UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-37918

iRhythm Technologies, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**20-8149544**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
699 8th Street, Suite 600 San Francisco, California	**94103**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 632-5700

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value $.001 Per Share	**IRTC**	**The Nasdaq Stock Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definition of "large accelerated filer", "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Small reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the Registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the Registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market LLC on June 30, 2022, was approximately $3.2 billion.

The number of shares of Registrant's Common Stock outstanding as of February 16, 2023,was 30,216,279.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the information called for by Part III of this Form 10-K is hereby incorporated by reference from the definitive Proxy Statements for our annual meeting of stockholders, which will be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2022.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements contained in this Annual Report on Form 10-K concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the expected impact of macroeconomic conditions, including inflation, increasing interest rates, and volatile market conditions, and global events, including the ongoing COVID-19 pandemic and the recent war in Ukraine, on our business, operations and financial results;
- the impact of supply chain disruptions on our operations and financial results;
- the impact of inflationary costs on our operations and financial results;
- plans to conduct further clinical studies, including any clinical trials initiated by third parties;
- our plans to modify our current systems and services, or identify and develop, or acquire, new products or services, to address additional indications;
- the expected growth of our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement or other regulatory actions or decisions;
- our expectations regarding the size of our sales organization and expansion of our sales and marketing efforts, including in international geographies;
- our expectations regarding revenue, cost of revenue, cost of service per device, operating expenses, including research and development expense, sales and marketing expense and general and administrative expenses;
- our ability to retain and recruit key personnel, including the continued development of a sales and marketing infrastructure;
- our ability to obtain and maintain intellectual property protection for our systems and services;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Annual Report on Form 10-K may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K. We assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report on Form 10-K to conform these statements to actual results or to changes in our expectations.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed with the Securities and Exchange Commission (the "SEC") as exhibits to the Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties, including those risks more fully described below. These risks include, among others, the following, which we consider our most material risks:

- Reimbursement by Medicare is highly regulated and subject to change, and our failure to comply with applicable regulations, including regulations not designed for diagnostic tests like our Zio Services, could prevent us from receiving reimbursement under the Medicare program and some commercial payors, subject us to penalties, and adversely affect our reputation, business and results of operations.
- If reimbursement or other payment for our Zio Services is reduced or modified in the United States, including through cost containment measures or changes to policies with respect to pricing, our business could suffer.
- If we are unable to expand the number of third-party commercial payors with which we contract or expand coverage for existing third-party commercial payors, our commercial success could be impacted.
- Our revenue relies on our Zio Services, which are currently our only offerings. If our Zio Services or future service offerings fail to gain, or lose, market acceptance, our business will suffer.
- The market for ambulatory cardiac monitoring solutions is highly competitive. If our competitors are able to develop or market monitoring devices and services that are more effective, or gain greater acceptance in the marketplace, than any services and related devices we develop, our commercial opportunities will be reduced or eliminated.
- Billing for our Zio Services is complex, and we must dedicate substantial time and resources to the billing process.
- Audits or denials of our claims by government agencies or payors could expose us to recoupment, regulatory scrutiny, and penalties.
- We are currently undertaking a transformation of our revenue cycle management function and we may fail to realize the anticipated benefits of these efforts.
- Although our current Zio Systems are comprised of medical devices that have received FDA marketing authorization (510(k) clearance), we may regularly engage in product enhancements and in iterative changes to existing products, as well as seeking to develop new technology or use of technology for new indications for use. These medical device developments may trigger further regulatory reviews and the results of those reviews are unpredictable.

- We are subject to extensive compliance requirements for the quality of the medical device we manufacture for use in our Zio Services, and for vigilance on complaint-handling, escalation, assessment, and reporting of adverse events and malfunctions. A wide range of quality, regulatory, or safety matters could trigger the need for a recall or correction to marketed products.
- Because of the patient populations for which our services are provided and the complexity of the healthcare environment in which we operate, a high degree of medical and clinical input may be necessary to evaluate complaints and adverse events, and in some cases, there may be disagreement over whether our services or the medical devices used in our service may have caused or contributed to an event.
- If we are unable to keep up with demand for our Zio Services, our revenue could be impaired, market acceptance for our Zio Services could be harmed, and physicians may instead order our competitors' services.
- We depend on third-party vendors for the supply and manufacture of certain components of our Zio Systems, as well as for other aspects of our operations.
- Our ability to compete depends on our ability to innovate successfully.
- We have entered into a development agreement with a third-party that may not result in the development of commercially viable devices or the generation of significant future revenues.
- International expansion of our business exposes us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.
- Our success depends on our ability to attract and retain senior management and key personnel.
- Failure to receive the Zio System patches used for the provision of the Zio Services we provide may result in a loss of capital as well as revenue where the receipt of returned devices and processing of data retrieved from returned devices is required to provide our Zio Services.
- Our plans include a high degree of focus on the mSToPs criteria for AF screening. There are risks that the clinical or payor community will not fully accept these criteria as a basis for selection of patients suitable for screening.
- We may face risks associated with acquisitions of companies, products, and technologies and our business could be harmed if we are unable to address these risks.
- Our use of third-party service providers or iRhythm company resources located outside the United States to support certain customer care, clinical and other operations of our independent diagnostic testing facilities ("IDTFs") may present challenges, and if we are ineffective in limiting work performed by these service providers or iRhythm consistent with applicable regulations or our contractual agreements with commercial payors, we may be subject to penalties or experience loss of revenue.
- If we fail to comply with medical device, healthcare and other governmental regulations, we could face substantial penalties and our business, results of operations, and financial condition could be adversely affected.
- Changes in applicable laws or regulations or the interpretation or enforcement policies of regulators governing our IDTFs and Zio Services may constrain or require us to restructure our operations or adapt certain business strategies, , which may harm our revenue and operating results.
- Our business relies on orders from licensed healthcare providers, and the continuing clinical acceptance and adoption of our Zio Services depends upon strong working relationships with healthcare providers, including physicians. These relationships, interactions, and arrangements are subject to a high degree of scrutiny by government regulators and enforcement bodies.
- Our communications with healthcare stakeholders – physicians and other healthcare professionals, payors and similar entities, as well as patients and lay caregivers – are subject to a high degree of scrutiny for compliance with a wide range of laws and regulations. Continuing or increasing our sales and marketing and other external communication efforts may expose us to additional risk of being alleged or deemed to be non-compliant by regulatory, enforcement authorities, or competitors.

- While most of our revenue results from claims submitted to payors for diagnostic medical procedures, we offer, and are looking to expand, alternative payment and service delivery models. Piloting, evaluating, and implementing these alternative payment and service delivery models requires interactions with commercial payors, physicians, and patients; these interactions are subject to laws and regulations aimed at preventing healthcare fraud and abuse. If these models are unsuccessful, or if we are unable to fully comply with such laws as we pursue these strategies, our commercial success could be compromised and we could face substantial penalties.
- In the future we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations.
- Our financial results may fluctuate significantly from quarter-to-quarter and may not fully reflect the underlying performance of our business.
- We are subject to legal proceedings and government investigations that could adversely affect our business, financial condition, and results of operations.
- We are subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from shipping affected devices, require us to obtain licenses from third parties or to develop non-infringing alternatives, and subject us to substantial monetary damages and injunctive relief.
- We are subject to complex and evolving U.S. and foreign laws and regulations and other requirements regarding privacy, data protection, security, and other matters. Many of these laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, monetary penalties, increased cost of operations, or declines in user growth or engagement, or otherwise harm our business.
- If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.
- Our stock price is highly volatile and investing in our stock involves a high degree of risk, which could result in substantial losses for investors.
- Increasing our financial leverage could affect our operations and profitability.
- We may be impacted by domestic and global economic and political conditions, as well as natural disasters, pandemics, and other catastrophic events, which could adversely affect our business, financial condition or results of operations.

PART I

ITEM 1: BUSINESS

Company Background

iRhythm Technologies Inc.[1] is a leading digital healthcare company that creates trusted solutions that detect, predict, and prevent disease. Our principal business is the design, development, and commercialization of device-based technology to provide ambulatory cardiac monitoring services that we believe allow clinicians to diagnose certain arrhythmias quicker and with greater efficiency than other services that rely on traditional technology.

Since first receiving clearance from the U.S. Food and Drug Administration (“FDA”) for our technology in 2009, we have supported physician and patient use of our technology and provided ambulatory cardiac monitoring services from our Medicare-enrolled independent diagnostic testing facilities ("IDTFs") and with our qualified technicians. We have provided our Zio ambulatory cardiac monitoring services, including long-term continuous monitoring, short-term continuous monitoring, and mobile cardiac telemetry (“MCT”) monitoring services (collectively, the “Zio Services”), using our Zio Systems (as defined below).

Each Zio System combines an FDA-cleared and CE-marked, wire-free, patch-based, 14-day wearable biosensor that continuously records electrocardiogram (“ECG”) data with a proprietary, FDA-cleared, CE-marked cloud-based data analytic software to help physicians monitor patients and diagnose arrhythmias. Since receiving FDA clearance, we have provided the Zio Services to over five million patients and have collected over one billion hours of curated heartbeat data.

The Company is a Delaware corporation, incorporated in September 2006 with corporate, clinical operations, and research and development headquarters located in San Francisco, California. We also operate a manufacturing facility in Orange County, California, and have clinical operations facilities in Deerfield, Illinois, and Houston, Texas. We employ 1,793 regular full-time employees as of December 31, 2022.

Our common stock is traded on the Nasdaq Global Select Market under the symbol “IRTC.”

Cardiac Arrhythmias and the Ambulatory Cardiac Monitoring Market

Cardiac Arrhythmias

Every year, millions of patients experience symptoms potentially associated with cardiac arrhythmias, a condition in which the electrical impulses that coordinate heartbeats do not occur properly, causing the heart to beat too quickly, too slowly or irregularly. Early detection of heart rhythm disorders, such as atrial fibrillation (“Afib”) and other clinically relevant arrhythmias, supports appropriate medical intervention and can help avoid more serious downstream medical events, including stroke.

According to the Centers for Disease Control and Prevention, approximately 11 million people in the United States have a heart rhythm disorder, or arrhythmia. The most common sustained type of arrhythmia is Afib, a condition which causes the upper chambers of the heart to beat irregularly and blood not to flow properly to the lower chambers of the heart. The American Heart Association (“AHA”) estimates that as many as six million people in the United States and 33.5 million patients worldwide have Afib with at least one-third of these patients presenting as asymptomatic at the time of their diagnosis. More than 450,000 hospitalizations occur each year in the United States because of Afib, and the condition contributes to an estimated 160,000 deaths each year. Since Afib is more common among people over the age of 60, these numbers are expected to increase as the U.S. population ages.

[1] As used throughout the text of Items 1 to 7, on Form 10-K, the term “iRhythm,”, "the Company," “we” or “us,” refers to iRhythm Technologies, Inc., a Delaware corporation, or iRhythm Technologies Inc. and its consolidated subsidiaries, as the context requires.

Atrial Fibrillation and Stroke

Afib is the leading risk factor for stroke because Afib can cause blood to collect in the heart and potentially form a clot, which can then travel to the brain possibly resulting in an ischemic stroke. While individuals with Afib are approximately five times more likely to suffer a stroke, the American Stroke Association estimates that up to 80% of strokes in people with Afib can be prevented through early detection and proper treatment. According to the AHA, stroke costs the United States an estimated $34 billion each year in healthcare costs and lost productivity and is a leading cause of serious long-term disability. The AHA estimates that ischemic strokes represent 85% of all strokes in the United States and that between 15% and 20% of the estimated 690,000 ischemic strokes are attributable to Afib.

We believe early detection of Afib is critical to optimizing patient care, delivering earlier treatment to help avoid further adverse clinical events, managing symptoms caused by Afib, and reducing the total public health burden of treating stroke. The AHA and American Stroke Association ("ASA") have published treatment guidelines for patients diagnosed with Afib to manage heart rhythm and rate and prevent stroke. These early treatments include medications such as oral anticoagulants, treatment with anti-arrhythmic drugs, and interventions such as cardiac ablation therapy to help control heart rhythm and rate.

Afib burden, the amount of time a patient spends in Afib during a monitoring period, has been identified in the clinical community as an important measure for determining appropriate and effective therapeutic interventions to manage patients with Afib and for assessing stroke risk. The calculated Afib burden is only as good as the data available for analysis during the monitoring period. Since the most common type of Afib occurs intermittently, long-term continuous patch-based monitoring, such as that performed with our Zio Systems, more accurately measures Afib burden because every heartbeat is recorded without interruption during the entire monitoring period. A study to determine the correlation between Afib burden, as measured using our Zio XT System, and the risk of stroke in patients was published in *JAMA Cardiology* in May 2018. Using this data, in combination with electronic health record ("EHR") data from 1,965 patients at two large integrated healthcare delivery systems, the researchers concluded that an increase in Afib burden is independently associated with a higher risk of ischemic stroke and arterial thromboembolism ("TE") in patients who are not taking oral anticoagulant medication. An Afib burden of 11.4% or higher was associated with more than three-fold increased risk for a stroke or TE event after adjusting for either CHA2DS2-VASc or ATRIA scores, two tools physicians use to assess stroke risk.

Ambulatory Cardiac Monitoring Overview

The ambulatory cardiac monitoring market is well-established in the United States with an estimated 6 million diagnostic tests performed annually with meaningful expansion anticipated in the coming years due to an aging population, a rising number of heart-related disorders globally, and broader acceptance of innovative medical technologies. Traditional ambulatory cardiac monitoring devices used by physicians for diagnosing patients with suspected arrhythmias – such as traditional, 24 to 48 hour Holter and cardiac event monitors – are constrained by short-term monitoring times, non-continuous data collection and reporting, cumbersome equipment, and/or lower patient compliance. For example, patients often remove traditional monitors when sleeping, showering or exercising, which can lead to a failure to capture critical data and result in incomplete diagnoses and repeat testing, which in turn can result in suboptimal patient care and higher costs to the health system.

Arrhythmia symptoms are generally monitored either in a physician's office or healthcare facility, or with the ambulatory cardiac monitoring services. Typically, physicians will administer a resting ECG test in their offices to record and analyze the electrical impulses of patients' hearts. If physicians determine that patients require monitoring for a longer wear period to generate a diagnosis, they have historically prescribed an ambulatory cardiac monitoring device such as a traditional Holter monitor, which is a non-invasive, battery powered device that typically records data continuously for 24 to 48 hours. For longer term (i.e., up to 30 days) event driven monitoring, physicians may prescribe ambulatory cardiac event monitoring services, including MCT services, which record ECG data upon auto-detection (i.e., asymptomatic events) and/or patient activation (i.e., symptomatic events) and may transmit such data wirelessly to a monitoring center like an IDTF. Physicians may also prescribe implantable loop recorders, which are implanted underneath the patient's skin in a minimally invasive, hospital-based procedure and record ECG data similar to cardiac event monitors but are intended for monitoring up to 3 years.

If the diagnosis is not definitive following the first monitoring period, physicians may prescribe a repeat traditional, 24 to 48 hour Holter monitoring test or, alternatively, event monitoring services, MCT, or implantable loop recorders. Physicians use frequency and acuity of symptoms to determine which monitoring device to prescribe. Some physicians own their own ambulatory cardiac monitoring devices and provide ambulatory monitoring services directly to their patients, while others outsource these services to third-party providers, including IDTFs.

Our Products and Services

Zio Systems and Zio Services

The Zio Systems and Services deliver a patient-friendly design that enables 98% patient compliance with minimal ECG data noise or artifact, thereby potentially delivering superior clinical accuracy to physicians diagnosing arrhythmias and reducing the cost of care for healthcare systems by avoiding costly downstream adverse events. We have developed a proprietary system that combines an FDA-cleared and CE-marked wire-free, patch-based, 14-day wearable biosensor that continuously records ECG data, with a proprietary FDA-cleared and CE-marked cloud-based data analytic platform to help physicians monitor patients and diagnose arrhythmias (collectively, the "Zio System"). We currently offer three Zio System options —the Zio XT System, the Zio AT System, and the Zio Monitor System.

Comparison of the Zio XT and Zio AT Systems

Zio XT

MONITOR TYPE
Long-term continuous monitor (up to 14 days)

ALERTS
None

DAILY REPORTS
None

FINAL REPORT
Comprehensive final XT patient report at end of prescribed wear period

Zio AT

MONITOR TYPE
Mobile cardiac telemetry monitor (up to 14 days)

ALERTS*
Included

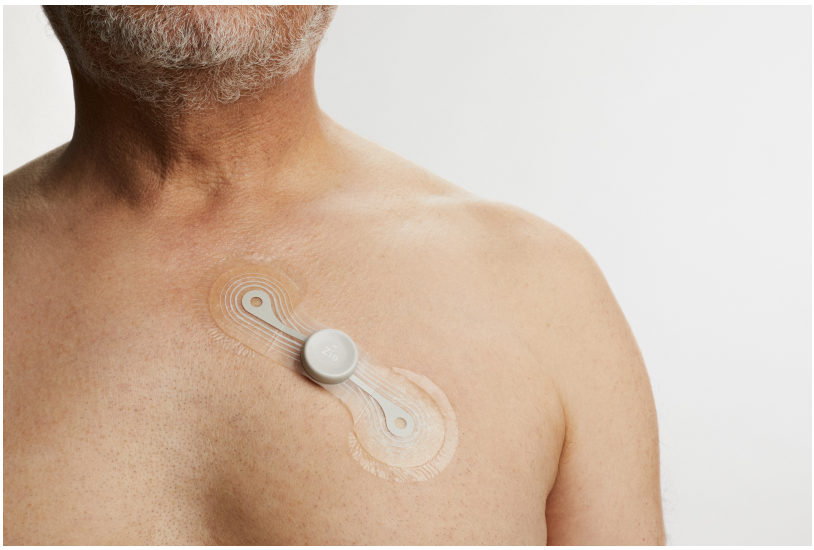
DAILY REPORTS
Yes

FINAL REPORT
Comprehensive final AT patient report at end of prescribed wear period

The Zio XT System is a prescription-only, remote ECG monitoring system that consists of a patch ECG monitor (the "Zio XT patch") that records the electric signal from the heart continuously for up to 14 days and the Zio ECG Utilization Software ("ZEUS") System, which supports the capture and analysis of ECG data recorded by the Zio XT patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS System.

Zio XT Patch

The Zio Monitor System is the next generation of the Zio XT System, and is a prescription-only, remote ECG monitoring system that consists of a patch ECG monitor (the "Zio Monitor patch") that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio Monitor patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS System. The Zio Monitor patch is 72% smaller, 55% lighter, and 20% thinner than our Zio XT patch, attributes which we believe will have a positive impact on patient experience, patient satisfaction and associated improvement in device wear times. Furthermore, the Zio Monitor patch incorporates a breathable adhesive construct, which enhances the patient experience by removing moisture otherwise captured next to the patient's skin, as well as Bluetooth communication capabilities and improved processing power.



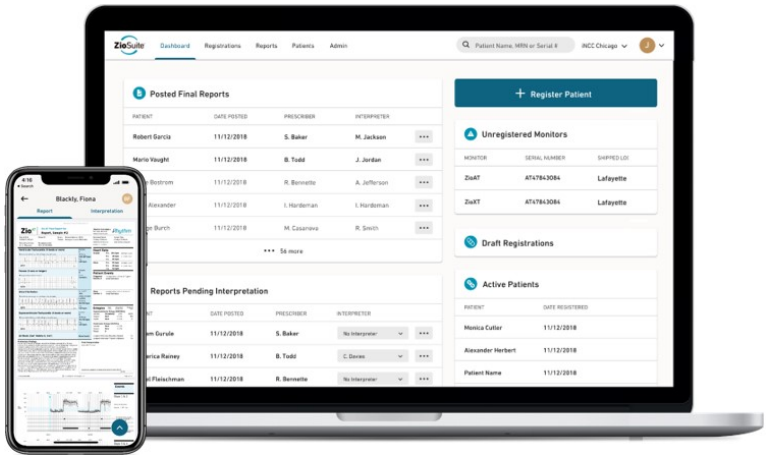
Zio Monitor Patch

The Zio AT System is a prescription-only, remote ECG monitoring system that similarly consists of a patch ECG monitor (the "Zio AT patch") that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, but which also incorporates the Zio AT wireless gateway that provides connectivity between the Zio AT patch and the ZEUS System during the patient wear period. The wireless gateway, slightly larger than a smart phone, is provided to the patient at the time of Zio AT patch application and collects and transmits data from the Zio AT patch to the cloud via a long-term evolution ("LTE") protocol.

