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**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. 3:24-cv-706

**COMPLAINT FOR VIOLATIONS OF
THE FEDERAL SECURITIES LAWS**

CLASS ACTION

DEMAND FOR JURY TRIAL

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

9
10 **I. INTRODUCTION**

11 1. Plaintiff brings this securities class action on behalf of all persons or entities that
12 purchased or otherwise acquired iRhythm common stock between January 11, 2022, and May 30,
13 2023, inclusive (the “Class Period”).

14 2. The claims asserted herein are alleged against iRhythm and certain of the
15 Company’s former and current senior officers (collectively, “Defendants”) and arise under
16 Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule
17 10b-5, promulgated thereunder.

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

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

9 5. The truth began to emerge on November 1, 2022, after the market closed, when the
10 Company reported revised fourth quarter and full-year guidance, in part due to “Zio AT
11 utilization.” The Company’s Chief Executive Officer, Defendant Blackford, explained during a
12 conference call with investors that “coming into the fourth quarter, [iRhythm] voluntarily issued a
13 Customer Advisory Notice to [its] Zio AT customers.” Consequently, the Company lowered its
14 Zio AT forecast for the quarter from the 40% growth target it had provided through the past three
15 quarters to just 20%. As a result of these disclosures, the price of iRhythm common stock declined
16 by \$5.60 per share, or 4.4%, on November 2, 2022. As the market digested this news and multiple
17 analysts cut their price targets, the price of iRhythm common stock declined by \$14.07 per share,
18 or 11.6%, on November 3, 2023.

19 6. Then, on Friday, November 4, 2022, after the market closed, the Company revealed
20 that on September 28, 2022, it initiated the Customer Advisory Notice as a result of its “assessment
21 of topics raised in an FDA inspection focused on Zio AT,” after which the FDA issued an
22 inspection observation report on Form 483. Notably, a Form 483 is issued in cases where an FDA
23 investigator observes conditions that constitute violations of the Food Drug and Cosmetic Act and
24 related Acts. Although iRhythm did not expand on the concerns the FDA raised, it did assure
25 investors that the Company did “not expect this Zio AT labeling correction or the activities
26 associated with the topics raised in the FDA inspection to present a material risk to [its] business
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1 at this time[.]” As a result of these disclosures, the price of iRhythm common stock declined by
2 \$2.43 per share, or 2.4%.

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

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

25 9. As a result of Defendants’ actions detailed herein, and the precipitous decline in the
26 market value of the Company’s common stock, Plaintiff and other Class members have suffered
27 significant losses and damages.
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1 **II. JURISDICTION AND VENUE**

2 10. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange
3 Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R.
4 § 240.10b-5.

5 11. This Court has jurisdiction over the subject matter of this action pursuant to Section
6 27 of the Exchange Act, 15 U.S.C. § 78aa.

7 12. Venue is proper in this District under Section 27 of the Exchange Act, 15 U.S.C. §
8 78aa, and 28 U.S.C. § 1391(b), because iRhythm’s principal executive office is located in San
9 Francisco, California, which is situated in this District, and many of the acts giving rise to the
10 violations complained of in this action, including the preparation and dissemination of materially
11 false and misleading statements, occurred in substantial part in this District.

12 13. In connection with the acts alleged in this Complaint, Defendants, directly or
13 indirectly, used the means and instrumentalities of interstate commerce, including, but not limited
14 to, the mails, interstate telephone communications, and the facilities of the national securities
15 markets.

16 **III. PARTIES**

17 **A. Plaintiff**

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

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22 **B. Defendants**

23 15. Defendant iRhythm is a digital healthcare company that develops and manufactures
24 heart monitoring devices designed to diagnose arrhythmia. The Company maintains its
25 headquarters at 699 8th Street, Suite 600, San Francisco, California. iRhythm common stock trades
26 on NASDAQ under the ticker symbol “IRTC.” As of October 23, 2023, iRhythm had over 30
27 million shares of common stock outstanding, owned by hundreds or thousands of investors.
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1 16. Defendant Quentin Blackford (“Blackford”) is, and was at all relevant times,
2 iRhythm’s Chief Executive Officer and a Director of the Company.

3 17. Defendant Brice Bobzien (“Bobzien”) has served as iRhythm’s Chief Financial
4 Officer since August 8, 2022.

