stating, "[t]oday, we hold . . . probably around 7% [of the market share] when we think about the [mobile cardiac telemetry monitoring] space or where Zio AT really can play" and assured investors that there is "opportunity that sits there from a product perspective."

32. On August 11, 2022, Defendant Devine participated in the Canaccord Growth Conference on behalf of iRhythm. During the conference, Devine stated, "in the standard 14-day monitoring, we are the overwhelming share leader" and elaborated that in the real-time monitoring space, iRhythm is "the third player in what is a little bit more well-developed [market]."

33. On September 21, 2022, iRhythm held its annual Investor Day conference. During the conference, Defendant Bobzien offered that the average sales price for the Zio AT, using the CMS reimbursement rate as a proxy, is "about $1,150," and by comparison, the rate for Zio XT is "$250 over the planning horizon" and emphasized the opportunity for profit growth with the addressable market expansion of the Zio AT platform.

34. The statements in paragraphs 24-33 were materially false and misleading and failed to disclose material facts necessary to make the statements made, in light of the circumstances in which they were made, not false and misleading. As detailed in the Warning Letter, "based on [iRhythm's] marketing materials, website, and other documentation," investors were led to believe that "the Zio AT System is intended for 'near real-time monitoring' and 'high-risk patients,' even though the Zio AT System is not cleared for these indications." iRhythm failed to comply with the FDA's marketing regulations and prohibitions against the promotion of products for uncleared and unapproved uses contrary to the representations it made to investors. Indeed, the Warning Letter noted that the Zio AT device is in "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***." (emphasis added). This is because the Company imposed a transmission limit on the number of arrhythmic events that triggered a notification to the

prescribing physician, resulting in harm to patients who reached the transmission limit during the wear period and whose arrhythmic events were not reported to physicians. As an example, the Warning Letter details that the Zio AT monitor failed to report significant arrhythmias that led to at least two reported deaths. What's more, iRhythm failed to report these adverse events, and other missed arrhythmic events, to the FDA in violation of the reporting requirements of Medical Device Reporting regulations.

VI. THE TRUTH EMERGES

35. The truth 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, which was also filed with the SEC on Form 8-K, 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 "softness in returned devices" and "Zio AT utilization" as challenges that will "persist[] into the fourth quarter" and "have led us to reduc[e] our full year revenue guidance."

36. Later that same day, iRhythm held a conference call with analysts and investors to discuss the Company's financial results. During that call, Defendant 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 "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."

37. 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.

38. However, during the November 1, 2022 conference call, Defendant Blackford assured investors that the Company would continue to grow the Zio AT platform in the real-time monitoring market. Blackford stated, "[w]e look forward to enhancing our Zio AT product to grow our market share in the [mobile cardiac telemetry monitoring] space." Blackford addressed investors' concerns by calling the slower growth "more of a near-term impact" and explaining that "once we get the packaging updated, the labeling updated, the field action notice starts to subside, I don't think it becomes nearly as big of a headwind." Blackford touted that "you're going to see us continue to innovate on the Zio AT side" and "continue[] to close some of the competitive gaps, and I think position[] us really well for growth in that [mobile cardiac telemetry monitoring] space."

39. The statements in paragraph 38 were 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. As noted by the receipt of the Form 483 and the subsequent Warning Letter, 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 for real-time reporting on a high-risk patient population, the Company knew it was promoting the product for unapproved and off-label uses. In light of this information, there was no basis for the Company to tell investors that it expected continued product growth in the mobile cardiac telemetry monitoring market.

40. 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, and that the Customer Advisory Notice warned patients of a "labeling correction" related to "the device's maximum transmission limits during wear," as well as other critical issues that prevent the device from working as advertised. 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."

41. 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.

42. 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."

43. 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, Defendant Blackford touted that "[t]here is significant runway ahead of us in the [mobile cardiac telemetry monitoring] market where we have less than 10% market share today." He added, "[w]e are excited about this next generation of our Zio AT product, which we believe will better position us to compete in the space and drive market share gains into the future." 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."

44. The statements in paragraphs 42-43 were materially false and misleading because the Company had failed to take sufficient measures to remediate the concerns the FDA raised in the Form 483. Since the Zio AT device was never approved for real-time reporting on a high-risk patient population, the Company falsely represented to investors that it was on track to grow the product in the mobile cardiac telemetry monitoring market.

45. 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 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."

46. 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.