Zio AT Patch and Wireless Gateway

We support physician and patient use of our Zio Systems through our Medicare-enrolled IDTF and certified cardiographic technicians ("CCTs"), who perform the technical monitoring services associated with a physician's order for long-term continuous monitoring or MCT monitoring services. Long-term continuous monitoring and MCT services are diagnostic medical procedures typically ordered by physicians for patients not suspected of having life-threatening arrhythmias, but who are suspected of having infrequent, difficult-to-detect, or asymptomatic arrhythmias. When physicians order long-term continuous monitoring service s with our Zio System, our technology collects an uninterrupted, long-term continuous recording of ECG data for up to 14 days and delivers a comprehensive end-of-wear report, which includes specific arrhythmia events detected by the ZEUS algorithm upon return of the Zio XT patch or Zio Monitor patch (and with the Zio AT patch, each, a "Zio patch") and analysis of the stored data by qualified technicians. A Zio patch typically collects approximately 1.5 million heartbeats of data for each patient during a single wear period of up to 14 consecutive days.

After we receive the Zio patch at our IDTF, the ECG data is uploaded to our secure cloud and preliminary findings are generated by our proprietary FDA-cleared deep learning algorithms. Each report is then validated by CCTs and sent to the patient's prescribing physician who may access the Zio report on our proprietary, cloud-based portal, referred to as the ZioSuite. Our technicians also notify physicians of potential urgent arrhythmias according to the ordering physician's specified notification criteria.



ZioSuite web portal via desktop or mobile application

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

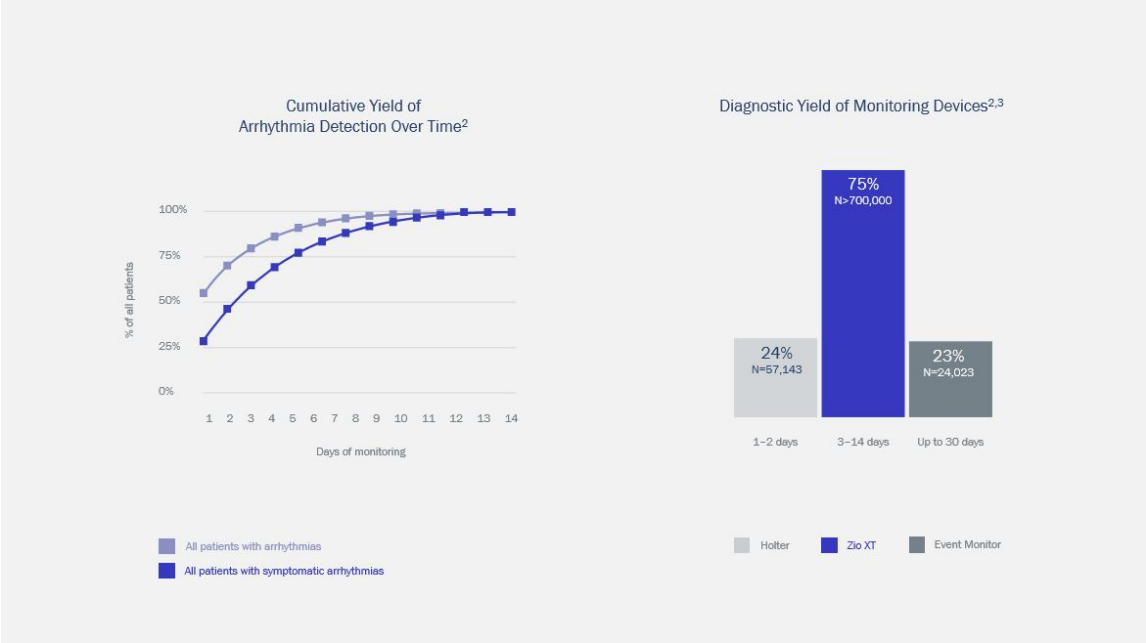
While wearing a Zio patch, patients can mark when symptoms occur by pressing a trigger button on the device and separately recording contextual data like activities and circumstances in a written symptom diary or digitally via the myZio application. This allows physicians to match symptoms and activity with ECG data. The Zio patches are not available for sale outside of use with our Zio Services. The Zio patches include the following features:

- patented clear, flexible, lightweight, wire-free design;
- unobtrusive and inconspicuous profile;
- proprietary adhesive backing designed to keep the Zio patch securely in place for the duration of the prescribed wear period;
- water-resistant functionality, allowing patients to shower, sleep, and perform normal daily activities, including moderate exercise;
- hydrogel electrodes and a compliant mechanical design to deliver a clear ECG with minimal artifact from movement;
- large symptom button, or patient trigger, that is easy to find and press;
- indicated single application wear period of up to 14 days (for longer prescribed wear periods for MCT services, additional Zio AT patches and gateways will be provided); and
- sufficient battery power for the entire wear period, without the need to recharge or replace batteries.

We believe there are strong benefits offered by our 14-day wear time, by the diagnostic yield possibly achieved through our technology, and by the clinical accuracy of our Zio report as enabled by our proprietary algorithm.

- A retrospective study by Turakhia et al, published in *The American Journal of Cardiology* in August 2013, analyzed data from 26,751 patients using the Zio XT System for the first time between January 1, 2011, and December 31, 2011. The study results showed that among the 16,142 patients with detected, clinically relevant arrhythmias, over 50% of the first-diagnosed symptomatic arrhythmias occurred after 48 hours of monitoring, suggesting that these arrhythmias could have been missed by traditional Holter monitoring during the typical maximum prescribed monitoring time. This data suggests that detection of infrequent arrhythmias requires longer monitoring times and ECG signal of consistent quality. For the Zio XT System, other published clinical literature has routinely reflected a high level of compliance with 14-day wear time and a high percentage of analyzable time (i.e., the proportion of the ECG signal recording which is free from artifact and of sufficient fidelity to enable rhythm analysis). Mean or median patient wear times for the Zio XT patch reported in the literature have ranged between 10.8 and 11.8 days, and Kaura et al. reported that the majority of 56 subjects randomized to the Zio XT System achieved the full 14-day wear time. Publications which include assessment of percentage analyzable time report rates between 94% and 99.6% (i.e., mean or median percent analyzable data across all subjects).
- In a recent study published in the *American Journal of Cardiology* in 2022, Gupta et al. compared diagnostic yield, outcomes, and resource utilization by arrhythmia monitoring strategy in 330 matched adults (mean age 64 years, 40% women, and 30% non-White) without previously documented Afib or atrial flutter who received remote ECG monitoring by the 14-day Zio XT System, 24-hour Holter, or 30-day event monitor (external loop recorder). Afib or atrial flutter was identified in 6% of patients undergoing screening with the Zio XT System, as compared to none (0%) detected by Holter monitoring ($p = 0.04$), and 3% detected by an event monitor ($p = 0.07$). Non-sustained ventricular tachycardia was noted in 24% of patients wearing the Zio XT patch, versus 8% detected by Holter ($p < 0.001$), and 4% via event monitor ($p<0.001$).

- Our Zio Services utilize advanced FDA-cleared artificial intelligence with the only deep-learned algorithm. As published in *Nature Medicine* in 2019, Hannun et al. used data from the Zio XT Service to develop a deep-neural network capable of diagnosing arrhythmias at a high diagnostic performance similar to that of expert cardiologists. The deep-neural network model met or exceeded the performance of cardiologists for 12 types of arrhythmia classes and recapitulated the misclassifications made by cardiologists. In clinical settings, this approach could reduce the amount of misdiagnosed computerized ECG interpretations and improve the efficiency of expert human ECG interpretation by accurately triaging or prioritizing the most urgent conditions.



Long-term, continuous monitoring maximizes diagnostic yield[2,3]

[2] Turakhia, M. et al. Diagnostic Utility of a Novel Leadless Arrhythmia Monitoring Device. The American Journal of Cardiology, 2013.
[3] Tsang, J.P. et al. Benefits of monitoring patients with mobile cardiac telemetry (MCT) compared with the Event or Holter monitors. Medical Devices: Evidence and Research, 2014.

Zio Watch

In early 2020, Verily (see "Collaboration with Verily" below) received FDA clearance for the Verily Study Watch wearable device for use in detecting irregular pulses that may indicate a cardiovascular issue. At the time, Verily shared that they had partnered with us to create clinical solutions that could improve cardiovascular care. By 2022, that partnership evolved into the Zio® Watch (Study Watch with Irregular Pulse Monitor) with our clinically integrated ZEUS System, a new health solution that is intended to be integrated into clinical care delivery and to assist healthcare providers in identifying and monitoring Afib. In July 2022, we received FDA clearance on the clinically integrated ZEUS System, and we currently plan to initiate a market evaluation of the Zio Watch with the clinically integrated ZEUS System in 2023.

Our Strategy

Our mission is to boldly innovate to create trusted solutions that detect, predict, and prevent disease. The key elements of our strategy include:

- ***Further penetrating and expanding the U.S. ambulatory cardiac monitoring market.*** Our goal is to be the leading provider of ambulatory cardiac monitoring for patients at risk for arrhythmias. We intend to expand our market penetration by targeting the large existing ambulatory cardiac monitoring market in the United States and driving broader awareness of its advantages. We plan to leverage our portfolio of products, including the Zio XT System and Zio AT System, and position the Zio Service as providing certainty in a single test due to high patient compliance and superior quality of uninterrupted data. Zio XT System, which provides continuous long-term ECG monitoring, is appropriate for the majority of patients that require ambulatory cardiac monitoring while Zio AT System, which includes near real-time monitoring, is appropriate for more acute patients that require timely notification. We estimate our current market penetration in the United States to be approximately 25%.

  Marketing and education throughout the medical community are key to bringing awareness and communicating the strong clinical evidence backing the Zio Service. In addition, we expect to continue developing and publishing clinical evidence to demonstrate the potential advantages of the Zio Service relative to legacy and competitive monitoring technologies. Also, within existing accounts, we expect to continue to introduce our Zio Service beyond cardiology and electrophysiology into other departments, including neurology, emergency rooms and primary care offices. To enable this broader adoption within a hospital system, we have successfully interfaced the Zio ordering and report posting processes into a number of large health systems' EHR systems. This seamless integration of Zio workflow processes has proven to be a key factor in spurring growth within existing and new accounts and is an important part of our ongoing market penetration strategy.

  We believe there is potential to increase the core symptomatic total addressable market by moving further upstream in the care pathway to the primary care physician call point. We estimate that 14 million patients in the United States visit a primary care physician annually with palpitations due to suspected cardiac disease. By educating primary care physicians on the benefits of the Zio Service for this patient population, we believe we can expand the market and reach more patients that are candidates for ambulatory cardiac monitoring.

- ***Pursuing international expansion opportunities.*** While our initial commercial focus is the U.S. market, we have initiated efforts that will allow for future expansion into international geographies. We have a presence in the United Kingdom with efforts underway to pursue national reimbursement. In September 2020, we were named a winner of the Artificial Intelligence in Health and Care Award run by the Accelerated Access Collaborate as part of the National Health Service ("NHS") AI Lab. This funding will bring the Zio Service to selected NHS sites over a three-year program measuring clinical, pathway and economic outcomes. We also received positive guidance from the National Institute for Health and Care Excellence ("NICE") in December 2020 for the adoption of the Zio XT Service which may facilitate future support of the Zio Service through the MedTech Funding Mandate. We are also conducting diligence and prioritizing other geographies based on market size, regulatory pathway, and reimbursement opportunity. We are initiating market development and market access initiatives in multiple European countries in 2023 and pursuing regulatory clearance in Japan. We estimate the total addressable market in our initial selected countries of the United Kingdom, Japan, and prioritized European countries to be at least 5 million existing ambulatory monitoring tests annually.

- ***Expanding into adjacent market opportunities***. We intend to continue assessing the potential pathways for expanding indications and clinical use cases for our Zio Services and developing new systems for patient populations with unmet needs. Leading with clinical and economical evidence, we are pursuing commercialization opportunities for our Know Your Rhythm by Zio program that is focused on patients at risk for undiagnosed arrhythmias. With at least 12 million individuals in the United States estimated to be at risk for undiagnosed and/or asymptomatic cardiac arrhythmias, we believe this is a significant market opportunity. Initial efforts to proactively monitor this population with Zio XT System, including end-to-end care pathway pilots, are planned for 2023.

  In addition, we are actively exploring opportunities in adjacent markets beyond cardiac monitoring. We have research and development efforts focused on exploring the use of our Zio Services and new systems and services for the following patient populations:

- Sleep apnea patients, with an estimated prevalence of over 40 million in the United States. Up to 80% of patients with Afib may also have sleep apnea, and there is a large prevalence of patients with undiagnosed sleep apnea.
- Heart failure patients, with an estimated prevalence of over 8 million in the United States. Afib is a cause of heart failure and 25% of heart failure patients have Afib.
- Patients with hypertension, with an estimated prevalence of over 140 million in the United States. Up to 90% of patients with Afib may also have hypertension.

- ***Advancing our system portfolio and core technology offering.*** We continue to invest in building a unique, innovative system portfolio and digital platform that addresses unmet needs in the ambulatory cardiac monitoring market and adjacent markets. We will continue to invest in research and development efforts to further differentiate our biosensor, data analytics and reporting, information system and digital platform. In 2021 and 2022, we received FDA clearance for our third-generation biosensor, the Zio Monitor, next generation Zio XT System, second-generation deep-learned ECG detection algorithm and the Zio Watch. During 2023, we plan to obtain CE mark for the Zio Monitor System.

Sales and Marketing

We directly market our Zio Services in the United States to healthcare professional through our internal organization comprised of sales representatives, field billing specialists, and customer experience representatives. Our sales team focuses on initial introduction of the Zio Services to those participants that are instrumental to the decision-making process for ambulatory cardiac monitoring, which include physician practices and healthcare systems. We also focus on continuing efforts to ensure healthcare professionals are knowledgeable about the clinical benefits and economic value of the Zio Services. We continue to invest in our sales force and focus on ensuring we optimize the structure of our U.S. sales organization to expand the current customer account base and support adoption of the Zio Services.

We market our Zio Services to a variety of physician specialties including general cardiologists, electrophysiologists, neurologists, primary care physicians, and other physician specialists who diagnose and manage care for patients with arrhythmias. We have found success focusing on integrated delivery networks (“IDNs”), in which large networks of facilities and providers work together to offer a continuum of care to a specific geographic area or market. Focusing on sales to IDNs gives us the opportunity to conduct a holistic sale for health systems interested in making value-based purchasing decisions.

In January 2021, we established a small direct sales and clinical infrastructure in Bagshot, Surrey in England to service the UK market. We have since focused efforts on the introduction of the Zio Services using the Zio XT System into new accounts and market access efforts, in particular through orders made by NHS Trusts and Hospitals. In addition, we are exploring sales opportunities and market access in Japan, Switzerland, the Netherlands, and Spain.

We typically experience reduced revenue during the third quarter, as well as during the year-end holiday season. We believe this is the result of physicians and patients taking vacations and patients electing to delay our monitoring services during the summer months or holidays.

Opportunities in Monitoring of Asymptomatic Afib Patients

Currently, the Zio Services are generally ordered by physicians for patients that are experiencing symptoms, with limited application for the estimated one-third of the patient population experiencing silent Afib. We see a future opportunity in supporting physicians in the proactive assessment of the approximately twelve million patients who are at high risk of asymptomatic Afib to identify those with the illness. To that end, iRhythm has established the “Know Your Rhythm” program with the goal of increasing Afib screening in the undiagnosed or asymptomatic population. We are partnering with payors and providers to offer the Know Your Rhythm program with the Zio XT System to Medicare Advantage beneficiaries and other patients that meet specified criteria. We intend to initiate commercial pilots and gather additional data in 2023 for the Know Your Rhythm program to demonstrate that these screenings can reduce healthcare costs over time.

We believe this opportunity is clinically appropriate and economically supported, as informed by our interpretation of several key studies:

- **SCREEN-AF**: Home-based Screening for Early Detection of Atrial Fibrillation ("SCREEN-AF"), a study examining early detection of Afib using the Zio XT System in high-risk patients, was published in the *Journal of the American Medical Association* ("JAMA") in February 2021. This randomized control trial recruited 856 participants 75 years or older with hypertension and no known Afib from 48 primary care clinics across Canada and Germany between 2015 and 2019. The intervention group included remote screening for Afib for two weeks with the Zio Service utilized at baseline and again at three months, in addition to standard care for six months. The results showed Afib was newly diagnosed in the screening group in 5.3% of subjects at six months compared to 0.5% in the standard of care control group. A secondary outcome showed oral anticoagulant therapy was prescribed for 75% of participants who had screen-detected Afib. We believe that proactive screening and monitoring using the Zio Services could increase Afib detection 10-fold over standard of care, potentially prompting oral anticoagulant use.

- **mSToPs**: The mHealth Screening to Prevent Strokes ("mSToPS") study, led by researchers at the Scripps Research Translational Institute in collaboration with Aetna Inc., Healthagen LLC, Janssen Research and Development, LLC, and Johnson & Johnson, utilized a web-based platform to remotely recruit 5,214 eligible patients from the Aetna Commercial Fully Insured and Medicare Advantage programs. Women over the age of 65 and men over 55 with certain risk factors were selected to participate based on information derived from claims data that placed them at a potentially increased risk of undiagnosed asymptomatic Afib. Three peer-reviewed articles were published on the mSToPS study between 2018 and 2021. The study design was published in the *JAMA* in July 2018. The one-year results were published in *Heart Rhythm O2* in December 2020. The results showed that at one year, Afib was newly diagnosed in 6.6% of patients who were actively monitored by the Zio Service versus 2.4% in the observational control group receiving routine care. In addition to this primary endpoint to evaluate the difference in new Afib diagnoses, active monitoring in an asymptomatic, moderate-risk population with the Zio Service was associated with an increase in cardiology outpatient visits but also significantly lower rates of emergency department visits and hospitalizations over the one year following monitoring.

We also hope that additional informative data will be generated in the GUARD-AF study.

In November 2019, we announced our participation in the "ReducinG stroke by screening for UndiAgnosed atRial fibrillation in elderly inDividuals" ("GUARD-AF") study, a randomized, controlled study sponsored by the Bristol-Myers Squibb-Pfizer Alliance. This ongoing study seeks to determine if earlier detection of Afib through screening in previously undiagnosed men and women ultimately impacts the rate of stroke compared to usual standard medical care. The GUARD-AF study population includes men and women at least 70 years of age visiting their primary care physician for usual follow-up care, and the screening arm utilizes the Zio XT Service. Though trial enrollment was limited to 11,931 participants due to the impact on COVID-19 pandemic on enrollment, GUARD-AF is the largest randomized trial in Afib screening to use a long-term continuous patch ECG monitor. The primary outcome measures will be stroke and bleeding events leading to hospitalization. The trial is designed to identify outcome events using insurance claims from a healthcare claims database, which is subject to certain limitations, and is expected to provide evidence on health outcomes associated with Afib detection intervention that may help inform future clinical practice guidelines.

Initial findings from the 5,713 patients who wore the Zio XT monitor in the GUARD-AF study were presented at The American College of Cardiology's 71st Annual Scientific Session & Expo in April 2022 and the trial's design and rationale were published by Singer et al. in the *American Heart Journal* in July 2022. Initial findings demonstrated that in the older primary care population, 0.5% of screened participants had persistent AFib and 4% had paroxysmal Afib (PAF) detected within two weeks of monitoring. In those with PAF, the average AFib burden was low but more than 25% had an episode of ≥4.6 hours of continuous AFib, suggesting increased stroke risk. In addition to the primary outcome measures, the study is designed to generate important information to inform clinical decisions regarding the need for stroke-preventive interventions – including anticoagulants – for screen-detected PAF.

Third-Party Reimbursement

We receive revenue for the Zio Services primarily from third-party payors, which include commercial payors and government agencies, such as the Centers for Medicare & Medicaid Services ("CMS"). Third-party payors require us to identify the service for which we are seeking reimbursement by using a Current Procedural Terminology ("CPT") code set maintained by the AMA. These CPT codes are subject to periodic change and update, which will impact the reimbursement rates for our Zio Services. See "Risk Factors—If reimbursement or other payment for our Zio Services is reduced or modified in the United States, including through cost containment measures or changes to policies with respect to pricing, our business could suffer" for additional information.

For the year ended December 31, 2022, we received 86% of our revenue through third-party payors and approximately 25% of our total revenue from the Medicare program. As we continue to contract with more commercial payors and the patient population ages into eligibility for the Medicare program, we believe more of our revenue will convert to third-party payor billing.