5 18. Defendant Douglas Devine (“Devine”) served as iRhythm’s Chief Financial
6 Officer from June 22, 2020, to August 8, 2022, and as Chief Operating Officer from December 1,
7 2021, to March 10, 2023.

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

19 **IV. BACKGROUND**

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

25 21. In 2017, iRhythm developed Zio AT, a device the Company described as
26 “offer[ing] the full benefits of [its] Zio XT Service, with the addition of real-time data transmission
27 and notification of actionable clinical events.” Actionable arrhythmic events include atrial
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1 fibrillation, a condition that can cause troubling symptoms and serious medical complications,
2 including blood clots that can lead to stroke and heart failure. The Zio AT comes with a cellular
3 transmittal device that provides connectivity between the Zio AT and the proprietary algorithmic
4 software that analyzes the ECG data and detects arrhythmic events for the 14-day wear period.
5 Importantly, given its purported capabilities to provide “real-time” notifications of arrhythmic
6 events, the Zio AT device is marketed to high-risk patients as a mobile cardiac telemetry device.

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

16 23. As a mobile cardiac telemetry device, Zio AT was not subject to the reimbursement
17 rate reduction imposed on Zio XT—a 14-day ambulatory cardiac monitoring device that does not
18 provide real-time notification and is intended for non-critical patients. The price premium on real-
19 time monitors is significant. iRhythm reported that for the year 2022, it billed the Zio AT device
20 at an average rate of \$1,150, whereas it billed the Zio XT device at an average rate of \$250.

21 **V. DEFENDANTS’ MATERIALLY FALSE AND MISLEADING STATEMENTS**
22 **CAUSE SUBSTANTIAL LOSSES TO INVESTORS**

23 24. The Class Period begins on January 11, 2022, when Defendant Blackford
24 represented iRhythm at the J.P. Morgan Healthcare Conference. During the conference, Blackford
25 touted iRhythm’s “best-in-class ZIO platform,” including the device’s “digital platform,” which
26 “enables [patient data] to easily be shared and understood by our physicians, our patients, our
27 payers all through desktop, mobile and [electronic health record] connectivity.”
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1 25. On February 23, 2022, iRhythm announced its financial results for the fourth
2 quarter and full year 2021. That same day, iRhythm held a conference call with analysts and
3 investors to discuss the Company’s financial results. During that call, Defendant Blackford touted
4 that “revenues from Zio AT doubled in 2021 versus 2020 and now represent approximately 10%
5 of [iRhythm’s] revenues,” and attributed the growth to the product’s expansion with use cases in
6 higher risk patients. Blackford stated that iRhythm “continue[s] to believe [Zio AT will] grow at
7 a faster rate than the XT business” because while “nearly 25% of the [ambulatory cardiac
8 monitoring] market [is] utilizing Zio XT, maybe no more than 7% or so of market share [is] in the
9 Zio AT opportunity.” In response to an analyst question about how a 20% increase in
10 reimbursement rates for mobile cardiac telemetry monitors would play into the pricing, margin,
11 and volume ramp of Zio AT, Blackford stated that the increase “demonstrate[s] that the value of
12 the product is being realized by” private health care insurers authorized to process Medicare
13 claims. Later on the call, Blackford added “the value of what you can get off of 14 days in that
14 [real-time monitoring] space versus a traditional 30-day monitor, it’s superior with our product[.]”

15 26. On February 28, 2022, iRhythm filed with the SEC its 2021 annual report on Form
16 10-K for the year ended December 31, 2021. The Form 10-K was signed by Defendants Blackford
17 and Devine and contained certifications by each that attested to the purported accuracy and
18 completeness of the 10-K. In the 10-K, the Company stated that its “Zio AT mobile cardiac
19 telemetry monitor . . . offers what our Zio XT offers plus the additional capability of transmissions
20 during the wear period to assist physicians in diagnosing and treating the small percentage of the
21 population requiring more timely action.” iRhythm further stated that its “Zio AT service delivers
22 the same comprehensive final report [as Zio XT], but also provides physicians with actionable
23 notifications” and highlighted that “Zio AT improves the speed and accuracy of diagnosis relative
24 to traditional mobile cardiac telemetry . . . devices and services.”