47. Although the Company refrained from providing additional detail about the DOJ's request, in a May 5, 2023, report, J.P. Morgan analysts noted that one of iRhythm's competitors, Boston Scientific, had also disclosed that it received a subpoena from the DOJ relating to its real-time monitoring product, which indicated to the analysts that the DOJ investigation into iRhythm was related to the Zio AT. The analysts also highlighted that while "the Consumer Protection Branch is part of the Civil Division of the DOJ and has a very broad mandate," the agency's "affirmative litigation is often used to recoup losses to fraud and abuse of federal funds" and the "closest precedent" in the industry is a recent settlement with Biotelemetry "to resolve claims of improper billing and usage of offshore technicians . . . for federal healthcare beneficiaries" related to its mobile telemetry device. In the report, analysts noted an "overhang until [investors] get further details into the nature of the investigation."

48. 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."

49. The Warning Letter—a notice that is only issued when "a manufacturer has significantly violated FDA regulations"—addressed a series of deficiencies tied to the marketing and capabilities of the Zio AT device. In particular, the FDA noted that iRhythm had falsely marketed the Zio AT as approved for use in high-risk patients that require real-time cardiac

monitoring. In truth, Zio AT is only approved for "long-term monitoring of arrhythmia events for ***non-critical care patients where real-time monitoring is not needed***." (emphasis added). Accordingly, the Warning Letter states that iRhythm is required 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."

50. Critically, the Warning Letter revealed that the Company was putting patients at risk given that the Zio AT device suffered from several critical flaws that were known to iRhythm since at least 2017, yet never disclosed to patients, physicians, or the FDA. Most significantly, "the device is only able to transmit 100 patient-triggered and 500 automatically detected arrhythmia events" and "[t]hus, when the transmission limit is hit, the device can no longer be used for its intended purpose of transmitting patient ECG for reporting." Moreover, the Warning Letter detailed that iRhythm failed to "inform the physician of 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." Likewise, iRhythm provided no information 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." Therefore, patients who relied on the device to report heart irregularities were never warned of this deficiency and were left unprotected.

51. Significantly, the transmission limitation prevents the Zio AT system from functioning as a mobile cardiac telemetry monitor that is intended for high-risk patients. The Warning Letter criticized iRhythm for violating its Quality Systems Regulations, stating "[w]hen the transmission limit is exceeded" the Zio AT is in "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***." (emphasis added).

52. The Warning Letter also highlighted that iRhythm failed to report to the FDA adverse events related to Zio AT as required by FDA regulations. Specifically, the Company failed to report complaints describing events where "the transmission limit was reached prior to

occurrence of a significant arrhythmia," including two deaths that resulted because the device stopped transmitting ECG data to the prescribing physician and the physician did not receive notice of the arrhythmia "until the final wear-period report was generated."

53. 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.

VII. LOSS CAUSATION

54. 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, and May 30, 2023, 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, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

VIII. CLASS ACTION ALLEGATIONS

55. 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.

56. 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.

57. 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 Officer 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.

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

59. 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.

60. 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.

IX. INAPPLICABILITY OF STATUTORY SAFE HARBOR

61. iRhythm's "Safe Harbor" warnings accompanying its forward-looking statements issued during the Class Period were ineffective to shield those statements from liability.

62. 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. PRESUMPTION OF RELIANCE

63. At all relevant times, the market for iRhythm common stock was an efficient market 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) 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.

64. 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.

65. 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' claims are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding iRhythm's business operations—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. SCIENTER ALLEGATIONS

66. As alleged herein, the Defendants acted with scienter since the Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Officer Defendants, by virtue of their receipt of information reflecting the true facts regarding iRhythm, their control over, and/or

receipt and/or modification of iRhythm's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning iRhythm, participated in the fraudulent scheme alleged herein.

XII. CLAIMS FOR RELIEF

COUNT I

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

(Against All Defendants)

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

68. 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.

69. 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.

70. 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.

71. 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.

72. The 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. The Defendants engaged in this misconduct to conceal iRhythm's true condition from the investing public and to support the artificially inflated prices of the Company's common stock.

73. 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. 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.

74. As a direct and proximate result of the Defendants' wrongful conduct, 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.

75. 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)

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

77. The Officer 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 Officer Defendants had the power and ability to control the actions of iRhythm and its employees. By reason of this conduct, the Officer Defendants are liable under Section 20(a) of the Exchange Act.

XIII. PRAYER FOR RELIEF

78. WHEREFORE, 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 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 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

79. Plaintiff demands a trial by jury.

DATED: Respectfully submitted,