Our clinical centers are enrolled in the Medicare program as IDTFs, which allows us to bill CMS directly for our Zio Services. To maintain enrollment, we must meet the CMS IDTF supplier standards, including having an independent medical director for oversight and qualified technicians who support the analysis of ECG data captured by the Zio patches as part of our Zio Services.

Competition

The market for remote cardiac monitoring is competitive, characterized by rapid change resulting from technological advances, scientific discoveries, and other market activities of industry participants.

In providing our Zio Services, we compete with BioTelemetry, Inc. (acquired by Royal Philips), Preventice Solutions, Inc. (acquired by Boston Scientific, Inc.), and Bardy Diagnostics, Inc. (acquired by Baxter International, Inc.) to offer remote cardiac monitoring technology and also function as diagnostic service providers. We also compete with companies that sell traditional, 24 to 48 hour Holter monitors, including GE Healthcare, Philips Healthcare, Mortara Instrument, Inc., Spacelabs Healthcare Inc. and Welch Allyn Holdings, Inc. (acquired by Baxter International, Inc.).

In the past three years, there has been an increase in acquisition activity and consolidation in our industry. Many of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we do. Furthermore, many of our competitors have well-established brands, widespread distribution channels, broader product offerings and an established customer base.

These competitors have also developed patch-based cardiac monitors that have received FDA and foreign regulatory clearances. We are also aware of some small start-up companies entering the patch-based cardiac monitoring market. Large medical device companies may continue to acquire or form alliances with these smaller companies in order to diversify their product offering and participate in the digital health space. These competitors and potential competitors may introduce new products and services that more directly compete with our Zio Services and Zio Systems.

Future competition could come from manufacturers of wearable fitness products or large information technology companies focused on general health and wellness. For example, in 2022, Apple Inc. and Fitbit added capabilities on its watch platform to measure non-continuous ECG and to alert users to the potential presence of irregular, not clinical grade, heartbeats suggestive of asymptomatic Afib, which were cleared by the FDA for such use in June 2022.

We believe the principal competitive factors in our market include:

- ease of use, comfort, and unobtrusiveness of the device for the patient;
- quality and clinical validation of the deep-learned algorithms used to detect arrhythmias;
- concise and comprehensive reports supporting efficient physician interpretation;
- ease of use of service workflow for physicians and supporting clinicians;
- digital tools for data management including the myZio mobile app, website tools and EHR integration;
- contracted rates with third-party payors;

- government reimbursement rates associated with our Zio Services and supporting Zio Systems;
- quality of clinical data and publications in peer-reviewed journals;
- size, experience, knowledge, and training of sales and marketing teams;
- availability and reliability of sales representatives and customer support services;
- workflow protocols for solution implementation in existing care pathways;
- reputation of existing device manufacturers and diagnostic service providers; and
- relationships with physicians, hospitals, administrators, and other third-party payors.

Manufacturing and Quality Assurance

We currently manufacture our Zio Systems, including the Zio XT System, Zio Monitor System and Zio AT System, in our leased facility in Cypress, California. This manufacturing facility is approximately 34,000 square feet and provides space for our manufacturing and production operations, including inspection, assembly, testing, packaging, labeling, storage, and shipping. We believe this manufacturing facility has capacity to meet our manufacturing needs for at least the next five years.

Outside suppliers are the source for components and sub-assemblies in the production of the Zio Systems. Any significant supplier of a critical component, such as the circuit boards for the Zio Systems provided by contract electronic manufacturers, is managed through our manufacturing team that is focused on reducing supply chain risk. These suppliers are evaluated, approved, and monitored by our quality team to ensure conformity with the specifications, policies, and procedures applicable to our devices.

Our manufacturing operations are subject to regulatory requirements of the FDA's Quality System Regulation ("QSR") for medical devices authorized for manufacturing and sale in the United States (set forth under 21 CFR Part 820), the Medical Devices Directive 93/42/EEC ("MDD") and the Medical Devices Regulation 2017/745 of the European Parliament and of the Council ("EU MDR"), which is required for doing business in the European Union ("EU"), and the UK Medical Device Regulations 2002 (as amended) ("UK MDR"). We are also subject to applicable requirements relating to the environment, waste management, and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal, sale, labeling, collection, recycling, treatment, and remediation of hazardous substances. See "Regulation" below for further information.

We purchase certain components and materials used in manufacturing from single sources due to quality considerations, costs, or constraints resulting from regulatory or other requirements. As of December 31, 2022, those single sources include suppliers of application-specific integrated circuits used in our transmitters, seals used for the applicators, and certain polymers used to synthesize polymeric membranes for our sensors.

Our manufacturing facilities are also ISO certified (EN ISO 13485:2016). We have registered our device establishments with FDA and with the UK's Medicines & Healthcare products Regulatory Agency ("MHRA").

Research and Development

We focus our research and development efforts on improvement of the Zio System, the clinically-integrated version of ZEUS for the Zio Watch, and efforts to support international expansion. We employ engineering and research and development staff to focus on delivering future innovations and sustaining improvements. Our research and development activities are focused on:

- ***Continuous improvement and extensions to existing products and services.*** We are continuously working to improve the Zio Services to increase patient comfort, product quality, operational scalability, and security.
- ***International expansion.*** We are working on building our infrastructure and ensuring global compliance as we identify appropriate opportunities for international growth.

- ***Advancing our technology offering.*** Our product portfolio includes patch-based solutions (utilized in the Zio XT System, Zio AT System, and Zio Monitor System) and the recently FDA-cleared Zio Watch that combine continuous monitoring for extended periods with accelerated notification of significant events through mobile transmission capabilities.

- ***Customer workflow optimization.*** We have initiatives that aim to increase customer productivity by optimizing workflow through easier patient enrollment, report access, and interpretation, in addition to integrating the reports from our Zio Services directly into EHRs.

- ***Data analytics.*** We are focused on improving and enhancing our back-end, deep-learning analytic platform, building on our core competency in data analytics.

- ***Developing clinical evidence.*** We frequently provide support to third parties conducting clinical studies that further support the benefits of the Zio System and we intend to support clinical research in hypertension, sleep, and the market evaluation of the Zio Watch.

- ***Continuing to solidify our footprint in digital healthcare.*** Using our repository of ambulatory ECG patient data, we will continue to look for ways to create value-driving opportunities in digital healthcare, such as expansion of indications for the Zio System, new therapeutic discoveries, development of an analytical engine for ambulatory consumers, other medical data and payor and provider decision support, and the potential for more complete system integration with large health systems.

We have supported clinical studies conducted by leading physicians and clinicians to explore and develop new techniques and applications for our Zio Systems, the clinically-integrated version of ZEUS for the Zio Watch, and other clinical and research activities, including healthcare economic outcomes research ("HEOR").

Our research and development activities consist of software development, algorithm and product development, regulatory affairs, and clinical research. Our research and development expense was $46.6 million, $38.7 million, and $41.3 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Intellectual Property

To establish and protect our proprietary and other intellectual property rights, we rely on a combination of trademark, copyright, patent, trade secret, and other intellectual property laws, and employment, non-disclosure and invention assignment agreements, and other protective contractual provisions with our employees, contractors, consultants, suppliers, partners, outside scientific collaborators, and advisors, and other third parties. In addition, we have entered into licenses in the ordinary course of business relating to a wide array of technologies or other intellectual property rights or assets.

We hold patents and pending patent applications in the United States and other parts of the world which, in aggregate, we believe to be of importance in the operation of our business. As of December 31, 2022, we owned, or retained an exclusive license to, thirty-six issued patents from the U.S. Patent Office ("USPTO"), ten issued patents from the Japanese Patent Office, three issued patents from the Australian Patent Office, four issued patents from the Canadian Patent Office, six issued patents from the European Patent Offices, four issued patents from the Korean Patent Office, and one issued patent from the Chinese Patent Office. Our U.S. issued patents as of December 31, 2022 are set to expire over a range of years, from November 2028 to August 2041, subject to any extensions. As of December 31, 2022, we had thirty-one pending patent applications globally, including eleven in the United States, four in the European Patent Office, four in Japan, three Patent Cooperation Treaty ("PCT") international applications, two in each of Australia, Korea, China, and India, and one in Canada.

Our patents and patent applications seek to protect aspects of our core technologies and our product concepts for ambulatory cardiac monitoring. We believe that our patent position provides us with sufficient rights to protect our current and proposed commercial products and services. However, our patent applications may not result in issued patents, and any patents that have been issued or might be issued may not protect our intellectual property rights. We also rely on trade secrets, technical know-how, and continuing innovation to develop and maintain our competitive position.

As of December 31, 2022, our trademark portfolio contained U.S. trademark registrations for the marks MyZIO, ZIO, ZIO SUITE, ZIO AT and IRHYTHM and pending U.S. trademark applications for the marks KNOW YOUR RHYTHM BY ZIO, KNOW YOUR RHYTHM, ZIO and ZIO MCT. It also contained registered trademarks for the mark IRHYTHM in Australia, the European Union, Austria, Canada, China, Denmark, Finland, France, Germany, Japan, Italy, Norway, Sweden, Switzerland, and the United Kingdom. It further contained trademark registrations for the mark ZIO in Australia, Canada, China, the European Union, Japan, Norway, and Switzerland. It also contained trademark registrations for the mark MYZIO in Canada, the United Kingdom, and the European Union, trademark registrations for the mark ZIO MCT in the United Kingdom and the European Union, and trademark registrations for the mark ZIOSUITE in the United Kingdom and the European Union.

Collaboration with Verily

On September 3, 2019, we entered into a Development Collaboration Agreement with Verily Life Sciences LLC, an Alphabet Company ("VLS") and Verity Ireland Limited ("VIL," and together with VLS, "Verily") (such Development Collaboration Agreement, as amended by Amendment No.1 dated April 26, 2021 and Amendment No.2 dated January 24, 2022, the "Development Agreement"). The Development Agreement involves collaboration development and production of intellectual property between us and Verily. Each party has primary responsibility for certain aspects of development and approval, with all processes to be performed at each respective party's own cost.

The parties agreed to develop certain next-generation Afib screening, detection, or monitoring products pursuant to the Development Agreement, which products will involve combining Verily's and our technology platforms and capabilities. Under the terms of the Development Agreement, we paid Verily an upfront fee of $5.0 million in 2019. In addition, we agreed to make additional cash payments to Verily up to an aggregate of $12.75 million in milestone payments upon achievement of various development and regulatory milestones over the term of the Development Agreement. We have achieved milestones tied to payments totaling $11.0 million to date and expect to make additional payments over the term of the Development Agreement of $1.75 million, subject to the achievement of certain development and regulatory milestones including receipt of certain units of the Zio Watch and related support in connection with the our anticipated market evaluation, which we currently plan to initiate in 2023.

The Development Agreement provides each party with licenses to use certain intellectual property of the other party for development activities in the field of Afib screening, detection, or monitoring, together with perpetual non-exclusive licenses to certain shared know-how (which licenses shared know-how excludes certain technology or intellectual property, such as patent rights). Ownership of developed intellectual property is allocated to us or Verily depending on the subject matter of the underlying developed intellectual property, and, for certain subject matter, is jointly owned.

Regulation

Based on the nature of the services we provide, the medical devices used to deliver our services, and the ways in which payment is available for our services, we are subject to a complex spectrum of intersecting laws and regulatory frameworks.

Our facilities in Illinois, California, and Texas are enrolled in the Medicare program as IDTFs, defined by CMS as entities independent of a hospital or physician's office in which diagnostic tests are performed by licensed or certified non-physician personnel under appropriate physician supervision. CMS has set certain performance standards that every IDTF must meet in order to obtain or maintain its billing privileges.

We are also regulated as a medical device manufacturer because of our role in the design, development, and manufacturing of the Zio Systems used in our Zio Services.

The United States has historically been the primary focus of the delivery of our services, but based on our operations we are subject to a range of laws and regulations outside the United States, and we expect the complexity of the global regulatory landscape to which we are subject to continue to increase.

U.S. Fraud and Abuse Laws and Other Healthcare Compliance Requirements

Medicare is a federal healthcare program administered by CMS that is available to individuals age 65 or over, and certain other individuals. The Medicare program provides, among other things, healthcare benefits that cover most medically necessary care for such individuals, subject to certain deductibles and copayments. CMS has established guidelines for the coverage and reimbursement of certain products, supplies, and services, including ambulatory cardiac monitoring services. In general, Medicare will only reimburse ambulatory cardiac monitoring services, such as our Zio Services, that are reasonable and necessary for the diagnosis or treatment of patient. CMS also administers the Medicaid program, a cooperative federal/state program that provides medical assistance benefits to qualifying low income and medically needy persons. State participation in Medicaid is optional, and each state is given discretion in developing and administering its own Medicaid program, subject to certain federal requirements. All CMS programs are subject to statutory and regulatory changes, retroactive and prospective rate adjustments, administrative rulings, interpretations of policy, intermediary determinations, and government funding restrictions, all of which may materially increase or decrease the rate of program payments to healthcare facilities and other healthcare providers, including those paid for our Zio Services.

Because of the significant federal funding involved, the government actively enforces a number of laws and regulations to eliminate fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws. The most significant of these laws for our business include the federal Anti-Kickback Statute and the federal False Claims Act.

Anti-Kickback Laws

Under the federal Anti-Kickback Statute (the "AKS"), it is a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for purchasing, ordering, or recommending, or arranging for, the purchase or order of items or services (or referrals of the same) reimbursable by a federal healthcare program. The AKS imposes criminal liability for both the party that provides or offers such remuneration and the party that receives or solicits such remuneration. Courts and enforcement agencies interpret the AKS broadly, such that it may be implicated whenever anything of value is provided to a party in a position to generate federal healthcare program business where any one purpose of an arrangement involving remuneration is to induce referrals. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment, and possible exclusion from Medicare, Medicaid, and other federal healthcare programs. Many states have adopted laws similar to the AKS. Some of these state prohibitions apply to referral of recipients for healthcare products or services reimbursed by any source, not only CMS programs. The Physician Payment Sunshine Act requires transparency around certain transfers of value and ownership interests that may raise parallel scrutiny of the appropriateness of financial relationships. Notably, some kickback allegations are also interpreted as violations of the federal False Claims Act ("FCA").

False Claims Act

The federal civil FCA prohibits: (i) knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval and (ii) knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim. Importantly, the FCA provides for "whistleblower" or qui tam actions, which allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the FCA and to share in any monetary recovery. The federal government has used the FCA to assert liability on the basis of inadequate care, kickbacks, and other improper referrals, and improper use of CMS billing numbers, as well as allegations of off-label promotion of products, and activities relating to the reporting of discount and rebate information. The FCA is the federal government's preferred enforcement vehicle for addressing a variety of alleged misconduct and provides for treble damages and civil money penalties ranging from $12,537 to approximately $25,076 per claim, as well as exclusion from participation in federal healthcare programs and potential criminal penalties, including imprisonment and criminal fines. Additionally, as part of any settlement, the government will often require the entity to enter into a corporate integrity agreement, which imposes certain ongoing compliance, certification, and reporting obligations. In addition, various states have enacted false claims laws analogous to the FCA, and many of these state laws apply where a claim is submitted to any third-party payor and not only a federal healthcare program.

Healthcare Reform

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. The Affordable Care Act ("ACA") substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. Any changes to, or repeal of, the ACA may have a material adverse effect on our results of operations.

Additionally, for out-of-network or cash pay patients, we may be subject to state and federal surprise billing laws that impose limits on amounts that can be charged to such patients and/or the amount we can receive for out-of-network services from commercial payors. One such law, the federal No Surprises Act, requires covered providers to provide "good faith estimates" to patients and establishes a detailed and potentially costly independent dispute resolution process governing fee disputes with those patients. These laws and regulations may change, and additional implementation regulations are expected for the No Surprises Act, and we anticipate these requirements may apply to our business in the future.

We are subject to risks related to the U.S. fraud and abuse laws and other healthcare compliance requirements described above, as well as others that are or may be adopted in future. For further details on these risks, see "Risk Factors," below.

U.S. Food and Drug Administration

Because we develop and manufacture the medical device technology used in the Zio Services (the hardware and software elements that FDA regulates as "devices"), we are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and its implementing regulations, as well as other federal and state regulatory bodies in the United States. The laws and regulations govern, among other things, product design and development, preclinical and clinical testing, manufacturing, packaging, labeling, storage, recordkeeping and reporting, clearance or approval, marketing, distribution, promotion, import and export, and post-marketing surveillance and associated regulatory reporting.

Most Class II devices, including the Zio patches and the ZEUS System, require 510(k) clearance from the FDA in order to be marketed in the United States. A 510(k) submission must demonstrate that the device is substantially equivalent to a device legally in commercial distribution in the United States. After clearance, changes made to devices must be evaluated on an ongoing basis, and may trigger the need for additional 510(k) clearances or – depending on the nature of the change – might require a higher level of FDA review (through the de novo premarket approval ("PMA") process). To date, our product changes have been managed within the 510(k) framework and we have not been required to provide clinical data to support these 510(k) submissions and clearances.

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- the FDA's QSR, which requires manufacturers, including their suppliers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the product lifecycle, including the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses, including parameters around manufacturer communications with payors and healthcare professionals;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device recalls, which require that manufacturers report to the FDA any recall of a medical device, provided the recall was initiated to either reduce a risk to health posed by the device, or to remedy a violation of the FD&C Act caused by the device that may present a risk to health; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

After a device receives 510(k) clearance or PMA approval, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, performance, or functionality may require a new clearance or approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with the determination not to seek a new 510(k) clearance or PMA approval, the FDA may retroactively require a new 510(k) clearance or PMA approval. The FDA could also require a manufacturer to cease marketing and distribution and/or recall the modified device until 510(k) clearance or PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines, penalties, and other enforcement actions, such as warning letters.

We have registered appropriate facilities with the FDA as a medical device specification developer, manufacturer, or designated complaint handling unit. We have also obtained a manufacturing license from the California Department of Public Health ("CDPH"). The FDA and CDPH have broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees, and civil penalties;
- repair, replacement, refunds, recall, or seizure of our products;
- operating restrictions, partial suspension, or total shutdown of production;
- refusing our requests for 510(k) clearance or PMA approval of new products, new intended uses, or modifications to existing products;
- withdrawing 510(k) clearance or PMA approvals that have already been granted; and
- criminal prosecution.

Privacy and Security Regulation

Our business is subject to foreign, federal, and state privacy and security laws concerning the collection, use, analysis, retention, storage, protection, transfer, disclosure, and/or disposal of individually identifiable information including, without limitation, the General Data Protection Regulation ("GDPR"), the Health Insurance Portability and Accountability Act of 1996, as amended by the final regulations promulgated pursuant to the Health Information Technology for Economic and Clinical Health Act ("HITECH"), found in the American Recovery and Reinvestment Act of 2009 (collectively, "HIPAA"), the Telephone Consumer Protection Act, the CAN-SPAM Act, and state privacy, consumer protection, and breach notification laws.

We are subject to risks related to privacy and security regulation. For further details on these risks, see "Risk Factors," below.

European Union and United Kingdom

The Zio XT patch is currently regulated in the European Union as a Class IIa medical device pursuant to the MDD. The MDD sets out the basic regulatory framework for medical devices in the European Union. In May 2021, the EU MDR, a more comprehensive regulatory framework, replaced the MDD.

The system of regulating medical devices operates by way of a certification for each medical device. Each certified device is marked with the CE mark which shows that the device has a certificate of conformance under the MDD or EU MDR. There are national bodies known as Competent Authorities (the "Competent Authorities") in each member state which oversee the implementation of the MDD and EU MDR within their jurisdiction. The means for achieving the requirements for the CE mark vary according to the nature of the device. Devices are classified in accordance with their perceived risks, similarly to the U.S. system. The class of a product determines the conformity assessment required before the CE mark can be placed on a product. Conformity assessments for our products are carried out as required by Notified Bodies. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a CE mark, the device can be sold throughout the European Union without further conformance tests being required in other member states. The CE mark is contingent upon continued compliance with the applicable regulations and the quality system requirements of the ISO 13485 standard. Our current CE mark for the Zio XT System is issued by the National Standards Authority of Ireland under the MDD. We are currently pursuing a CE mark under the new EU MDR with the British Standards Institution ("BSI").