25 27. In the same 10-K, iRhythm announced that it had “received FDA clearance for [its]
26 Zio AT ECG Monitoring System, which is designed to provide timely transmission of data during
27 the wear period.” Moreover, the Company acknowledged that “[t]he FDA and the Federal Trade
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1 Commission (“FTC”) . . . regulate the advertising and promotion of [its] products and services to
2 ensure that the claims [iRhythm] make[s] are consistent with [its] regulatory clearances.”
3 According to the 10-K, iRhythm is required to follow the “labeling regulations and FDA
4 prohibitions against the promotion of products for un-cleared, unapproved or off-label uses.”
5 Significantly, iRhythm acknowledged that “[m]aterial modifications to the Zio monitors, labelling
6 of the Zio monitors, or Zio service,” which include changing the products’ addressable market
7 “may require new [FDA] clearances” and may additionally require “premarket approvals or may
8 require [iRhythm] to recall or cease marketing [its] products and services until clearances are
9 obtained.”

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

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

21 30. On August 4, 2022, iRhythm issued a press release announcing its financial results
22 for the second quarter of 2022. In the press release, which was also filed with the SEC on Form
23 8-K, iRhythm raised its full year 2022 revenue guidance to between \$415 million and \$420 million,
24 which represented between 29% and 30% growth over prior year results due to its top-line results
25 in the second quarter. The Company stated that the increase in the second quarter was “primarily
26 driven by Zio XT and AT volume growth and increases in Medicare pricing.”
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1 31. Later that same day, iRhythm held a conference call with analysts and investors to
2 discuss the Company’s financial results. During that call, Defendant Blackford, assured investors
3 about the growth opportunity in the real-time monitoring space for Zio AT, stating, “[t]oday, we
4 hold . . . probably around 7% [of the market share] when we think about the [mobile cardiac
5 telemetry monitoring] space or where Zio AT really can play” and assured investors that there is
6 “opportunity that sits there from a product perspective.”

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

11 33. On September 21, 2022, iRhythm held its annual Investor Day conference. During
12 the conference, Defendant Bobzien offered that the average sales price for the Zio AT, using the
13 CMS reimbursement rate as a proxy, is “about \$1,150,” and by comparison, the rate for Zio XT is
14 “\$250 over the planning horizon” and emphasized the opportunity for profit growth with the
15 addressable market expansion of the Zio AT platform.

16 34. The statements in paragraphs 24-33 were materially false and misleading and failed
17 to disclose material facts necessary to make the statements made, in light of the circumstances in
18 which they were made, not false and misleading. As detailed in the Warning Letter, “based on
19 [iRhythm’s] marketing materials, website, and other documentation,” investors were led to believe
20 that “the Zio AT System is intended for ‘near real-time monitoring’ and ‘high-risk patients,’ even
21 though the Zio AT System is not cleared for these indications.” iRhythm failed to comply with
22 the FDA’s marketing regulations and prohibitions against the promotion of products for uncleared
23 and unapproved uses contrary to the representations it made to investors. Indeed, the Warning
24 Letter noted that the Zio AT device is in “nonconformance because the device is unable to transmit
25 ECG information for monitoring and *is not remotely capable of delivering near-real-time*
26 *monitoring for high-risk patients.*” (emphasis added). This is because the Company imposed a
27 transmission limit on the number of arrhythmic events that triggered a notification to the
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1 prescribing physician, resulting in harm to patients who reached the transmission limit during the
2 wear period and whose arrhythmic events were not reported to physicians. As an example, the
3 Warning Letter details that the Zio AT monitor failed to report significant arrhythmias that led to
4 at least two reported deaths. What’s more, iRhythm failed to report these adverse events, and other
5 missed arrhythmic events, to the FDA in violation of the reporting requirements of Medical Device
6 Reporting regulations.

7 **VI. THE TRUTH EMERGES**

8 35. The truth began to emerge on November 1, 2022, after the market closed, when
9 iRhythm issued a press release announcing revised revenue guidance for its fourth quarter and full
10 year 2022. In the press release, which was also filed with the SEC on Form 8-K, the Company
11 provided revised revenue guidance for 2022 of between \$407 million and \$411 million, a quarter
12 after the Company had increased guidance to between \$415 million and \$420 million. The
13 Company attributed “softness in returned devices” and “Zio AT utilization” as challenges that will
14 “persist[] into the fourth quarter” and “have led us to reduc[e] our full year revenue guidance.”