Due to United Kingdom's departure from the European Union, the MHRA has issued new requirements associated with the UK Conformity Assessed ("UKCA") mark. The UKCA marking is a new UK product marking that is used for goods being placed on the market in Great Britain. It covers most goods which previously required the CE marking, including medical devices. The UKCA requirement became effective on January 1, 2021. However, to allow businesses time to adjust to the new requirements, we will still be able to use the CE marking in the United Kingdom until 2024. We are currently pursuing a UKCA mark with the BSI. We are registered with the UK's Care Quality Commission ("CQC") to carry out diagnostic and screening procedures.

Additionally, the EU Notified Body and UK Approved Body regularly audit our manufacturing, design and operational facilities to ensure ongoing ISO 13485 and EU MDR compliance and periodically audit technical design files in accordance with the EU MDR in order to maintain our CE mark or issue a CE mark or UKCA mark for new or updated devices.

Anti-Bribery and Anti-Corruption Laws

The U.S. Foreign Corrupt Practices Act ("FCPA") and similar laws in foreign jurisdictions generally prohibit any U.S. corporations and their representatives from offering, promising, authorizing, or making payments, gifts, or transfers of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to obtain or retain business. The scope of the FCPA includes interactions with certain healthcare professionals and hospital administrators in many countries.

In addition, in Europe, various countries have adopted anti-bribery laws providing for severe consequences in the form of criminal penalties and significant fines for individuals or companies committing a bribery offense. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the U.K. Bribery Act 2010, a bribery occurs when a person offers, gives, or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the U.K. Bribery Act 2010. An individual found in violation of the U.K. Bribery Act 2010, faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

Environmental, Social and Governance Matters

At iRhythm, we believe that effectively managing environmental, social, and corporate governance ("ESG") risks and opportunities drives business success, and that when fully integrated into the business, ESG can provide a competitive advantage. In 2022, we further developed our approach to ESG by conducting an ESG Priority Assessment to identify the ESG priority topics that are important to internal and external stakeholders and operationalizing ESG within the organization by forming an ESG Steering Committee and multiple ESG Working Groups focusing on specific ESG substantive areas or workstreams. We continue to work as an organization to advance our strategic ESG roadmap by pursuing key ESG workstreams.

Human Capital

As of December 31, 2022, we had 1,793 employees globally. While the COVID-19 pandemic initially disrupted how and where we work, our employees demonstrated resilience, flexibility, and camaraderie and we transitioned to a hybrid work model. In our new hybrid work model, our positive company culture has ensured that we performed well financially, long-term productivity was maintained, and employee engagement remained high. During 2022, employees continued to effectively navigate strict safety protocols for those working onsite, primarily in manufacturing, and the majority of our employees were not required to be onsite and worked from home.

The Compensation and Talent Management Committee of our Board of Directors has oversight of our culture and human capital management, including diversity, equity, and inclusion with respect to our employees.

Diversity, Equity and Inclusion

We believe in the richness and quality of a working environment that is informed by people from all walks of life and strive to create a genuinely inclusive environment. As of December 31, 2022, our workforce was comprised of more than 60% female employees and more than 50% of employees identified as ethnically diverse.

To further build on our commitment to diversity, equity, and inclusion ("DEI"), we have formed a DEI Counsel that is led by our Chief Risk Officer to support strategic initiatives, partnerships, advocacy, and educational programs to foster a more diverse, equitable, and inclusive culture. We value our differences, recognizing that from those differences comes our strengths, and we are committed to continuing to build a culture of diversity, equity, and inclusion.

Board and Management Oversight

The Compensation and Human Management Committee of our Board of Directors has oversight of human capital management, including our approach to talent recruiting, development, progression and retention, culture, human health and safety, and total rewards. We are committed to nurturing our workforce and have also established a Global Leadership Forum that is led by our Chief Human Resource Officer to ensure broader alignment across organization's leadership on key corporate initiatives, company culture, and transformation objectives. We have also established a Talent and Headcount Review committee that reviews the talent pipeline on a regular basis to ensure we are able to make decisions to keep pace with internal and external circumstances.

Health and Safety

We believe that to date we have materially complied with applicable health, safety, and environmental laws as well as related company policies and procedures and provide necessary training as appropriate by role and location.

Total Rewards

We believe that we employ a fair and merit-based total compensation system, and we evaluate our compensation programs regularly to help ensure that our employees are compensated fairly for their work while fostering a pay-for-performance culture that is aligned with the interests of our stockholders.

We believe that we offer our employees competitive benefits that follow industry standards and support physical, mental, and financial wellness. We offer health benefits, a 401(k) plan with company match, paid time off and family leave, an Employee Stock Purchase Plan for employees in the United States, which allows them to purchase our stock at a discount, and an employee wellness program that is generally available to employees and their families globally with a variety of support services.

Workforce Development

The growth and success of our employees is one of our top priorities as it impacts our overall company performance. We are investing heavily to build in-house tools and resources to support managers and employees. Our core competencies are the foundation for programs and tools being developed to identify top talent, prepare future managers and leaders, and provide equal access to growth opportunities.

We offer a variety of training opportunities, whether focused on building vocational, management, or leadership skills. We facilitate sessions around our core competencies, interview skills and coaching practices, and we rolled out a toolbox on our intranet with resources for employees and managers across the employee lifecycle.

Corporate Information

We were incorporated in the state of Delaware in September 2006. Our principal executive offices are located at 699 8th Street, Suite 600, San Francisco, California 94103, and our telephone number is (415) 632-5700. Our common stock is listed on The Nasdaq Global Select Market under the symbol "IRTC."

Available Information

Our website address is http://www.iRhythmtech.com/, and our investor relations website is located at https://www.investors.irhythmtech.com. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Exchange Act are available free of charge on our investor relations website as soon as reasonably practicable after we file such material with the SEC.

iRhythm investors and others should note that we announce material information to the public about our company, products, and services, and other issues through a variety of means – including via our website, our investor relations website, press releases, SEC filings, and public conference calls – to achieve broad, non-exclusionary distribution of information to the public and to comply with our disclosure obligations under Regulation FD. We encourage our investors and others to review the information we make public in these locations as such information could be deemed material. Please note that this information may be updated from time to time.

ITEM 1A. RISK FACTORS

Our short and long-term success is subject to numerous risks and uncertainties, many of which involve factors that are difficult to predict or beyond our control. Before making a decision to invest in, hold or sell our common stock, stockholders and potential stockholders should carefully consider the risks and uncertainties described below, in addition to the other information contained in or incorporated by reference into this Annual Report on Form 10-K, as well as the other information we file with the SEC. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that case, the value of our common stock could decline and stockholders may lose all or part of their investment. Furthermore, additional risks and uncertainties of which we are currently unaware, or which we currently consider to be immaterial, could have a material adverse effect on our business, financial condition and results of operations. Refer to our disclaimer regarding forward-looking statements at the beginning of Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of this Annual Report.

Risks Related to Our Industry, Business and Operations

Reimbursement by Medicare is highly regulated and subject to change, and our failure to comply with applicable regulations, including regulations not designed for diagnostic tests like our Zio Services, could prevent us from receiving reimbursement under the Medicare program and some commercial payors, subject us to penalties, and adversely affect our reputation, business and results of operations.

In 2022, we received approximately 25% of our total revenue from the Medicare program (inclusive of Medicare Advantage). The Medicare program is administered by CMS, which imposes extensive and detailed requirements on diagnostic services providers, including IDTFs. These requirements include, but are not limited to, rules that govern how we structure our relationships with physicians, how we operate our IDTFs and market our Zio Services, when we may perform diagnostic tests, and how and when we submit reimbursement claims. Our failure to comply with the applicable Medicare rules and requirements could result in discontinuation of our reimbursement under the Medicare payment program, a requirement to return funds already paid to us, civil monetary penalties, criminal penalties, and/or exclusion from the Medicare program, which would have a material adverse impact on our reputation, business and results of operations.

Notably, CMS has acknowledged that the IDTF regulations were designed for "traditional" IDTFs that administer tests to patients in-person, at a single point in time, and from a single location, and only recently has CMS initiated changes to the regulations to address IDTFs like iRhythm that furnish "indirect tests" that do not require in-person interaction and involve technicians performing computer analyses offsite or at another location. The changes, however, do not address all gaps identified by CMS relating to IDTF operations and the Medicare billing requirements. Our failure to comply with the applicable Medicare regulations, or regulators' disagreement with our interpretation of the regulations as applied to indirect tests, such as the Zio Services, could result in the discontinuation of our reimbursement under the Medicare program, a requirement to return funds already paid to us, civil monetary penalties, criminal penalties, and/or exclusion from the Medicare program.

In addition, many commercial payors require our IDTFs to maintain enrollment with the Medicare program as well as accreditation and certification with the Joint Commission. If we fail to obtain and maintain IDTF enrollment or accreditation and certification, our Zio Services may no longer be reimbursed by those commercial payors, which could have a material adverse impact on our reputation, business and results of operations.

If reimbursement or other payment for our Zio Services is reduced or modified in the United States, including through cost containment measures or changes to policies with respect to pricing, our business could suffer.

We receive a substantial portion of our revenue from Medicare and third-party commercial payors with which we contract, and we cannot predict whether and to what extent existing reimbursement rates will continue to be available. If CMS or any of our key commercial payors reduce reimbursement rates for our Zio Services, our business, operating results, and prospects would be adversely affected.

CMS updates the reimbursement rates for diagnostic tests performed by IDTFs annually via the Medicare Physician Fee Schedule. Effective January 1, 2023, CMS established national payment rates for the CPT codes we use to report the long-term continuous monitoring services we perform with our Zio XT System and our Zio Monitor System: CPT codes 93247 (for wear-time of greater than 7 days and up to 15 days) and 93243 (for wear-time of greater than 48 hours and up to 7 days). Based on the relative value units CMS assigned to CPT codes 93247 and 93243, the national reimbursement rates for these services in 2023 are $243.65 and $231.79, respectively, and range from $247.59 to $334.46 and $235.54 to $318.17 for our Medicare-enrolled IDTF locations in Deerfield, Illinois, Houston, Texas, and San Francisco, California, when considering the geographic practice cost index for these locations. Because remote cardiac monitoring technology, including the Zio System, are rapidly evolving, there is a continuing risk that relative value units assigned, and reimbursement rates set, by CMS may not adequately reflect the value and expense of this technology and associated monitoring services, and CMS may reduce these rates in the future, which would adversely affect our financial results.

Additionally, commercial payors with which we contract may seek to reduce our reimbursement rate through further contract negotiations. For example, the recent actions taken by CMS to finalize national reimbursement rates for CPT Codes 93247 and 93243 reduced the Medicare reimbursement rates for these services performed at our Deerfield, Illinois location. Accordingly, we may observe certain commercial payors in this region seeking to adjust their reimbursement rates for these services as well.

In addition, our agreements with commercial payors typically allow either party to terminate the contract at any time by providing prior written notice, in accordance with the agreement, to the other party, which means our commercial payors may elect to terminate their contracts with us for any reason. A commercial payor who terminates or does not renew their contract with us may, or may not, alter their coverage for the type of services we provide. In the event any of our key commercial payors terminate their agreements with us, elect not to renew or enter into new agreements with us upon expiration of their current agreements, or do not renew or establish new agreements on terms as favorable as are currently contracted, our business, operating results, and prospects would be adversely affected.

If we are unable to expand the number of third-party commercial payors with which we contract or expand coverage for existing third-party commercial payors, our commercial success could be impacted.

There is significant uncertainty concerning third-party reimbursement of any new service until a contracted rate is established for that service with the commercial payor. Reimbursement by a commercial payor may depend on several factors, including, but not limited to, a payor's determination that the ordered service is not experimental or investigational, medically necessary and appropriate for the specific patient, cost effective, supported by peer-reviewed publications, and accepted and used by physicians and other clinicians within their provider network.

Since each payor decides whether to establish a policy concerning reimbursement or to contract with us to set the price of reimbursement, seeking reimbursement on a payor-by-payor basis is a time-consuming and costly process to which we dedicate substantial resources. If we do not dedicate sufficient resources to establishing contracts with commercial payors and supporting payors' reimbursement determinations by demonstrating the clinical value of our Zio Services through studies and physician adoption, we may encounter several adverse consequences that could compromise the commercial success of our business. Such adverse consequences may include an inability to secure additional contracts with commercial payors, reluctance by physicians to order our Zio Services due to concerns that patients may face significant out-of-pocket expenses associated with an out-of-network IDTF, a decline in the amount that we are reimbursed for our services, less predictable revenue, and an increase in the efforts and resources necessary to obtain reimbursement for our services on a claim-by-claim basis.

Additionally, for our out-of-network or cash pay patients, we may be subject to state and federal surprise billing laws that impose limits on amounts that can be charged to such patients and/or the amount we can receive for out-of-network services from commercial payors. One such law, the federal No Surprises Act, requires covered providers to provide "good faith estimates" to patients and establishes a detailed and potentially costly independent dispute resolution process governing fee disputes with those patients. These laws and regulations may change, and additional implementation regulations are expected for the No Surprises Act, and we anticipate these requirements may apply to our business in the future.

Our revenue relies on our Zio Services, which are currently our only offerings. If our Zio Services or future service offerings fail to gain, or lose, market acceptance, our business will suffer.

Our current revenue is dependent on orders for our Zio Services, and we expect that reimbursement for our Zio Services will account for substantially all our revenue for the foreseeable future. We are in various stages of research and development for other diagnostic screening solutions and new indications for our technology and our Zio Services; however, there can be no assurance that we will be able to successfully develop and commercialize any new services and related devices. Any new services may not be accepted by physicians or may merely replace revenue generated by our Zio Services and not generate additional revenue. If we have difficulty launching new services, our reputation may be harmed and our financial results adversely affected. In order to substantially increase our revenue, we will need to target physicians other than cardiologists, such as emergency room doctors, primary care physicians, and other physicians with whom we have had little contact and who may require a different type of marketing effort. If we are unable to increase orders for our Zio Services, expand reimbursement for our Zio Services, or successfully develop and commercialize new services and related devices, our revenue and our ability to achieve and sustain profitability would be impaired.

The market for ambulatory cardiac monitoring solutions is highly competitive. If our competitors are able to develop or market monitoring devices and services that are more effective, or gain greater acceptance in the marketplace, than any services and related devices we develop, our commercial opportunities will be reduced or eliminated.

The market for remote cardiac monitoring products and services is competitive, characterized by rapid change resulting from technological advances, scientific discoveries, and other market activities of industry participants. Our Zio Services compete with a variety of products and services that provide alternatives for remote cardiac monitoring, including traditional, short-term Holter monitors and event monitors. Our industry is highly fragmented and characterized by a small number of large manufacturers and a large number of smaller regional service providers. These third parties compete with us in marketing to payors and ordering physicians, recruiting and retaining qualified personnel, acquiring technology, and developing products and services that compete with our Zio Services and related devices. Our ability to compete effectively depends on our ability to distinguish our company and our Zio Services from our competitors and their products, and includes such factors as safety and effectiveness; acute and long-term outcomes; ease of use; price; physician, hospital, and clinic acceptance; and third-party reimbursement.

Our industry is subject to rapid change and is significantly affected by new product introductions, results of clinical research, corporate combinations, and other factors. Large competitors in the remote cardiac market include companies that sell standard Holter monitors including GE Healthcare, Philips Healthcare, Mortara Instrument, Inc., Spacelabs Healthcare Inc. and Welch Allyn Holdings, Inc., (acquired by Hill-Rom Holdings, Inc.). Additional competitors, such as BioTelemetry, Inc. (acquired by Royal Philips), Preventice Solutions, Inc. (acquired by Boston Scientific, Inc.), and Bardy Diagnostics, Inc. (acquired by Hill-Rom Holdings, Inc. which was acquired by Baxter International, Inc.) manufacture remote cardiac monitoring devices and also offer monitoring services. These companies have also developed other patch-based cardiac monitors that have received FDA and foreign regulatory clearances. There are also several small start-up companies trying to compete in the patch-based cardiac monitoring space, as well as several entering the patch-based cardiac monitoring market.

We have also seen a trend in the market for large medical device companies to acquire, invest in, or form alliances with these smaller companies in order to diversify their product offerings and participate in the digital health space. Future competition could come from makers of wearable fitness products or large information technology companies focused on improving healthcare. For example, Apple Inc. and Fitbit have added capabilities on their platforms to measure non-continuous ECG and to alert users to the potential presence of irregular heartbeats suggestive of asymptomatic Afib. These competitors and potential competitors may introduce new products and services that more directly compete with our Zio Services and related devices.

Billing for our Zio Services is complex, and we must dedicate substantial time and resources to the billing process.

Billing for diagnostic services is complex, time-consuming, and expensive. Depending on the billing arrangement and applicable law, we bill several types of entities and payors, including federal healthcare programs, third-party commercial payors, healthcare providers, and healthcare institutions, which may have different billing requirements, coverage criteria, procedures, or expectations. We also bill insured patients for co-payments, co-insurance, and deductible amounts, as well as bill self-pay patients directly.

We also face risk in our collection efforts, including potential write-offs of doubtful accounts and long collection cycles, which could adversely affect our business, financial condition, and results of operations.

Several factors make the billing and collection process uncertain, including differences between the submitted claim price for our Zio Services and the reimbursement rates of payors; compliance with complex federal and state regulations related to billing the Medicare and Medicaid programs; the effect of patient co-payments, co-insurance, and deductible amounts, which may vary depending on the timing of the claim relative to the insured's annual policy year; differences in coverage policies, criteria, and billing requirements among payors; and incorrect or missing patient history, indications, or billing information and delays in verifying and resolving the same.

Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, subcontractors, and agents, and undertake internal review procedures to evaluate compliance with applicable laws, regulations, and internal policies. These activities require a tremendous dedication of resources and, as a result, we have engaged third-party vendors, such as XIFIN, Inc. ("XIFIN"), to undertake certain components of our billing and collections operations. The complexities we face related to billing for our Zio Services, and the related uncertainty in obtaining payment for our Zio Services, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

Audits or denials of our claims by government agencies or payors could expose us to recoupment, regulatory scrutiny, and penalties.

As an IDTF, we submit claims directly to, and receive reimbursement from, federal healthcare programs, including Medicare, as well as other third-party commercial payors. These programs and payors, including contractors on their behalf, may conduct pre- and post-payment audits and reviews of claims submitted for reimbursement. Further, the federal healthcare programs may impose suspensions on both payment and participation in response to allegations of fraud or other noncompliance.

Other controls imposed by CMS and commercial payors designed to reduce costs, commonly referred to as "utilization review," may also affect our operations. Federal law contains numerous provisions designed to ensure that services rendered to CMS patients meet professionally recognized standards and are medically necessary, appropriate for the specific patient, and cost-effective. These provisions include a requirement that a quality improvement organization review a sampling of claims for Medicare beneficiaries to assess the quality of care and appropriateness of the services provided. These quality improvement organizations may deny payment for services or assess fines and have the authority to recommend to CMS that a provider in substantial noncompliance applicable Medicare requirements and quality standards be excluded from participation in the Medicare program. The Affordable Care Act also expands the use of prepayment review by Medicare Administrative Contractors by eliminating statutory restrictions on their use and, as a result, we except efforts to impose more stringent cost controls to continue. As a provider enrolled in federal healthcare programs, we expect to be subject to such audits and claims reviews in the future, which may result in suspensions or other restrictions on our ability to submit claims for our services, payment delays, overpayment recoupments, and claims denials, which would negatively impact our business, financial condition, and results of operations, and may jeopardize our participation in these federal healthcare programs.

We are currently undertaking a transformation of our revenue cycle management function and we may fail to realize the anticipated benefits of these efforts. These activities involve significant time and resources, and our failure to execute these activities efficiently and effectively may cause our revenue and accounts receivable to be delayed or reduced and could have an adverse effect on our business and cause reputational harm.

We are undertaking a transformation of our revenue cycle management function, which plan contemplates the engagement of service providers to support certain activities. The success of this plan depends on our ability to integrate these service providers in a timely manner to scale our operations to facilitates growth opportunities, without adversely affecting current revenues and accounts receivable. If we are not able to successfully achieve these objectives, the anticipated benefits of this transformation may not be realized fully or at all or may take longer to realize than expected. In addition, there is a significant degree of difficulty and management distraction inherent in the process of integrating with service providers. These difficulties include challenges supporting certain operations and activities with more than one service providers, integrating technologies (including IT systems and processes, procedures, policies and operations, and retaining key personnel). These activities may be complex and time consuming and involve delays or additional and unforeseen expenses. The process of transitioning to these service providers, the integration process and other disruptions may also disrupt our ongoing businesses or cause inconsistencies in standards, controls, procedures and policies that could adversely affect our relationships with payors, patients, employees and others. Any failure to execute these activities effectively and efficiently may cause our revenue and account receivable to be delayed or reduced and could have an adverse effect on our business and cause reputational harm.

Although our current Zio Systems are comprised of medical devices that have received FDA marketing authorization (510(k) clearance), we may regularly engage in product enhancements and in iterative changes to existing products, as well as seeking to develop new technology or use of technology for new indications for use. These medical device developments may trigger further regulatory reviews and the results of those reviews are unpredictable.

Before a new medical device or a new intended use for a medical device can be marketed in the United States, a company must first submit an application and receive either 510(k) clearance, De Novo marketing rights or premarket approval from the FDA, unless an exemption applies. All of these processes can be expensive, lengthy and unpredictable. We may not be able to obtain the clearances or approvals we seek or may be unduly delayed in doing so, which could harm our business. Even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained 510(k) clearances to market our Zio System, our clearances can be revoked if safety, efficacy, or significant regulatory compliance problems develop. Even planned changes and improvements to devices and their uses can trigger the need for a new 510(k). FDA requirements dictate that we must evaluate potential changes and document our decision-making regarding the need for additional submissions and clearances.

Significant changes or modifications in design, components, method of manufacturer or the intended use or technological characteristics of our Zio System may require new FDA marketing authorization or CE Mark certification (European Union) or UKCA Mark certification (United Kingdom). Unless effectively planned for in advance of our desired marketing timeline, in some circumstances we may be required to cease marketing certain products until clearances or approvals are obtained, for example, if a change was made to reduce risk to health or remedy an FDA violation. FDA requires device manufacturers to internally analyze and document a decision that a new clearance or approval is viewed as unnecessary. We have made modifications to our Zio System in the past that we believe do not require additional clearances or approvals, and we may make additional modifications in the future. If the FDA or an EU/UK Notified/Approved Body disagrees and requires new marketing authorization for any of these modifications, we may be required to recall and to stop selling the impacted Zio System, which could harm our operating results and require us to redesign our products or services. In these circumstances, we may be subject to significant enforcement actions. We may not be able to obtain additional marketing authorizations in a timely fashion, or at all, which could harm our ability to introduce new or enhanced products in a timely manner, which in turn could harm our future growth.

We are subject to extensive compliance requirements for the quality of the medical device we manufacture for use in our Zio Services, and for vigilance on complaint-handling, escalation, assessment, and reporting of adverse events and malfunctions. A wide range of quality, regulatory, or safety matters could trigger the need for a recall or correction to marketed products.

Our design and manufacturing facilities and processes and those of certain third-party suppliers are subject to unannounced FDA, state, and Notified/Approved Body regulatory inspections for compliance with various medical device regulations and standards, including the QSR, MDD, EU MDR, UK MDR requirements. Developing and maintaining a compliant quality system is time consuming and investment intensive. Requirements and standards may change and evolve over time, and we will need to adapt. Failure to maintain compliance with, or not fully complying with the requirements of the FDA and state regulators could result in enforcement actions, which could include the issuance of warning letters, adverse publicity, seizures, prohibitions on product sales, recalls, and civil and criminal penalties, any one of which could significantly impact our manufacturing supply and provision of services and impair our financial results. Failure to maintain full compliance with the requirements of EU MDD, EU MDR, and UK MDR could result in similar disruptions in these markets.

We are required to file various reports with the FDA, and EU or UK regulators, including reports required by each jurisdiction's adverse event and field action reporting regulations. These reports are often required if our Zio System may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. They may also be necessary or prudent for a range of other reasons relating to the importance of gathering information in the post marketing setting and managing risk throughout the product lifecycle. If these reports are not filed in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. These reports are typically publicly available information in most jurisdictions, including the United States. If we initiate a field action (whether a “correction” made relative to a device that remains in the field, which could be through a labeling or software update, or “removal” or “recall” and return of that device to us, or field advisory notices) to reduce a risk to health posed by our Zio System, we would be required to report the Correction or Removal to the FDA and, in many cases, similar reports to other regulatory agencies. If these reports are not filed in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. These reports are typically publicly available information in most jurisdictions, including the United States.

For example, on September 28, 2022, we initiated a Customer Advisory Notice to Zio AT customers regarding a Zio AT labeling correction; the labeling changes involve additions and modifications to the Zio AT labeling precautions relating to the device’s maximum transmission limits during wear, and also to the need for healthcare providers to complete registration to initiate monitoring services. We 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. This labeling correction follows our assessment of topics raised in an FDA inspection focused on Zio AT. We have been in dialogue with the FDA in relation to the inspection process, and in connection with our Customer Advisory Notice and 806 report. These communications and discussions are continuing at this time, following our 483 responses submitted in September of 2022. Although 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, FDA observation responses, field action or corrections and the 806 process can be unpredictable and can present regulatory and commercial risks and uncertainties relating to matters including product labeling, the scope and approach of the correction, and/or customer and patient perception of our technologies and services.

Depending on the reason for the correction or removal and the potential severity of the impact to patient safety or the effectiveness of the device, the FDA may require differing degrees of communication to alert those who may be in possession of an impacted device. We would generally be subject to similar requirements in jurisdictions outside the United States where the Zio products are used. Furthermore, even if we adhere to regulatory standards and expectations in our corrective actions, the public nature of such actions can result in broader negative publicity and perceptions, which could harm our reputation.

If we assess a potential quality issue or complaint or product enhancement as not requiring either field action or notification, respectively, regulators may review documentation of that decision during a subsequent audit. If regulators disagree with our decision, or take issue with either our investigation process or the resulting documentation or course of action, we may be subject to a range of potential regulatory enforcement actions or required to take corrective actions, which depending on their nature and scope could harm our business.

Because of the patient populations for which our services are provided and the complexity of the healthcare environment in which we operate, a high degree of medical and clinical input may be necessary to evaluate complaints and adverse events, and in some cases, there may be disagreement over whether our services or the medical devices used in our service may have caused or contributed to an event.

Our Zio System and Zio Services are not intended to be prescribed or ordered for use as an emergency system, nor are they intended to be used where inpatient monitoring is needed or life-threatening arrhythmias are suspected. Given the nature of arrhythmias and the patient population for which our Zio Services are ordered by physicians, in which there may be several health conditions present, there are instances in which a patient may experience a medical event during the wear period of our Zio System, and it may be medically and logistically challenging to obtain information sufficient to definitively determine all contributing factors. In some instances, we may receive initial reports of complaints from our CCTs or through our customer service representatives. The initial reports of these non-physicians are likely to contain information that requires verification and further investigation. We are subject to FDA requirements to investigate complaints about our Zio System. If we do not effectively manage and monitor our complaint-handling procedures, we may be subject to regulatory enforcement action, litigation risks, and risk of negative publicity.

If we are unable to keep up with demand for our Zio Services, our revenue could be impaired, market acceptance for our Zio Services could be harmed, and physicians may instead order our competitors' services.

As demand for our Zio Services increases, we may encounter production or service delays or shortfalls. Such production or service delays or shortfalls may be caused by many factors, including the following:

- while we intend to continue to expand our manufacturing capacity, our production processes may have to change to accommodate this growth, potentially involving significant capital expenditures;
- we may experience technical challenges to increasing manufacturing capacity, including in connection with equipment design, automation, validation and installation, contractor issues and delays, licensing and permitting delays or rejections, materials procurement, manufacturing site expansion, problems with production yields and quality control and assurance;
- key components of our Zio Systems are provided by a sole or single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components; if we experience a shortage or quality issues in any of these components, we would need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays;
- global demand and supply factors concerning commodity components common to all electronic circuits, including Zio Systems, could result in shortages that manifest as extended lead times for circuit boards, which could limit our ability to sustain and/or grow our business;
- we may experience a delay in completing validation and verification testing for new production processes and/or equipment at our manufacturing facilities;
- to increase our manufacturing output significantly and scale our services, we will have to attract and retain qualified employees for our operations; and
- in response to unexpectedly rapid growth of our business, clinical operations capacity may not meet demand while new resources are being recruited and trained, which could negatively impact our volume capacity for our Zio Services.

If we were unable to successfully manufacture our Zio Systems in sufficient quantities, or to maintain sufficient capacity to provide our Zio Services, it could materially harm our business.

We depend on third-party vendors for the supply and manufacture of certain components of our Zio Systems, as well as for other aspects of our operations.

We rely on third-party vendors for components and sub-assemblies used in our Zio Systems and in connection with certain logistical aspects of our Zio Services. Our reliance on third-party vendors subjects us to a number of risks, including:

- inability to obtain adequate supply in a timely manner or on commercially reasonable terms, including due to our reliance on a single supplier for certain critical components and materials for which, in some cases, there are relatively few alternative sources of supply;
- modifications to, or discontinuation of, a vendor's operations due to natural disasters, labor disruptions, human error, infrastructure failure, pandemics, military conflicts, or political or economic disruption, which may adversely impact our operations or otherwise lead to interruption of or shortage or delays in supply, including shortages impacting our printed circuit board assembly;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications;
- inability of the manufacturer or supplier to comply with our quality criteria and specifications and, where applicable, the QSR, state regulatory authorities, and, in some cases, the Notified Body audits;
- miscommunication of design specifications due to errors/omissions by either the vendor or our company, resulting in delayed delivery of acceptable materials or components for incorporation into our devices;
- delays in device shipments resulting from quality issues or defects, reliability issues, or a supplier's failure to consistently produce quality components;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability to control the quality of products manufactured by third parties;
- delays in delivery by our suppliers due to changes in demand from us or their other customers; and
- delays in obtaining required materials and components that are in short supply within the time frames we require, at an affordable cost, or at all.

Further, we rely on single suppliers for the supply of our adhesive sub-assembly, disposable plastic housings, instruments and other materials that we use to manufacture and label our Zio patches. We have not qualified additional suppliers for some of these components and materials and we do not carry a significant inventory of these items. While we believe that alternative sources of supply may be available, we cannot be certain whether they will be available if and when we need them and that any alternative suppliers would be able to provide the quantity and quality of components and materials that we would need to manufacture our Zio patches if our existing suppliers were unable to satisfy our supply requirements.

Any significant delay or interruption in the supply of components or sub-assemblies, such as those that we have experienced during the COVID-19 pandemic, or our inability to obtain substitute components, sub-assemblies or materials from alternate sources at acceptable prices and in a timely manner could impair our ability to meet the demand for our Zio Services, significantly affect our future revenue and harm our relations and reputation with physicians, hospitals, clinics, and patients.

We also rely on certain third-party vendors in connection with the analysis we perform to create diagnostic reports for our Zio Services, which is dependent upon a recording made by each Zio System. For long-term continuous monitoring utilizing our Zio XT System, for example, requires the physical return of the Zio XT patch to one of our clinical centers and we predominantly rely on the U.S. Postal Service ("USPS") to perform this delivery service. Delivery of the Zio XT patch to one of our clinical centers may be subject to disruption to the USPS delivery infrastructure. Further, for the MCT monitoring services utilizing our Zio AT System, we rely on the provision of cellular communication services for the timely transmission of patient information and reportable events. The reliability of the electronic communication and cloud services required for these operations are subject to natural disasters, labor disruptions, human error, and infrastructure failure. Any of these disruptions may render it difficult or temporarily impossible for us to provide some or all our Zio Services and bill for those services, adversely affecting our operating results, causing significant distraction for management, and negatively impacting our business reputation. We also expect that our reliance on third-party vendors will increase as our business grows, exposing us to increased harm if such disruptions occur.

Our ability to compete depends on our ability to innovate successfully.

The market for medical devices, including the remote cardiac monitoring segment, is competitive, dynamic, and marked by rapid and substantial technological development and product innovation. While there are barriers that would challenge new entrants or existing competitors from developing products that compete directly with the devices used in our Zio Services, these barriers can be overcome. Demand for our Zio Services and future related devices or services could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our services and related devices could become obsolete and our revenue would decline as our customers prescribe or purchase our competitors' services.

In order to remain competitive, we must continue to develop new product offerings and enhancements to our Zio Services. We can provide no assurance that we will be successful in fully recognizing the strategic value of our ECG database, expanding the indications for our Zio Services, developing new services and related devices, or commercializing them in ways that achieve market acceptance. In addition, if we develop new services, sales of those services may reduce revenue generated from our existing services. Maintaining adequate research and development personnel and resources to meet the demands of the market is essential. If we are unable to develop new services and related devices, applications, or features, or improve our algorithms due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills, or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors devote a considerably greater amount of funds to their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

We have entered into a development agreement with a third-party that may not result in the development of commercially viable devices or the generation of significant future revenues.

We have entered into the Development Agreement with Verily to develop certain next-generation AF screening, detection, or monitoring devices to enhance our Zio Services, which involves combining our technology platforms and capabilities with those of Verily. As part of the Development Agreement, we paid Verily an up-front fee of $5.0 million in cash, and through December 31, 2022, we have achieved milestones and additional related payment obligations totaling $11.0 million. We have agreed to make additional payments over the term of the Development Agreement up to an aggregate of $1.75 million, subject to the achievement of certain development and regulatory milestones. The success of our collaboration with Verily is highly dependent on the efforts provided to the collaboration by Verily and us and the skill sets of our respective employees. Support of these efforts requires significant resources, including research and development, manufacturing, quality assurance, and clinical and regulatory personnel. Even with the FDA's clearance of our clinically-integrated ZEUS System for the Zio Watch, continued product testing, market research, and related activities may result in a delay to device launch and additional expense associated with any commercialization efforts. Even if and when launched, the developed devices may also not be accepted in the marketplace, and there is no assurance that adequate coverage or reimbursement would be available, or that an alternative payment model can be developed.

After the initial term and scope of the Development Agreement, and in order to commercialize any services in connection with the developed devices with Verily, we will need to enter into a commercialization agreement. There is no guarantee that we will be able to enter into such an agreement on commercially reasonable terms or at all. If we are unable to reach agreement with Verily on terms, the up-front fee and regulatory and development milestone payments and our internal development costs would not be recovered and the licenses to use Verily's technology will expire.

This collaboration may not result in the development of devices, and ultimately services, that achieve commercial success and could be terminated prior to developing any devices. In the event of any termination or expiration of the Development Agreement, we may be required to devote additional resources to device development and we may face increased competition, including from Verily. Verily may use the experience and insights it develops in the course of the collaboration with us to initiate or accelerate their development of products that compete with our devices and services, which may create competitive disadvantages for us. Accordingly, we cannot provide assurance that our collaboration with Verily or any other third party will result in the successful development of commercially viable devices and services or result in significant additional future revenues for our company.

International expansion of our business exposes us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

While we currently derive substantially all of our revenue and maintain substantially all of our assets in the United States, we intend to continue to pursue growth opportunities outside of the United States, especially in the Philippines and the United Kingdom, and we may increase our use of administrative and support functions from locations outside the United States, which could expose us to risks associated with international sales and operations. Additionally, our international expansion efforts may not be successful, we may experience difficulties in scaling these functions from locations outside the United States, and we may not experience the expected cost efficiencies.

Our international operations are, and will continue to be, subject to a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- obtaining and sustaining regulatory approvals, certifications, and regulatory compliance where required for the sale of our Zio Services in various countries;
- requirements to maintain data and the processing of that data on servers located within such countries;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- logistics and regulations associated with shipping and returning our Zio patches following use;
- limits on our ability to penetrate international markets if we are required to process our Zio Services locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the effect of local and regional financial pressures on demand and payment for our services, fluctuations in trade policy and tariff regulations, changes in international tax regulations applicable to our business, and exposure to foreign currency exchange rate fluctuations, which may reduce the reported value of our foreign currency denominated revenues, expenses, and cash flows;
- decreased emphasis or enforcement or intellectual property protections in some countries outside the United States in comparison to that in the United States;
- increased risk of litigation or administrative proceedings in connection with our relationships with international business partners, including litigation against persons whom we believe have infringed on our intellectual property, infringement litigation filed against us, litigation against a competitor, or litigation filed against us by distributors or service providers resulting from a breach of contract or other claim, as well as disputes regarding government and public tenders, any of which may result in substantial costs to us, adverse judgments, settlements, and diversion of our management's attention;
- natural disasters, political and economic instability, including wars, terrorism, political unrest, outbreak of disease, boycotts, curtailment of trade, and other market restrictions;
- regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the FCPA, UK Bribery Act of 2010, and comparable laws and regulations in other countries;
- compliance risks associated with the GDPR (including as it applies in the United Kingdom by virtue of the Data Protection Act 2018), enacted to protect the privacy of all individuals in the European Union and the United Kingdom, and which places certain restrictions on the export of personally identifiable data outside of the European Union or the United Kingdom, as applicable;
- compliance risks associated with the revised regulations in the EU MDR that outline the requirements for medical device CE marking; and

- compliance risks associated with the UK MDR, which replaced the CE marking requirements for medical devices marketed and sold in the United Kingdom with a UKCA mark following the United Kingdom's withdrawal from the European Union.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

Exposure to United Kingdom political developments, including the outcome of its withdrawal from membership in the European Union, could be costly and difficult to comply with and could seriously harm our business.

Our operations in the United Kingdom account for approximately 2% of our revenue for the twelve months ended December 31, 2022, and we intend to continue to pursue growth opportunities in the United Kingdom. There are still a number of areas of uncertainty in connection with the future of the United Kingdom and its relationship with the European Union following the United Kingdom's exit from the European Union in 2020 (commonly referred to as "Brexit"), including the application and interpretation of the UK-EU trade agreement (the "Trade and Cooperation Agreement"), which went into force in May 2021. For example, because a significant proportion of the regulatory framework in the United Kingdom is currently derived from EU directives and regulations, Brexit could result in material changes to the regulatory regime applicable to many of our current operations. The UK government and the MHRA began undertaking public consultations on the future regulation of medical devices in 2022 and plan to introduce the new regulatory system at the beginning of July 2024. Although the Trade and Cooperation Agreement offers UK and EU companies preferential access to each other's markets, ensuring imported goods will be free of tariffs and quotas, economic relations between the United Kingdom and the European Union are on more restricted terms than existed previously. Therefore, at this time, we cannot predict the impact that the Trade and Cooperation Agreement and any future agreements contemplated under the terms of the Trade and Cooperation Agreement will have on our future business efforts to commercialize our Zio Services in the United Kingdom and the European Union. Accordingly, it is possible that the Trade and Cooperation Agreement may adversely affect our operations and financial results.

Our success depends on our ability to attract and retain senior management and key personnel.

Our success depends on our ability to retain our senior management and to attract and retain qualified personnel in the future. Competition for senior management personnel, as well as salespersons, scientists, clinicians, and engineers, is intense and we may not be able to retain our personnel. The loss of key personnel, including key members of our senior management team or members of our board of directors, as well as certain of our key finance, legal, regulatory, research and development, and clinical personnel, could disrupt our operations and have a material and adverse effect on our ability to grow our business. Each of our officers may terminate their employment at any time without notice and without cause or good reason. The loss of a member of our senior management team or our professional staff would require the remaining executive officers to divert immediate and substantial attention to seeking a replacement.

We have recently experienced significant changes in our executive leadership, including the appointment of Quentin S. Blackford as our President and Chief Executive Officer in October 2021 following the resignation of our prior President and Chief Executive Officer, Kevin King, in January 2021. Douglas Devine, our Chief Operating Officer, and Michael Coyle served as Chief Executive Officer from June 2021 to October 2021 and January 2021 to June 2021, respectively, before Mr. Blackford's appointment. We have had additional executive officer positions change in the year ended December 31, 2022, and may experience further changes in executive leadership in the future.

Changes to strategic or operating goals, which can often times occur with the appointment of new executives, can create uncertainty, may negatively impact our ability to execute quickly and effectively, and may ultimately be unsuccessful. If we do not integrate new executives successfully, we may be unable to manage and grow our business, and our financial condition and profitability may suffer as a result. In addition, to the extent we experience additional management turnover, competition for top management is high and it may take months to find a candidate that meets our requirements. If we are unable to attract and retain qualified management personnel, our business could suffer.

Further, we may undertake reorganizations of our workforce from time to time, which may result in a temporary reduction in the number of employees in certain locations. We would undertake a reorganization to reduce operating expenses or achieve other business objectives, though we cannot guarantee any specific amount of long-term cost savings. Further, the turnover in our employee base could result in operational and administrative inefficiencies, which could adversely impact the results of our operations, stock price, and customer relationships, and could make recruiting for future management and other positions more difficult.

Our continued rapid growth could strain our personnel resources and infrastructure, and if we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.