15 36. Later that same day, iRhythm held a conference call with analysts and investors to
16 discuss the Company’s financial results. During that call, Defendant Blackford explained that the
17 Company reduced the revenue outlook for the full year in part because it had “voluntarily issued
18 a Customer Advisory Notice to [its] Zio AT customers” and “ha[s] seen reduced growth with Zio
19 AT within the fourth quarter-to-date.” Blackford further announced that “[w]ith the Customer
20 Advisory Notice” the Company “adjusted [its] Zio AT forecast for the quarter to grow closer to
21 approximately 20%, which is a step down from the upper 40% growth [it] had seen through the
22 first nine months of the year.”

23 37. As a result of these disclosures, the price of iRhythm common stock declined by
24 \$5.60 per share, or 4.4%, from a closing price of \$126.77 on November 1, 2022, to a closing price
25 of \$121.17 on November 2, 2022. As the market digested this news and multiple analysts cut their
26 price targets, the price of iRhythm common stock declined by an additional \$14.07 per share, or
27 11.6%, to a closing price of \$107.10 on November 3, 2022.

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

11 39. The statements in paragraph 38 were materially false and misleading because the
12 Company knew that the issues it faced with Zio AT’s transmission limit were not a “near-term”
13 headwind. As noted by the receipt of the Form 483 and the subsequent Warning Letter, the
14 Company knew that it faced severe scrutiny from the FDA regarding the transmission limit and its
15 failure to disclose the limit to end users and physicians. Moreover, since the device was never
16 approved for real-time reporting on a high-risk patient population, the Company knew it was
17 promoting the product for unapproved and off-label uses. In light of this information, there was
18 no basis for the Company to tell investors that it expected continued product growth in the mobile
19 cardiac telemetry monitoring market.

20 40. On November 4, 2022, after the market closed, the Company filed with the SEC its
21 quarterly report on Form 10-Q for the third quarter of 2022. In the 10-Q, the Company revealed
22 additional details regarding the Customer Advisory Notice. Specifically, iRhythm disclosed that
23 the Company initiated the Customer Advisory Notice on September 28, 2022, following issues
24 raised by the FDA during an inspection that culminated in an inspection observation report on
25 Form 483, and that the Customer Advisory Notice warned patients of a “labeling correction”
26 related to “the device’s maximum transmission limits during wear,” as well as other critical issues
27 that prevent the device from working as advertised. iRhythm stated that it “reported this Customer
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1 Advisory Notice and related information to the FDA under 21 C.F.R., Part 806, and are in ongoing
2 communication with the FDA on this matter.”

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

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

10 43. On February 23, 2023, after the market closed, iRhythm announced its financial
11 results for the fourth quarter and full year 2022. Later that evening, iRhythm held a conference
12 call with analysts and investors to discuss the Company’s financial results. During the conference
13 call, Defendant Blackford touted that “[t]here is significant runway ahead of us in the [mobile
14 cardiac telemetry monitoring] market where we have less than 10% market share today.” He
15 added, “[w]e are excited about this next generation of our Zio AT product, which we believe will
16 better position us to compete in the space and drive market share gains into the future.” In response
17 to an analyst question regarding the growth of Zio AT in view of the Customer Advisory Notice,
18 Blackford responded, “that business is going to grow right around 30% for us . . . we certainly
19 have seen a difference in that growth profile coming out of that field advisory notice. Now we’ve
20 made all the updates in the labeling that we need to do and in the packaging that we need to do.”

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

26 45. Then, on May 4, 2023, the Company filed with the SEC its quarterly report on Form
27 10-Q for the first quarter of 2023. In the 10-Q, iRhythm announced that “on April 4, 2023, [it]
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1 received a Subpoena Duces Tecum from the Consumer Protection Branch, Civil Division of the
2 U.S. Department of Justice, requesting production of various documents regarding [its] products
3 and services.”

4 46. This news caused the price of iRhythm common stock to decline by \$9.25 per share,
5 or 6.9%, from a closing price of \$134.04 on May 4, 2023, to a closing price of \$124.79 on May 5,
6 2023.

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

18 48. On May 30, 2023, after the market closed, iRhythm filed with the SEC a Current
19 Report on Form 8-K, disclosing that it had received a Warning Letter from the FDA, which
20 “resulted from the inspection of the Company’s facility located in Cypress, California that
21 concluded in August 2022” and “alleges non-conformities to regulations for medical devices,
22 including medical device reporting requirements, relating to the Company’s Zio AT System and
23 medical device quality system requirements.”