We have experienced rapid growth in our headcount and in our operations. Any growth that we experience in the future will provide challenges to our organization, requiring us to expand our sales personnel, manufacturing, clinical, customer care, and billing operations and general and administrative infrastructure. In addition to the need to scale our operational and service capacity, future growth will impose significant added responsibilities on management, including the need to identify, recruit, train, and integrate additional employees. Rapid expansion in personnel could impact our capacity to manufacture our Zio patches, market, sell and support our Zio Services, and analyze the data to produce Zio reports, which could result in inefficiencies and unanticipated costs, impacts to our Zio Services, including our Zio patches, and disruptions to our service operations. Additionally, rapid expansion could require us to rely on overtime to increase capacity that could, in turn, result in greater employee attrition and/or a loss in productivity during the process of recruiting and training additional resources and add to our operating expenses.

As we seek to gain greater efficiency, we may look for ways to expand the automated portion of our Zio Services and require productivity improvements from our CCTs, within the framework of our wide-ranging regulatory obligations. Such improvements could impact the content of our Zio reports. In addition, rapid and significant growth may strain our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial, and management controls, reporting systems, and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

Failure to receive the Zio System patches used for the provision of the Zio Services we provide may result in a loss of capital as well as revenue where the receipt of returned devices and processing of data retrieved from returned devices is required to provide our Zio Services.

Our Zio System patches and gateways are provided to patients either (1) during in-office visits with a healthcare provider or (2) remotely via at-home hookup. Although in both scenarios there is the potential that a patient will not return the device(s) at the conclusion of the wear period, home hookups result in a higher likelihood that the patient will fail to return his or her device, which negatively impacts our financial condition when we are unable to provide the Zio Services. For example, when the patient returns the Zio XT patch to us at the end of the patient wear period, we provide the Zio XT Services, which include the end of service report based on the data stored on the Zio XT patch, after which we submit a claim to the relevant payor or to the patient for the services rendered. If a patient fails to return a device, we experience financial losses, which include the cost of the device as well as the loss of potential revenue for the service that is contingent on the returned device for the submission of the associated claim.

Our plans include a high degree of focus on the mSToPs criteria for AF screening. There are risks that the clinical or payor community will not fully accept these criteria as a basis for selection of patients suitable for screening.

In January 2022, the USPSTF published a recommendation statement on the screening criteria for AF screening, stating that the current evidence (including the mSToPs study) is insufficient to assess the balance of benefits and harm of AF screening, and thus found that it could neither recommend for or against screening of adults 50 years or older without a diagnosis or symptoms of AF and without a history of transient ischemic attack or stroke. In its recommendation, the USPSTF also identified research needs and gaps, including for example assurance that future research involves randomized trials of diverse patient populations and conducting research to optimize the accuracy of screening for Afib. This USPTSF recommendation statement may deter some clinicians or payors from accepting the mSToPs study inclusion and exclusion criteria as a standard for selecting patients for screening for Afib. We cannot predict whether or when the USPSTF's recommendation on Afib screening will change or be modified based on findings from additional randomized trials, other research or through the continued use of our products and services or other similarly situated products and services designed for remote cardiac monitoring.

We may face risks associated with acquisitions of companies, products, and technologies and out business could be harmed if we are unable to address these risks.

If we are presented with appropriate opportunities, we could acquire or make other investments in complementary companies, products, or technologies. We may not realize the anticipated benefit of our acquisitions, or the realization of the anticipated benefits may require greater expenditures than anticipated by us. We will likely face risks, uncertainties, and disruptions associated with the integration process, including difficulties in the integration of the operations and services of any acquired company, integration of acquired technology with our Zio Services, including our Zio Systems, diversion of our management's attention from other business concerns, the potential loss of key employees or suppliers of the acquired businesses, and impairment charges if future acquisitions are not as successful as we originally anticipated. If we fail to successfully integrate other companies, products or technologies that we acquire, our business could be harmed. Furthermore, we may have to incur debt or issue equity or equity-linked securities to pay for any future acquisitions or investments, the issuance of which could be dilutive to our existing stockholders. In addition, our operating results may suffer because of acquisition-related costs, amortization expenses, or charges relating to acquired intangible assets.

Risks Related to Healthcare Regulatory Matters

Our use of third-party service providers or iRhythm company resources located outside the United States to support certain customer care, clinical and other operations of our IDTFs may present challenges, and if we are ineffective in limiting work performed by these service providers or iRhythm consistent with applicable regulations or our contractual agreements with commercial payors, we may be subject to penalties or experience loss of revenue.

Beginning in the third quarter of 2022, we engaged Sutherland Healthcare Solutions, Inc. and Techindia Infoway Private Limited, to support certain customer care and clinical operations of our IDTFs. We have developed operational and technical controls to limit the work performed by these vendors consistent with our interpretation of the Medicare coverage exclusion for items of services furnished outside the United States, other applicable laws and regulations, and any requirements imposed pursuant to our contracts with commercial payors. If these controls do not work as intended, or if regulators or commercial payors disagree with our interpretation of these requirements and their application to our operations, we may be subject to a requirement to return funds already paid to us, civil monetary penalties, other government enforcement, as highlighted by a recent enforcement action against our competitor, BioTelemetry, Inc., with respect to the support of certain clinical operations by vendors performing work outside the United States, and termination of contracts with commercial payors, as well as the loss of revenue associated with those contracts.

In addition, we are currently engaging with other third-party service providers that have resources located outside the United States, and we are establishing iRhythm company resources in the Philippines to provide services in support our IDTFs. We intend for these services to include benefits verification, billing, collections, and customer service, which will require complex oversight and monitoring for appropriate capture and escalation of complaint information that may be relevant to the quality, performance, and safety of our medical devices or the quality of our clinical services. If we are unable to effectively manage this oversight and monitoring, we may be subject to regulatory enforcement action or inquiries which may be expensive and time consuming to resolve. In addition, certain contracts with commercial payors include restrictions related to accessing patient data outside the United States and we have implemented technical controls intended to prohibit access to patient data by service providers and iRhythm company resources located outside the United States for these commercial payors, as appropriate. If these controls do not work as intended, or if the payor information we receive from ordering healthcare providers is delayed or inaccurate, we may encounter the suspension or termination of contracts with commercial payors, as well as any contractual remedies such payors might pursue. The suspension or loss of any of our key commercial payor agreements would have an adverse impact on our revenue and our results of operations.

If we fail to comply with medical device, healthcare and other governmental regulations, we could face substantial penalties and our business, results of operations, and financial condition could be adversely affected.

The services and related devices we offer are highly regulated, and the regulatory environment in which we operate may change significantly and adversely in the future. Our arrangements with physicians, hospitals, clinics, and other stakeholders in the healthcare industry may expose us to broadly applicable medical device laws and healthcare fraud and abuse and other laws and regulations that may restrict the financial arrangements and relationships through which we market, sell, distribute, and provide our services and related devices. Our employees, consultants, and commercial partners and collaborators may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. Federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- federal and state laws and regulations regarding billing and claims payment;
- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the FCPA, the UK Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities;
- the federal Physician Payment Sunshine Act, or Open Payments, and its implementing regulations, which requires us to report payments or other transfers of value made to licensed physicians and certain mid-level health practitioners and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which impose certain requirements relating to the privacy, security, and transmission of individually identifiable health information; HIPAA also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the GDPR and the UK Data Protection Act 2018, which each provide legal requirements for the handling and disclosure (including across borders) of personal data collected in the European Union and the United Kingdom, respectively;
- the FDA's Code of Federal Regulations, including but not limited to, 21 CFR Parts 820, 803, 806, and 801, that outlines requirements for medical device design, testing, marketing authorization, manufacturing, labeling, distribution, and post-market surveillance requirements;
- the EU MDD and EU MDR that outline requirements for medical device CE marking;
- the UK MDR, which, post the United Kingdom's withdrawal from the European Union, replaces the CE marking requirement for medical devices sold in the United Kingdom with a UKCA mark; and
- state law equivalents of each of the above U.S. federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

These laws are broad in scope and available exceptions and exemptions are narrow; it is possible that some of our activities could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal FCA including mandatory treble damages and significant per-claim penalties, which were increased from $12,537 to $25,076 per false claim in May 2022. For example, our industry has experienced recent False Claims Act enforcement, which highlights the importance of compliance with the rules and regulations governing claims submitted to federal healthcare programs.

Although we have adopted policies and procedures designed to comply with these laws and regulations and conduct internal reviews of our compliance with these laws, our compliance is also subject to governmental review. The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the federal, state, or foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment for individuals, exclusion from participation in government programs, such as Medicare, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Changes in applicable laws or regulations or the interpretation or enforcement policies of regulators governing our IDTFs and Zio Services may constrain or require us to restructure our operations or adapt certain business strategies which may harm our revenue and operating results.

Healthcare laws and regulations, and interpretations of the same, change frequently and may change significantly in the future. We may not be able to adapt our operations to address every new regulation or interpretation, and new regulations or interpretations may adversely affect our business. We also cannot assure that a review of our business by courts or regulatory authorities would not result in a determination that adversely affects our revenue and operating results.

Our business relies on orders from licensed healthcare providers, and the continuing clinical acceptance and adoption of our Zio Services depends upon strong working relationships with healthcare providers, including physicians. These relationships, interactions, and arrangements are subject to a high degree of scrutiny by government regulators and enforcement bodies.

As a CMS-enrolled IDTF, we may only provide our Zio Services upon receipt of a valid order from a licensed healthcare provider for use in the diagnosis and treatment of a patient's medical condition. Accordingly, our revenue and the success of our business rely on the continued clinical acceptance and adoption of our Zio Services by healthcare providers whose patients require remote cardiac monitoring services. In addition to continuing to demonstrate the clinical value of our Zio Services, we also must support widespread clinical acceptance and adoption of our Zio Services by maintaining strong working relationships with these healthcare providers, including physicians. However, as we work to establish and maintain these relationships, we face significant scrutiny of these relationships, interactions, and arrangements by government regulators and enforcement agencies. Failure to maintain these relationships, interactions, and arrangements in compliance with applicable laws and regulations, including those targeted at fraud and abuse like the federal Anti-Kickback Statute and the False Claims Act, could expose us to significant legal and financial repercussions, including government civil and criminal investigations, civil monetary penalties, criminal penalties, and/or exclusion from federal healthcare programs.

Our communications with healthcare stakeholders – physicians and other healthcare professionals, payors and similar entities, as well as patients and lay caregivers – are subject to a high degree of scrutiny for compliance with a wide range of laws and regulations. Continuing or increasing our sales and marketing and other external communication efforts may expose us to additional risk of being alleged or deemed to be non-compliant by regulatory, enforcement authorities, or competitors.

Our sales and marketing efforts and initiatives may subject us to additional scrutiny of our practices of effective communication of risk information, benefits, or claims under the oversight of the FDA, the Federal Trade Commission ("FTC"), or both agencies. For example, the FDA applies a heightened level of scrutiny to comparative claims when applying its statutory standards for advertising and promotion, including with regard to its requirement that promotional labeling be truthful and not misleading. The FTC also recently released updated guidance on health claims, with a high expectation for clinical data to support these claims. There is potential for differing interpretations of whether certain communications are consistent with a product's FDA-required labeling, and FDA will evaluate communications on a fact-specific basis.

In addition, making comparative claims may draw scrutiny from our competitors. Where a company makes a claim in advertising or promotion that its product is superior to the product of a competitor (or that the competitor's product is inferior), this creates a risk of a lawsuit by the competitor under federal and state false advertising or unfair and deceptive trade practices law, and possibly also state libel law. Such a suit may seek injunctive relief against further advertising, a court order directing corrective advertising, and compensatory and punitive damages where permitted by law. If our compliance program and training and monitoring do not effectively keep pace with our sales and marketing growth, we may encounter increased risk in execution of activities by our personnel, potential enforcement and other exposure.

We may also seek to communicate certain information with physicians and scientists or with payors and similar entities, and may rely on a range of laws, regulations, regulatory guidance governing topics including scientific exchange and communication of healthcare economic information ("HCEI") and product information under the Preapproval Information Exchange Act.

Changes in laws and regulations governing our communications with patients or the interpretation or enforcement policies of regulators could subject us to regulatory scrutiny, damage awards, or fines.

As a Medicare-enrolled IDTF, we are prohibited from directly soliciting patients for diagnostic medical procedures. While we can engage in general marketing initiatives, consistent with applicable law, we cannot make telephone, computer, and in-person contacts for the purpose of soliciting business for our IDTF.

Regarding patients for whom we have received a valid order for our Zio Services, we may send or make text messages, emails, phone calls and other communications for various informational, business purposes, including to confirm accurate demographic and payor information or to assist a patient via a home hookup. Communication-related laws require consent prior to certain communications and provide a specified monetary damage award or fine for each violation could result in particularly significant damage awards or fines. For example, under the Telephone Consumer Protection Act ("TCPA"), plaintiffs may seek actual monetary loss or statutory damages of $500 per violation, whichever is greater, and courts may treble the damage award for willful or knowing violations. In the wake of a 2021 decision by the U.S. Supreme Court that limited the applicability of the TCPA, several states have enacted or introduced legislation that would regulate text messages and certain telephone calls to individuals. We may be subject to lawsuits (including class-action lawsuits) containing allegations that our business violated the TCPA or other communications laws. These lawsuits may seek damages (including statutory damages) and injunctive relief, among other remedies. A determination that there have been violations of the TCPA or other statutes regulating communications with patients could expose us to significant damage awards that could, individually or in the aggregate, materially harm our business.

While most of our revenue results from claims submitted to payors for diagnostic medical procedures, we offer, and are looking to expand, alternative payment and service delivery models. Piloting, evaluating, and implementing these alternative payment and service delivery models requires interactions with commercial payors, physicians, and patients; these interactions are subject to laws and regulations aimed at preventing healthcare fraud and abuse. If these models are unsuccessful, or if we are unable to fully comply with such laws as we pursue these strategies, our commercial success could be compromised and we could face substantial penalties.

Our operations may be directly or indirectly affected by various broad state and federal healthcare fraud and abuse laws, including the AKS, the FCA, the Anti-Mark Up Rule, and the Medicare Beneficiary Inducement Statute. For some of our services, we directly bill physicians or other healthcare entities, that, in turn, bill payors, and the amounts we bill may include a risk-based pricing component. We are also developing alternative service delivery models that include using our Zio XT System to screen at-risk patient populations as part of a value-added service offered by managed care organizations, including Medicare Advantage Organizations, to qualifying participants. Although we believe these billing and service models and our program development efforts are properly designed to comply with laws and regulations, these types of initiatives may draw a high degree of scrutiny and may subject us to assertions of non-compliance. If our past, present, or future operations are found to be in violation of fraud and abuse laws, we or our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from Medicare program participation. Furthermore, if we knowingly file, or "cause" the filing of, false claims for reimbursement with government programs such as Medicare, we may be subject to substantial civil penalties, including treble damages.

Risks Related to Financial and Accounting Matters

In the future we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations.

We previously identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. As previously disclosed, in preparing our consolidated financial statements as of and for the years ended December 31, 2021 and 2020, our management concluded that our disclosure controls and procedures were not effective at the reasonable assurance level due to a failure to maintain a sufficient number of professionals with an appropriate level of accounting and internal control knowledge, training, and experience to timely and accurately analyze, record, and disclose accounting matters. This material weakness contributed to additional material weaknesses, which have been previously disclosed and remediated. In aggregate, these material weaknesses (including the previously remediated material weaknesses) contributed to the misstatement of our revenues, revenue reserves, bad debt expense, property and equipment, research and development expense, and related financial disclosures, and in the revision of the Company's consolidated financial statements for the years ended December 31, 2017, December 31, 2018, and each interim period therein as well as the quarters ended March 31, 2019, June 30, 2019, and September 30, 2019. Additionally, this material weakness could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

To address this material weakness, we took actions designed to improve our internal control over financial reporting and remediate the control deficiencies that led to the material weakness, including hiring additional accounting and finance personnel with an appropriate level of expertise, providing for additional management oversight over financial reporting including through the establishment of a SOX Steering Committee within our internal audit function, and implementing new controls and processes. As of the year ended December 31, 2022, we concluded that our remediation efforts have been successful and that the previously identified material weakness in internal control over financial reporting has been remediated. However, while the material weakness has been remediated, we continue to seek improvements to enhance our control environment and to strengthen our internal controls to provide reasonable assurance that our financial statements continue to be fairly stated in all material respects.

If we discover additional weaknesses in our system of internal financial and accounting controls and procedures, our consolidated financial statements may contain material misstatements, and we could be required to restate our financial results. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

Any failure to implement and maintain effective internal control over financial reporting could cause investors to lose confidence in our reported financial and other information, adversely impact our stock price, cause us to incur increased costs to remediate any deficiencies, and attract regulatory scrutiny or lawsuits that could be costly to resolve and distract management's attention, limit our ability to access the capital markets or cause our stock to be delisted from The Nasdaq Global Select Market or any other securities exchange on which it is then listed. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our financial results may fluctuate significantly from quarter-to-quarter and may not fully reflect the underlying performance of our business.

Our revenue and operating results may fluctuate significantly from quarter to quarter as a result of a variety of factors, a number of which are outside our control, and may therefore not fully reflect the underlying performance of our business. Such factors may include, for example, seasonal variations in prescription rates. We typically experience reduced revenue during the third quarter, as well as during the year-end holiday season. We believe this is the result of physicians and patients taking vacations, and patients electing to delay our monitoring services during the summer months and holidays. We believe that period-to-period comparisons of our operating results may not be meaningful and should not be relied on as an indication of our future performance. If quarterly revenues or operating results fall below the expectations of investors or public market analysts, the trading price of our common stock could decline substantially. Factors that might cause quarterly fluctuations in our operating results include:

- our inability to manufacture an adequate supply of our Zio Systems to support demand for our Zio Services at appropriate quality levels and acceptable costs;
- possible delays in our research and development programs or in the completion of any third-party clinical trials relating to our Zio Services;
- a lack of acceptance of our Zio Services, including our Zio Systems, by physicians and potential patients;
- the inability of patients to receive reimbursements from third-party payors;
- the purchasing patterns of physicians and patients, including as a result of seasonality;
- failures to comply with regulatory requirements, which could lead to withdrawal of our Zio Services, including our Zio Systems, from the market;
- our failure to continue the commercialization of our Zio Services;
- competition;
- inadequate financial and other resources; and
- global political and economic conditions, including inflation, increasing interest rates and the impact of the ongoing COVID-19 pandemic, political instability, and military hostilities, including the conflict in Ukraine.

Further, we recognize a portion of our revenue from non-contracted third-party commercial payors. For example, during the year ended December 31, 2022, revenue from non-contracted third-party commercial payors accounted for approximately six percent of our total revenue. We have limited visibility as to when we will receive payment for our Zio Services with non-contracted payors and we or XIFIN must appeal any negative payment decisions, which often delays collections further. Additionally, a portion of the revenue from non-contracted payors is received from patient co-pays, which we may not receive for several months following delivery of service or may not receive at all. For revenue related to non-contracted payors, we estimate an average collection rate based on factors including historical cash collections. Subsequent adjustments, if applicable, are recorded as an adjustment to revenue. Fluctuations in revenue may make it difficult for us, research analysts, and investors to accurately forecast our revenue and operating results or to assess our actual performance. If our revenue or operating results fall below expectations, the price of our common stock would likely decline.

We have a history of operating losses and may not achieve or sustain profitability in the future.

We have incurred net losses since our inception in September 2006. We generated net losses of $116.2 million and $101.4 million during fiscal 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $522.2 million. We have financed our operations to date primarily through private and public offerings of equity securities and revenue generated by prescriptions of our Zio Services. We have and expect to continue to incur significant research and development, sales and marketing, regulatory, and other expenses as we expand our marketing efforts to increase the prescription of our Zio Services, expand existing relationships with physicians, obtain regulatory clearances or approvals for our current or future services and related devices, conduct clinical trials on our existing and future services, and develop new services or add new features to our existing Zio Services. We also expect that our general and administrative expenses will continue to increase due, among other things, to the operational and regulatory burdens applicable to medical service providers that are public companies. As a result, we expect to continue to incur operating losses in the future. These losses, among other things, may have an adverse effect on our stockholders' equity and the value of our common stock.

We may require additional capital to support the growth of our business, and this capital might not be available on acceptable terms, if at all.

Our operations have consumed substantial amounts of cash since inception. We intend to continue to make investments to support our business, which may require us to engage in equity or debt financings to secure additional funds. Additional financing may not be available on a timely basis on terms acceptable to us, or at all. Any additional financing may be dilutive to stockholders or may require us to grant a lender a security interest in our assets. The amount of funding we may need will depend on many factors, including:

- the revenue generated by our Zio Services;
- the costs, timing, and risks of delay of additional regulatory approvals;
- the expenses we incur in manufacturing, developing, selling, and marketing our Zio Services;
- our ability to scale our manufacturing operations to meet demand for the Zio Systems used in our current and any future Zio Services or other offerings;
- the costs of filing, prosecuting, defending, and enforcing any patent claims and other intellectual property rights;
- the rate of progress and cost of our clinical trials and other development activities;
- the success of our research and development efforts;
- the emergence of competing or complementary technologies;
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish;
- the cost of ongoing compliance with legal and regulatory requirements, and third-party payors' policies;
- the cost of obtaining and maintaining regulatory or payor clearance or approval for our current or future offerings including those integrated with other companies' products; and
- the acquisition of business, products, and technologies.

If adequate funds are not available, we may not be able to commercialize our Zio Services at the rate we desire and/or we may have to delay the development or commercialization of our Zio Services or license to third parties the rights to commercialize services or technologies that we would otherwise seek to commercialize. We also may have to reduce sales, marketing, customer support, or other resources devoted to our Zio Services. Any of these factors could harm our business and financial condition.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations which could subject our business to higher tax liability.

Our ability to use our net operating losses ("NOLs") to offset future taxable income may be subject to certain limitations which could subject our business to higher tax liability. We may be limited in the portion of NOL carryforwards that we can use in the future to offset taxable income for U.S. federal and state income tax purposes, and federal tax credits to offset federal tax liabilities. Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state law provisions, limit the use of NOLs and tax credits after a cumulative change in corporate ownership of more than 50% occurs within a three-year period. The statutes place a formula limit on how much NOLs and tax credits a corporation can use in a tax year after a change in ownership. Avoiding an ownership change is generally beyond our control. We could experience an ownership change that might limit our use of NOLs and tax credits in the future. In addition, realization of deferred tax assets, including NOL carryforwards, depends upon our future earnings in applicable tax jurisdictions. If we have insufficient future taxable income in the applicable tax jurisdiction for any reason, including any future corporate reorganization or restructuring activities, we may be limited in our ability to utilize some or all of our net operating losses to offset such income and reduce our tax liability in that jurisdiction. See Note 10, Income Taxes, to the Consolidated Financial Statement for additional information.

There is also a risk that due to regulatory changes or changes to federal or state law, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable either in whole or in part to offset future income tax liabilities. For example, under the Coronavirus Aid, Relief, and Economic Security Act of 2020, which amended certain provisions of the Tax Cuts and Jobs Act ("TCJA"), NOLs arising in taxable years beginning after December 31, 2017 may offset no more than 80% of current taxable income annually for taxable years beginning after December 31, 2020. Therefore, we may be required to pay U.S. federal income taxes in future years despite the NOL carryforwards we have accumulated.

Risks Related to Other Legal and Regulatory Matters

We are subject to legal proceedings and government investigations that could adversely affect our business, financial condition, and results of operations.

We are involved in legal proceedings related to securities litigation and may become involved in other legal proceedings that arise from time to time in the future. For example, as discussed further in Note 8 to our Consolidated Financial Statements (as defined below), a putative securities class action lawsuit has been filed against the Company and certain current officers or former officers of the Company alleging violations of Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder.

Any claims against us, whether meritorious or not, can be time-consuming, result in costly litigation, be harmful to our reputation, require significant management attention, and divert significant resources. In addition, the expense of litigation and the timing of this expense from period to period are difficult to estimate and subject to change. Litigation and other claims are subject to inherent uncertainties and management's view of these matters may change in the future. Given the uncertain nature of legal proceedings generally, we are not able in all cases to estimate the amount or range of loss that could result from an unfavorable outcome. We could incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations in any particular period.

In addition, healthcare companies are subject to numerous investigations and inquiries by various governmental agencies. For example, as discussed further in Note 8 to our Consolidated Financial Statements, in March 2021, we received a grand jury subpoena from the U.S. Attorney's Office for the Northern District of California requesting information related to communications with the FDA and our Zio Systems, and, in October 2021, received a second subpoena requesting additional information. We continue to cooperate fully with the U.S. Attorney's Office and to provide any requested information in connection with this matter. Any future investigations of our executives, our managers, or our company could result in significant liabilities or penalties to us, as well as adverse publicity. Even if we are found to have complied with applicable law, the investigation or litigation may pose a considerable expense and would divert management's attention, and have a potentially negative impact on the public's perception of us, all of which could negatively impact our financial position and results of operations. Further, should we be found out of compliance with any of these laws, regulations, or programs, depending on the nature of the findings, our business, our financial position, and our results of operations could be negatively impacted.

Compliance with requirements of being a public company matters and reporting may strain our resources and divert management's attention.

As a public company, we are subject to laws and regulations relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the rules and regulations implemented by the SEC, and The Nasdaq Stock Market listing rules. Compliance with these laws and regulations, including new laws and regulations or revisions to existing laws and regulations, has required and will continue to require substantial management time and oversight and the incurrence of significant accounting and legal costs. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to continue to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

We could be subject to changes in our tax rates, new U.S. or international tax legislation, or additional tax liabilities.

We are subject to taxes in the United States and numerous foreign jurisdictions, where certain of our subsidiaries are organized. The tax laws in the United States and in other countries in which we and our subsidiaries do business could change on a prospective or retroactive basis, and any such changes could adversely affect our business and financial condition. Our effective tax rates could be affected by numerous factors, including changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, and changes in tax laws or their interpretation, both in and outside the United States.

For example, in 2017, the U.S. government enacted the TCJA, which made significant changes to the taxation of business entities, including a permanent reduction to the corporate income tax rate, changes in the taxation of foreign earnings, and limitations on the deductibility of expenses. Although we are still awaiting guidance from the Internal Revenue Service on how some of the TCJA changes will impact us, beginning in 2022, the TCJA eliminated the option to immediately deduct research and development expenditures and required taxpayers to amortize domestic expenditures over five years and foreign expenditures over fifteen years. While it is possible that Congress may modify or repeal this provision, we have no assurance that this provision will be modified or repealed and even if Congress makes any such decision, it may not be retroactive to January 1, 2022, and could still therefore result in an impact on cash from operating activities and on the balance of our deferred taxes. In addition, we have a significant presence in the United Kingdom, as well as significant sales in the United Kingdom, such that any changes in tax laws in the United Kingdom will impact our business. The overall impact of these changes is uncertain, and our business and financial condition could be adversely affected.

Our tax returns and other tax matters also are subject to examination by the U.S. Internal Revenue Service and other tax authorities and governmental bodies. We regularly assess the likelihood of an adverse outcome resulting from these examinations to determine the adequacy of our provision for taxes. We cannot guarantee the outcome of these examinations. If our effective tax rates were to increase, particularly in the United States, or in other jurisdictions implementing legislation to reform existing tax legislation, including the United Kingdom, or if the ultimate determination of our taxes owed is for an amount in excess of amounts previously accrued, our financial condition, operating results, and cash flows could be adversely affected.

We may be liable for contamination or other harm caused by materials that we handle, and changes in environmental regulations could cause us to incur additional expense.

Our research and development and manufacturing operations may involve the use or handling of hazardous materials. We are subject to a variety of federal, state, local, and international laws, rules, and regulations governing the use, handling, storage, disposal and remediation of hazardous and biological materials, as well as the sale, labeling, collection, recycling, treatment, and disposal of products containing such hazardous substances, and we incur expenses relating to compliance with these laws and regulations. If we violate environmental, health and safety laws, including as a result of human error, equipment failure, or other cases, we could face substantial liabilities, fines, and penalties, personal injury and third-party property damage claims, and substantial investigation and remediation costs. These expenses or this liability could have a significant negative impact on our financial condition. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We are subject to potentially conflicting and changing regulatory agendas of political, business, and environmental groups. Changes to or restrictions on the procedures for hazardous or biological material storage or handling might require unplanned capital investment or relocation of our facilities. Failure to comply, or the cost of complying, with new or existing laws or regulations could harm our business, financial condition, and results of operations.

Risks Related to Intellectual Property

We are subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from shipping affected devices, require us to obtain licenses from third parties or to develop non-infringing alternatives, and subject us to substantial monetary damages and injunctive relief.

We rely on a combination of patents, copyrights, trademarks, trade secret laws, and confidentiality and invention assignment agreements with employees and third parties to protect our intellectual property rights. Our patents and patent applications are directed to covering key aspects of the design, manufacture and use of our Zio Services, including our Zio Systems.

Third parties may assert infringement or misappropriation claims against us with respect to our current or future Zio Services, including our Zio Systems. We are aware of numerous patents issued to third parties that may relate to aspects of our business, including the design and manufacture of the Zio Systems used in connection with our Zio Services. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of such third parties or others. Our competitors may assert that our Zio Systems or the methods we employ to deliver our Zio Services are covered by U.S. or foreign patents held by them and we may be required to settle such allegations in the future. This risk is exacerbated by the fact that there are numerous issued patents and pending patent applications relating to remote cardiac monitoring services and the associated devices. There may be existing patents or patent applications now pending of which we are unaware that may later result in issued patents that our Zio Services, including our Zio Systems, inadvertently infringe. As the number of competitors in the remote cardiac monitoring market grows, the possibility of patent infringement by us or a patent infringement claim against us increases. If we are unable to successfully defend any such claims as they may arise or enter into or extend settlement and license agreements on acceptable terms or at all, our business operations may be harmed.

Any infringement or misappropriation claim could cause us to incur significant costs, place significant strain on our financial resources, divert management's attention from our business, and harm our reputation. In addition, if the relevant patents are upheld as valid and enforceable and we are found to infringe such patents, we could be prohibited from using any portion of our Zio Services, including our Zio Systems, that is found to infringe such patent unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain a license on terms acceptable to us, if at all, and we may not be able to redesign our Zio Services, including our Zio Systems, to avoid infringement. We may be unable to maintain or renew licenses on terms acceptable to us, if at all, and we may be prohibited from selling any portion of our Zio Services, including our Zio Systems, that required the technology covered by the relevant licensed patents. Although patent and intellectual property disputes in the healthcare and medical devices area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and would likely include ongoing royalties. Even if we are able to redesign our Zio Services, including our Zio Systems, to avoid an infringement claim, we may not receive FDA approval for such changes in a timely manner or at all.

Further, if we are found to infringe third-party patents, a court could order us to pay damages to compensate the patent owner for the infringement, such as a reasonable royalty amount and/or profits lost by the patent owners, along with prejudgment and/or post-judgment interest. Furthermore, if we are found to willfully infringe third-party patents, we could, in addition to other penalties, be required to pay treble damages; and if the court finds the case to be exceptional, we may be required to pay attorneys' fees for the prevailing party. If we are found to infringe third-party copyrights or trademarks or misappropriate third-party trade secrets, based on the intellectual property at issue, a court could order us to pay statutory damages, actual damages, or profits, such as reasonable royalty or lost profits of the owners, unjust enrichment, disgorgement of profits, and/or a reasonable royalty, and the court could potentially award attorneys' fees or exemplary or enhanced damages. If litigation were to be initiated by intellectual property owners, there could significant legal fees and costs incurred in defending litigation (which may include filing administrative actions to attack the intellectual property) as well as a potential monetary settlement payment to the owners, even if the matter is resolved before going to trial. Moreover, the owners may take an overly aggressive approach and/or include multiple allegations in a single litigation.

Our inability to adequately protect our intellectual property could allow our competitors and others to produce devices and offer services based on our technology, which could substantially impair our ability to compete.

Our success and our ability to compete depend, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patent, copyright, and trademark law, and trade secrets and nondisclosure agreements to protect our intellectual property. However, such methods may not be adequate to protect us or permit us to gain or maintain a competitive advantage.

For example, our patent applications may not issue as patents in a form that will be advantageous to us, or at all. Our issued patents, and those that may issue in the future, may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related devices and services. In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the USPTO, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. We also may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of invention assignment and confidentiality agreements and other contractual restrictions we include in contracts with such parties. These agreements may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that employees, consultants, vendors, and clients have executed such agreements or have not breached or will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. In addition, we rely on trademarks, service marks, trade names and brand names, such as our registered trademark "ZIO," to distinguish our products from the products of our competitors, and have registered or applied to register these trademarks. We cannot assure you that our trademark applications will be approved. Further, during trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Additionally, we are aware of at least one third party that has registered the "IRHYTHM" mark in the European Union in connection with computer software for controlling and managing patient medical information, heart rate monitors, and heart rate monitors to be worn during moderate exercise, among other uses. We and the third party are involved in adversary proceedings before the Trademark Office in the European Union, and those proceedings could impact our ability to obtain a European Union trade mark registration for the "IRHYTHM" mark, although we already own many national registrations for IRHYTHM in Europe.

To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties. The outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets, or trademarks is highly unpredictable, could result in substantial costs and diversion of resources, and could have a material adverse effect on our business, financial condition, and results of operations regardless of the final outcome of such litigation. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, or are invalid or unenforceable, and could award attorneys' fees.

Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not succeed in doing so or the steps taken by us in this regard may not be adequate to detect or deter misappropriation of our technology or to prevent an unauthorized third party from copying or otherwise obtaining and using our devices, technology or other information that we regard as proprietary. In addition, third parties may be able to design around our patents. Furthermore, the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the United States.

Risks Related to Privacy and Security

Cybersecurity risks, including those involving network security breaches and services interruptions, could result in the compromise of confidential data or critical data systems and give rise to potential harm to our patients, remediation and other expenses, expose us to liability under HIPAA, breach notification laws, consumer protection laws, or other common law theories, subject us to litigation and federal and state governmental inquiries, damage our reputation, and otherwise be disruptive to our business and operations.

Cybersecurity threats can come from a variety of sources, ranging in sophistication from an individual hacker to malfeasance by employees, consultants or other service providers to criminal or other unauthorized threat actors, including state-sponsored attacks. Unauthorized parties may also attempt to gain access to our systems or facilities through fraud, trickery or other forms of deceiving our employees, contractors and temporary staff. Cyber threats may be generic, or they may be custom-crafted against our information systems. Cyber incidents can result from deliberate attacks or unintentional events. Over the past several years, cyber-attacks have become more prevalent and much harder to detect and defend against. These threat actors may be able to penetrate our security measures, breach our information technology systems, misappropriate or compromise confidential and proprietary information of our company, customers, and patients, cause system disruptions and shutdowns, or introduce ransomware, malware, or vulnerabilities into our devices, systems, and networks or those of our partners. Our network and storage applications, as well as those of our contractors, may be vulnerable to cyber-attack, malicious intrusion, malfeasance, loss of data or other significant disruption and may be subject to unauthorized access by hackers, employees, consultants or other service providers. In addition, hardware, software or applications we develop or procure from third parties may contain defects in design or manufacture or other problems that could unexpectedly compromise information security or other problems that unexpectedly could interfere with our business operations. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and may not immediately produce signs of intrusion, we may be unable to anticipate these incidents or techniques, timely discover them, or implement adequate preventative measures.

We have in the past been subject to cyber-attacks and data breaches and expect that we will be subject to additional cyber-attacks in the future and may experience future data breaches. Such incidents may impact the integrity, availability or confidentiality of the sensitive data we maintain or disrupt our information systems, devices or business, including our ability to deliver our services. As a result, cybersecurity, physical security and the continued development and enhancement of our controls, processes and practices designed to protect our enterprise, information systems and data from attack, damage or unauthorized access remain a priority for us. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any cybersecurity vulnerabilities.

We are subject to complex and evolving U.S. and foreign laws and regulations and other requirements regarding privacy, data protection, security, and other matters. Many of these laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, monetary penalties, increased cost of operations, or declines in user growth or engagement, or otherwise harm our business.

In the ordinary course of our business, we collect and store sensitive data, such as our proprietary business information and that of our suppliers, contractors, customers, vendors and others, as well as personal information, including health information, of these parties and of our patients. As a result, we are subject to several foreign, federal and state laws and regulations protecting the use, disclosure and confidentiality of certain personal information, namely individually identifiable information (e.g., names, social security numbers, addresses, birth dates), and restricting the use and disclosure of that information. These laws include foreign, federal and state healthcare privacy laws, telehealth laws, breach notification laws and consumer protection laws. These frameworks impose stringent privacy and security standards and potentially significant non-compliance penalties and liability. Foreign data protection, privacy, and related laws and regulations can be more restrictive than those in the United States. For example, data localization laws in some countries generally mandate that certain types of data collected in a particular country be stored and/or processed solely within that country. In addition, both foreign and U.S. legislators and regulators may make legal and regulatory changes, or interpret and apply existing laws, in ways that require us to incur substantial costs, expose us to unanticipated civil or criminal liability, or cause us to change our business practices. These changes or increased costs could negatively impact our business and results of operations in material ways.

The secure maintenance, processing and transmission of this sensitive information is critical to our business operations, particularly as we are increasingly dependent on sophisticated information technology systems to operate our business. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud-based systems during or as a result of the COVID-19 pandemic, or failures to adequately scale our data platforms and architectures support patient care could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting. We have implemented multiple layers of security measures and monitoring to protect the confidentiality, integrity and availability of this data and the systems and devices that store and transmit such data. Despite our security measures and business controls, which undergo routine testing internally and by external parties, our information technology and infrastructure may be vulnerable to attacks by hackers, breaches due to employee, contractor or vendor error, or malfeasance or other disruptions or subject to the inadvertent or intentional unauthorized release of information. Any such occurrence could compromise our data centers and networks and the information stored thereon could be inappropriately accessed, publicly disclosed, lost or stolen. Further, any such access, disclosure or other loss of information could result in legal claims or proceedings, and liability under laws that protect the privacy of personal information and regulatory penalties, increase in operating expenses, incurrence of expenses, including notification and remediation costs, disrupt our operations and the services we provide to our clients or damage our reputation, any of which could adversely affect our profitability, revenue and competitive position.

Cyber-attacks aimed at accessing our devices and services, or related devices and services, and modifying or using them in a way inconsistent with our FDA clearances and approvals, could create risks to users.

Medical devices are increasingly connected to the Internet, hospital networks, and other medical devices to provide features that improve healthcare and increase the ability of healthcare providers to treat patients and of patients to manage their conditions. As such, cyber-attacks aimed at accessing our devices and services, or related devices and services, and modifying or using them in a way inconsistent with our FDA clearances and approvals, may create risks to users and potential exposure to the company.

Risks Related to Our Common Stock

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the analysts, or the content and opinions included in their reports. If any of the analysts who cover us issues an adverse or misleading opinion regarding us, our business model, our intellectual property, or our stock performance, or if any third-party preclinical studies and clinical trials involving our Zio Services or our results of operations fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

Our stock price is highly volatile and investing in our stock involves a high degree of risk, which could result in substantial losses for investors.

Historically, the market price of our common stock, like the securities of many other medical service providers that are public companies, has fluctuated. It is likely that our stock price will continue to be volatile in the future. In addition, the trading prices for our common stock and the common stocks of other medical service providers been highly volatile as a result of macroeconomic conditions, including inflation, rising interest rates, and the impacts of the ongoing COVID-19 pandemic and the war between Russia and Ukraine.

The market price of our common stock is influenced by many factors that are beyond our control, including the following:

- securities analyst coverage or lack of coverage of our common stock or changes in their estimates of our financial performance;
- variations in quarterly operating results;
- future sales of our common stock by our stockholders;
- investor perception of us and our industry;
- announcements by us or our competitors of significant agreements, acquisitions, or capital commitments or service or product launches or discontinuations;
- changes in market valuation or earnings of our competitors;
- negative business or financial announcements regarding our partners;
- general economic conditions;
- regulatory actions;
- legislation and political conditions;
- global health pandemics, such as the COVID-19 pandemic;
- terrorist acts, acts of war, or periods of widespread civil unrest, including the conflict in Ukraine and actions taken by third parties in response to such conflict; and
- general economic, industry, and market conditions, including inflation, rising interest rates, and foreign currency exchange rates.

Please also refer to the factors described elsewhere in this “Risk Factors” section. In addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated and disproportionate to the operating performance of companies in our industry. These broad market and industry factors may materially reduce the market price of our common stock, regardless of our operating performance.

Securities class action litigation has often been brought against public companies that experience periods of volatility in the market prices of their securities. Securities class action litigation could result in substantial costs and a diversion of our management’s attention and resources.

Anti-takeover effects of our charter documents and Delaware law could make a merger, tender offer, or proxy contest difficult, thereby depressing the trading price of our common stock.