24 49. The Warning Letter—a notice that is only issued when “a manufacturer has
25 significantly violated FDA regulations”—addressed a series of deficiencies tied to the marketing
26 and capabilities of the Zio AT device. In particular, the FDA noted that iRhythm had falsely
27 marketed the Zio AT as approved for use in high-risk patients that require real-time cardiac
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1 monitoring. In truth, Zio AT is only approved for “long-term monitoring of arrhythmia events for
2 *non-critical care patients where real-time monitoring is not needed.*” (emphasis added).
3 Accordingly, the Warning Letter states that iRhythm is required to submit a new 510(k) because
4 iRhythm’s “labeling describes a new patient population” which “affect[s] the safety or
5 effectiveness of the device.”

6 50. Critically, the Warning Letter revealed that the Company was putting patients at
7 risk given that the Zio AT device suffered from several critical flaws that were known to iRhythm
8 since at least 2017, yet never disclosed to patients, physicians, or the FDA. Most significantly,
9 “the device is only able to transmit 100 patient-triggered and 500 automatically detected
10 arrhythmia events” and “[t]hus, when the transmission limit is hit, the device can no longer be used
11 for its intended purpose of transmitting patient ECG for reporting.” Moreover, the Warning Letter
12 detailed that iRhythm failed to “inform the physician of the existence of a transmission limit, when
13 the transmission limit is reached, or include any information about the action a physician should
14 take if the device reaches the transmission limit.” Likewise, iRhythm provided no information to
15 the patient “that a transmission limit exists, no notification to the patient when the transmission
16 limit is reached, and no information provided to the patient about what to do when the transmission
17 limit is reached.” Therefore, patients who relied on the device to report heart irregularities were
18 never warned of this deficiency and were left unprotected.

19 51. Significantly, the transmission limitation prevents the Zio AT system from
20 functioning as a mobile cardiac telemetry monitor that is intended for high-risk patients. The
21 Warning Letter criticized iRhythm for violating its Quality Systems Regulations, stating “[w]hen
22 the transmission limit is exceeded” the Zio AT is in “nonconformance because the device is unable
23 to transmit ECG information for monitoring and *is not remotely capable of delivering near-real*
24 *time monitoring for high-risk patients.*” (emphasis added).

25 52. The Warning Letter also highlighted that iRhythm failed to report to the FDA
26 adverse events related to Zio AT as required by FDA regulations. Specifically, the Company failed
27 to report complaints describing events where “the transmission limit was reached prior to
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1 occurrence of a significant arrhythmia,” including two deaths that resulted because the device
2 stopped transmitting ECG data to the prescribing physician and the physician did not receive notice
3 of the arrhythmia “until the final wear-period report was generated.”

4 53. These disclosures caused the price of iRhythm common stock to decline by \$7.41
5 per share, or 6.1%, from a closing price of \$121.68 on May 30, 2023, to a closing price of \$114.27
6 on May 31, 2023.

7 **VII. LOSS CAUSATION**

8 54. During the Class Period, as detailed herein, Defendants made materially false and
9 misleading statements and omissions, and engaged in a scheme to deceive the market. These
10 misleading statements and omissions artificially inflated the price of iRhythm common stock and
11 operated as a fraud or deceit on the Class (as defined below). Later, when the alleged
12 misrepresentations and fraudulent conduct were disclosed to the market on November 1, 2022,
13 November 4, 2022, May 4, 2023, and May 30, 2023, the price of iRhythm common stock fell
14 precipitously as the prior artificial inflation came out of the price over time. As a result of their
15 purchases of iRhythm common stock during the Class Period, Plaintiff and other members of the
16 Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

17 **VIII. CLASS ACTION ALLEGATIONS**

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

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

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

- 4 (a) Whether Defendants violated the Exchange Act;
- 5 (b) Whether Defendants omitted and/or misrepresented material facts;
- 6 (c) Whether Defendants' statements omitted material facts necessary in order
7 to make the statements made, in light of the circumstances under which they
8 were made, not misleading;
- 9 (d) Whether the Officer Defendants are personally liable for the alleged
10 misrepresentations and omissions described herein;
- 11 (e) Whether the Defendants knew or recklessly disregarded that their
12 statements and/or omissions were false and misleading;
- 13 (f) Whether Defendants' conduct impacted the price of iRhythm common
14 stock;
- 15 (g) Whether Defendants' conduct caused the members of the Class to sustain
16 damages; and
- 17 (h) The extent of damage sustained by Class members and the appropriate
18 measure of damages.

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

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

24 60. A class action is superior to other available methods for the fair and efficient
25 adjudication of this controversy. Joinder of all Class members is impracticable.
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1 **IX. INAPPLICABILITY OF STATUTORY SAFE HARBOR**

2 61. iRhythm’s “Safe Harbor” warnings accompanying its forward-looking statements
3 issued during the Class Period were ineffective to shield those statements from liability.

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

13 **X. PRESUMPTION OF RELIANCE**

14 63. At all relevant times, the market for iRhythm common stock was an efficient market
15 for the following reasons, among others:

- 16 (a) iRhythm common stock met the requirements for listing, and was listed and
17 actively traded on NASDAQ, a highly efficient and automated market;
- 18 (b) As a regulated issuer, iRhythm filed periodic public reports with the SEC
19 and NASDAQ;
- 20 (c) iRhythm regularly and publicly communicated with investors via
21 established market communication mechanisms, including through regular
22 disseminations of press releases on the national circuits of major newswire
23 services and through other wide-ranging public disclosures, such as
24 communications with the financial press and other similar reporting
25 services; and
- 26 (d) iRhythm was followed by several securities analysts employed by major
27 brokerage firm(s) who wrote reports which were distributed to the sales
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1 force and certain customers of their respective brokerage firm(s). Each of
2 these reports was publicly available and entered the public marketplace.

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

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

20 **XI. SCIENTER ALLEGATIONS**

21 66. As alleged herein, the Defendants acted with scienter since the Defendants knew
22 that the public documents and statements issued or disseminated in the name of the Company were
23 materially false and/or misleading; knew that such statements or documents would be issued or
24 disseminated to the investing public; and knowingly and substantially participated or acquiesced
25 in the issuance or dissemination of such statements or documents as primary violations of the
26 federal securities laws. As set forth elsewhere herein in detail, the Officer Defendants, by virtue
27 of their receipt of information reflecting the true facts regarding iRhythm, their control over, and/or
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1 receipt and/or modification of iRhythm's allegedly materially misleading misstatements and/or
2 their associations with the Company which made them privy to confidential proprietary
3 information concerning iRhythm, participated in the fraudulent scheme alleged herein.

4 **XII. CLAIMS FOR RELIEF**

5 **COUNT I**

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

7 **(Against All Defendants)**

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

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

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

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

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

1 72. The Defendants had actual knowledge of the misrepresentations and omissions of
2 material facts set forth herein, or recklessly disregarded the true facts that were available to them.
3 The Defendants engaged in this misconduct to conceal iRhythm's true condition from the investing
4 public and to support the artificially inflated prices of the Company's common stock.

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

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

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

COUNT II

For Violations of Section 20(a) of the Exchange Act

(Against the Officer Defendants)

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

19 77. The Officer Defendants acted as controlling persons of iRhythm within the meaning
20 of Section 20(a) of the Exchange Act. By virtue of their high-level positions, participation in and
21 awareness of the Company's operations, direct involvement in the day-to-day operations of the
22 Company, and intimate knowledge of the Company's actual performance, and their power to
23 control public statements about iRhythm, the Officer Defendants had the power and ability to
24 control the actions of iRhythm and its employees. By reason of this conduct, the Officer
25 Defendants are liable under Section 20(a) of the Exchange Act.
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1 **XIII. PRAYER FOR RELIEF**

2 78. WHEREFORE, Plaintiff prays for judgment as follows:

- 3 (a) Determining that this action is a proper class action under Rule 23 of the
4 Federal Rules of Civil Procedure;
- 5 (b) Awarding compensation to Plaintiff and other Class members against all
6 Defendants, jointly and severally, for all damages sustained as a result of
7 Defendants' wrongdoing, in an amount to be proven at trial, including
8 interest thereon;
- 9 (c) Awarding Plaintiff and the Class their reasonable costs and expenses
10 incurred in this action, including attorneys' fees and expert fees; and
- 11 (d) Awarding such equitable/injunctive or other further relief as the Court may
12 deem just and proper.

13 **XIV. JURY DEMAND**

14 79. Plaintiff demands a trial by jury.

15 DATED:

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