There are provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions in the Delaware General Corporation Law ("DGCL"), that may discourage, delay, or prevent a change of control of our company that might otherwise be beneficial to stockholders. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. For example:

- our board of directors may, without stockholder approval, issue shares of preferred stock with special voting or economic rights;
- our stockholders do not have cumulative voting rights and, therefore, each of our directors can only be elected by holders of a majority of our outstanding common stock;
- a special meeting of stockholders may only be called by a majority of our board of directors, the chairman of our board of directors, our chief executive officer, or our president (in the absence of a chief executive officer);
- our stockholders may not take action by written consent; and
- we require advance notice for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

Moreover, Section 203 of the DGCL may discourage, delay, or prevent a change of control of our company. Section 203 imposes certain restrictions on mergers, business combinations, and other transactions between us and holders of 15% or more of our common stock.

The exclusive forum provision in our organizational documents may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims.

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a claim of breach of fiduciary duty owed by any director, officer, or other employee or agent of the company to us or our stockholders; any action asserting a claim against us arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act.

Notwithstanding the foregoing, our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder. Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions. The exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results, and financial condition.

We do not intend to pay dividends for the foreseeable future.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends on our capital stock in the foreseeable future. As a result, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

Risks Related to Our Debt

Increasing our financial leverage could affect our operations and profitability.

We are party to a Third Amended and Restated Loan and Security Agreement, dated as of October 23, 2018, with Silicon Valley Bank (as amended by the Second Amendment to Third Amended and Restated Loan and Security Agreement, dated as of March 28, 2022, the "SVB Loan Agreement"), which provides for a (i) a revolving line of credit in the aggregate principal amount of up to $25.0 million and (ii) a term loans facility in the aggregate principal amount of up to $75.0 million. As of December 31, 2022, we had nothing outstanding under the revolving credit line and $35.0 million outstanding under the term loans.

Our leverage ratio, combined with our other financial obligations and contractual commitments, may affect our ability to obtain additional capital resources as well as our operations in several ways, including:

- the possible lack of availability of additional credit;
- the terms on which credit may be available to us could be less attractive, both in the economic terms of the credit and the legal covenants;
- the potential for higher levels of interest expense to service or maintain our outstanding debt;
- the possibility that we are required to incur additional debt in the future to repay our existing indebtedness when it comes due;
- the possibility that our level of indebtedness make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry, and competitive conditions and adverse changes in government regulation;
- limiting our ability to borrow additional amounts to fund acquisitions, for working capital, and for other general corporate purposes;
- the possible diversion of capital resources from other uses; and
- making an acquisition of our company less attractive or more difficult.

Any of these factors could harm our business, results of operations, and financial condition. While we believe we will have the ability to service our obligations under the SVB Loan Agreement and obtain additional financing in the future if and when needed, that will depend upon our results of operations and financial position at the time, the then-current state of the credit and financial markets, and other factors that may be beyond our control. Therefore, we cannot give assurances that sufficient credit will be available on terms that we consider attractive, or at all, if and when necessary or beneficial to us.

Failure to comply with covenants in the SVB Loan Agreement could result in our inability to borrow additional funds and adversely impact our business.

The SVB Loan Agreement imposes numerous financial and other restrictive covenants on our operations, including financial covenants. As of December 31, 2022, we were in material compliance with the covenants imposed by the SVB Loan Agreement. If we violate these or any other covenants under the SVB Loan Agreement or fail to make payments in connection therewith, Silicon Valley Bank could declare an event of default, which would give it the right to terminate its commitment to provide additional loans and declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, Silicon Valley Bank would have the right to proceed against the assets we provided as collateral pursuant to the loan. Any of the foregoing may limit our ability to borrow additional funds and pursue other business opportunities or strategies that we would otherwise consider to be in our best interests.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the SVB Loan Agreement, depends on our future financial condition and operating performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to satisfy our obligations under the SVB Loan Agreement and any future indebtedness we may incur and to make necessary capital expenditures.

If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as reducing or delaying investments or capital expenditures, selling assets, refinancing, or obtaining additional equity capital on terms that may be onerous or highly dilutive. These alternative measures may not be successful and may not permit us to meet our scheduled debt servicing obligations. Further, we may need to refinance all or a portion of our debt on or before maturity, and our ability to refinance the SVB Loan Agreement or any future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities on commercially reasonable terms or at all, which could result in a default under the SVB Loan Agreement or any future indebtedness.

General Risk Factors

We may be impacted by domestic and global economic and political conditions, as well as natural disasters, pandemics, and other catastrophic events, which could adversely affect our business, financial condition or results of operations.

Our operations and performance may vary based on worldwide economic and political conditions, which have been adversely impacted by continued global economic uncertainty, political instability, and military hostilities in multiple geographies, including the COVID-19 pandemic, the ongoing military conflict between Russia and Ukraine, domestic and global inflationary trends, rising interest rates, global supply shortages, and a tightening labor market. For example, we have experienced staff shortages at our contact centers as a result of the COVID-19 pandemic and federal, state and local responses thereto. A severe or prolonged economic downturn or period of global political instability could drive hospitals and other healthcare professionals to tighten budgets and curtail spending, which could in turn negatively impact rates at which physicians prescribe our Zio Services. In addition, higher unemployment rates or reductions in employer-provided benefits plans could result in fewer commercially insured patients, resulting in a reduction in our margins and impairing the ability of uninsured patients to make timely payments. A weak or declining economy could also strain our suppliers, possibly resulting in supply delays and disruptions. There is also a risk that one or more of our current service providers, suppliers, or other partners may not survive such difficult economic times, which could directly affect our ability to attain our goals on schedule and on budget. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. We cannot predict the timing, strength, or duration of an economic downturn, instability, or recovery, whether worldwide, in the United States, or within our industry.

In addition, climate-related events, including the increasing frequency of extreme weather events, natural disasters, or other catastrophic events may cause damage or disruption to our operations, international commerce, and the global economy, and could have an adverse effect on our business, operating results, and financial condition. In the event of a natural disaster, including a major earthquake, blizzard, or hurricane, or a catastrophic event such as a fire, power loss, cyberattack, or telecommunications failure, we may be unable to continue our operations and may endure system and service interruptions, reputational harm, delays in development of our Zio Systems and Zio Services, breaches of data security, and loss of critical data, all of which could cause us to experience higher attrition, losses, and additional costs to maintain or resume operations, or otherwise have an adverse effect on our business and operating results. Further, we do not maintain insurance sufficient to compensate us for the potentially significant losses that could result from disruptions to our services. Additionally, all the aforementioned risks may be further increased if our or our partners' disaster recovery plans are inadequate.

Environmental, social, and corporate governance ("ESG") regulations, policies, and provisions may make our supply chain more complex and may adversely affect our relationships with customers.

There is an increasing focus from certain investors, physicians, patients, employees, and other stakeholders concerning corporate citizenship and sustainability matters and the governance of environmental and social risks. An increasing number of participants in the medical services industry are joining voluntary ESG groups or organizations, such as the Responsible Business Alliance. These ESG provisions and initiatives are subject to change, can be unpredictable, and may be difficult and expensive for us to comply with, given our reliance on our supply chain and the outsourced manufacturing of certain components and sub-assemblies of the Zio Systems used with our Zio Services.

Further, we have in the past and may continue to communicate certain initiatives, including goals, regarding environmental matters, responsible sourcing and social investments. We could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could fail in fully and accurately reporting our progress on such initiatives and goals. In addition, we could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly in connection with these matters.

If we are not effective in addressing ESG matters affecting our business, or setting and meeting relevant ESG goals, our reputation and financial results may suffer.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 2. PROPERTIES

We currently lease approximately 117,600 square feet for our corporate headquarters located in San Francisco, California under a twelve-year lease term which will expire in September 2031. In the United States, we also lease (i) approximately 44,600 square feet in Deerfield, Illinois, for our corporate office under a lease agreement that will expire in June 2033, (ii) approximately 20,300 square feet in Houston, Texas for a clinical center under a lease agreement that will expire on October 2027, (iii) approximately 68,900 square feet in Cypress, California for our office and manufacturing facilities under a lease agreement that will expire in April 2032, (iv) approximately 3,200 square feet in Encinitas, California for office space under a lease agreement that will expire in February 2024.

We lease approximately 9,000 square feet of office space in London, U.K. under a lease agreement that will expire in January 2029.

We believe that these facilities are sufficient to meet our current and anticipated future needs.

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we are involved in claims and legal proceedings or investigations, that arise in the ordinary course of business. Such matters could have an adverse impact on our reputation, business, and financial condition and divert the attention of our management from the operation of our business. These matters are subject to many uncertainties and outcomes that are not predictable.

On February 1, 2021, a putative class action lawsuit was filed in the United States District Court for the Northern District of California (the "Court") alleging that we and our former Chief Executive Officer, Kevin M. King, violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder ("Securities Class Action Lawsuit"). On August 2, 2021, the lead plaintiff filed an amended complaint, and filed a further amended complaint on September 24, 2021. The amended complaint names as defendants, in addition to us and Mr. King, our former Chief Executive Officer, Michael J. Coyle, and former Chief Financial Officer and current Chief Operating Officer, Douglas J. Devine. The purported class in the amended complaint includes all persons who purchased or acquired our common stock between August 4, 2020 and July 13, 2021, and seeks unspecified damages purportedly sustained by the class. On October 27, 2021, we filed a motion to dismiss the amended complaint. The motion to dismiss was fully briefed and the Court held a hearing on the motion on February 4, 2022, after which the Court took the matter under submission. On March 31, 2022, the Court issued an order granting our motion to dismiss the Securities Class Action Lawsuit, without allowing plaintiff further leave to amend, and entered judgment in favor of us and the other defendants. On April 29, 2022, the plaintiff that filed the initial complaint in the action filed a notice of appeal. On September 7, 2022, the plaintiff-appellant filed its opening brief, and we filed a motion to dismiss for lack of standing to appeal and Article III standing on September 27, 2022. On October 17, 2022, the plaintiff filed its response to our motion to dismiss, and we filed our reply in support of the motion to dismiss on November 3, 2022. Our motion to dismiss the appeal was denied without prejudice on December 8, 2022. We filed our responding brief on the appeal on February 16, 2023. We believe the Securities Class Action Lawsuit to be without merit and plan to defend ourselves vigorously.

On March 26, 2021, we received a grand jury subpoena from the U.S. Attorney's Office for the Northern District of California requesting information related to communications with the Food and Drug Administration and our products. On September 14, 2021, we received a second subpoena requesting additional information. We are cooperating fully and are providing the requested information.

At this time, we are unable to predict the eventual scope, duration or outcome of the aforementioned proceedings. See also Part I, Item 1A "Risk Factors — Risks Related to Other Legal and Regulatory Matters" for more information on these matters.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information for Common Stock

Our common stock is traded on The Nasdaq Global Select Market under the symbol "IRTC" and began trading on October 20, 2016. Prior to that, there was no public trading market for our common stock.

As of February 16, 2023, there were 420 holders of record of our common stock. Certain shares are held in "street" name and, accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number.

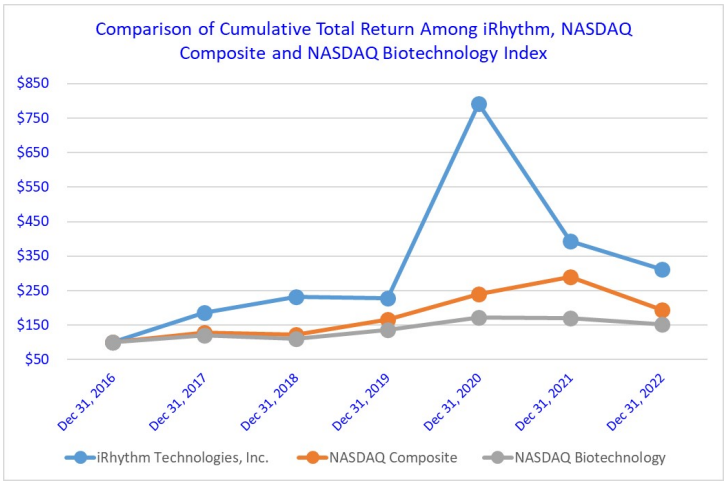
Dividend Policy

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

Performance Graph

This graph is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference into any filing of iRhythm Technologies, Inc. under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph shows the total stockholder return of an investment of $100 in cash at market close on December 31, 2016, through December 31, 2022 for (i) our common stock, (ii) the NASDAQ Composite Index (U.S.) and (iii) the NASDAQ Biotechnology Index. Pursuant to applicable Securities and Exchange Commission rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



	12/31/2016	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022
iRhythm Technologies, Inc.	$ 100	$ 187	$ 232	$ 227	$ 791	$ 392	$ 312
NASDAQ Composite	$ 100	$ 128	$ 123	$ 167	$ 239	$ 291	$ 194
NASDAQ Biotechnology	$ 100	$ 121	$ 110	$ 137	$ 172	$ 171	$ 152

Securities Authorized for Issuance under Equity Compensation Plans

Information regarding our equity compensation plans and the securities authorized for issuance thereunder is set forth in Part III, Item 12 of this Annual Report on Form 10-K.

Recent Sales of Unregistered Equity Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion and analysis of our financial condition and results of operations together with the financial statements and related notes included elsewhere in Item 8 of Part II of this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this Annual Report on Form 10-K entitled "Risk Factors."

Overview

We are a leading digital healthcare company that creates trusted solutions that detect, predict, and prevent disease. Our principal business is the design, development, and commercialization of device-based technology to provide remote cardiac monitoring services that we believe allow clinicians to diagnose certain arrhythmias quicker and with greater efficiency than other services that rely on traditional technology.

Each Zio System combines FDA-cleared and CE-marked, wire-free, patch-based, 14-day wearable biosensor that continuously records ECG data with a proprietary cloud-based data analytic software to help physicians monitor patients and diagnose arrhythmias. Since receiving FDA clearance, we have provided the Zio Services to over five million patients and have collected over one billion hours of curated heartbeat data.

Since first receiving clearance from the FDA for our technology in 2009, we have supported physician and patient use of our technology and provided remote cardiac monitoring services from our Medicare-enrolled IDTFs and our qualified technicians. We have provided our Zio Services using our Zio Systems.

We receive revenue for the Zio Services primarily from third-party payors, which include contracted third-party payors and the CMS. The remainder of our revenue comes from healthcare institutions, which are typically hospitals or private physician practices, who purchase the Zio Services from us directly. We rely on third-party billing partners to submit patient claims and collect from commercial payors, certain government agencies, and patients.

The following are Zio Services shown as a percentage of revenue:

	Year Ended December 31,		
	2022	2021	2020
Contracted third-party payors	55 %	60 %	51 %
Centers for Medicare and Medicaid	25 %	14 %	27 %
Healthcare institutions	14 %	18 %	16 %
Non-contracted third party payors	6 %	8 %	6 %

Key Business Metric

Non-GAAP Financial Measure

Adjusted EBITDA is a key measure we use to assess our financial performance and it is also used for internal planning and forecasting purposes. We believe Adjusted EBITDA is helpful to investors, analysts and other interested parties because it can assist in providing a more consistent and comparable overview of our operations across our historical financial periods. In addition, this measure is frequently used by analysts, investors and other interested parties to evaluate and assess performance.

We define Adjusted EBITDA for a particular period as net loss or income before interest, taxes, depreciation and amortization, interest expense and interest income and as further adjusted for stock-based compensation expense, impairment and restructuring charges and transformation costs.

Adjusted EBITDA is a non-GAAP financial measure and is presented for supplemental informational purposes only and should not be considered as an alternative or substitute to financial information presented in accordance with GAAP. This measure has certain limitations in that it does not include the impact of certain expenses that are reflected in our consolidated statements of operations that are necessary to run our business. Other companies, including other companies in our industry, may not use this measure or may calculate this measures differently than as presented in this Annual Report on Form 10-K, limiting their usefulness as a comparative measure.

The following table presents a reconciliation of net loss, the most directly comparable financial measure calculated in accordance with GAAP, to Adjusted EBITDA (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Net loss	$ (116,155)	$ (101,361)	$ (43,830)
Income tax provision	269	367	229
Depreciation and amortization	13,405	9,842	6,900
Interest expense	4,138	1,169	1,519
Interest income	(2,350)	(249)	(1,138)
Stock-based compensation	57,740	54,527	41,515
Impairment and restructuring charges	26,608	—	—
Transformation costs	5,082	—	—
Adjusted EBITDA	$ (11,263)	$ (35,705)	$ 5,195

Macroeconomic Factors and the Effects of COVID-19

Our future results of operations and liquidity could be materially adversely affected by macroeconomic factors contributing to delays in payments of outstanding receivables, supply chain disruptions, including shortages and inflationary pressure, uncertain or reduced demand, and the impact of any initiatives or programs that we may undertake to address financial and operational challenges faced by our customers.

We have experienced business disruptions affecting the availability and cost of materials, which has impacted our supply chain and reduced margins, from the COVID-19 pandemic. In addition, we have continued to deliver our Zio Services by operating with remote employees and essential employees on site.

The current macroeconomic environment is impacting our customers, both financially and operationally. Hospitals are experiencing staffing shortages and supply chain issues that could affect their ability to provide patient care. Additionally, hospitals are facing significant financial pressure as supply chain constraints and inflation drive up operating costs, rising interest rates make access to credit more expensive, unrealized losses decrease available cash reserves, and fiscal stimulus programs enacted during the COVID-19 pandemic wind down. As a consequence of the financial pressures and decreased profitability, some hospitals have indicated that they are lowering their capital investment plans and tightening their operational budgets.

We have adapted our Zio Services to meet the immediate needs of physicians, customers, and patients and significantly increased the utilization of our home enrollment service, which allows patients to receive and wear the single-use Zio patch without going to a healthcare facility.

In the first quarter of 2022, we re-opened our offices for use and certain groups of employees have begun returning to work in our offices across the United States. We continue to monitor developments regarding health pandemics or other health concerns, including COVID-19, and will implement any additional safety protocols that may become necessary in the future.

Our remote work arrangements subsequent decision to pursue a sublease for the 5th floor of our San Francisco headquarters caused us to recognize an impairment on our right of use asset and related leasehold improvements and furniture and fixtures and we believe we may incur additional impairment charges related to our real property lease agreements.

Revenue

The majority of our revenue is derived from provision of our Zio Services to customers in the United States. We earn revenue from the provision of our Zio Services primarily from contracted third-party payors, CMS and healthcare institutions. A small percentage of our revenue is from non-contracted third-party payors.

We recognize revenue on an accrual basis based on estimates of the amount that will ultimately be realized, which is the difference between the amount submitted for payment and the amount received. These estimates require significant judgment by management. In determining the amount to accrue for the Zio Services (including a delivered report), we consider factors such as claim payment history from both payors and patient, available reimbursement, including whether there is a contract between us and the payor or healthcare institution and historical amount received for the service, and any current developments or changes that could impact reimbursement and healthcare institution payments.

We typically experience reduced revenue during the third quarter, as well as during the year-end holiday season. We believe this is the result of physicians and patients taking vacations and patients electing to delay our monitoring services during the summer months or holidays. Revenue may be impacted by the outcome of adjudications with contracted and non-contracted payors, as well as changes in CMS reimbursement rates like we experienced with final rates being established for our Zio Services as of January 1, 2023. Clinical capacity limitations may also restrict our ability to complete the performance obligations to achieve revenue recognition.

Cost of Revenue and Gross Margin

Cost of revenue includes direct labor, material costs, equipment and infrastructure expenses, amortization of internal-use software, allocated overhead, and shipping and handling. Direct labor includes payroll-related costs including stock-based compensation involved in manufacturing, clinical data curation, and customer service. Material costs include both the disposable materials costs of the Zio patches and amortization of the re-usable printed circuit board assemblies (“PCBAs”). Each Zio XT patches includes a PCBA, and each Zio AT patch includes a PCBA and gateway board, the cost of which is amortized over the anticipated number of uses of the board. We expect cost of revenue to increase in absolute dollars as our revenue increases due to increased direct labor, direct materials, and variable spending, partially offset by economies of scale in relation to fixed costs such as overhead, depreciation and amortization, and facilities costs.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, including increased contracting with third-party payors and institutional providers. We have in the past been able to increase our pricing as third-party payors become more familiar with the benefits of the Zio Services and move to contracted pricing arrangements. We expect to continue to decrease the cost of revenue per device by obtaining volume purchase discounts for our material costs, implementing scan-time algorithms and process improvements, automating manufacturing assembly and packaging, and through software-driven and other workflow enhancements to reduce labor costs. These decreases may be offset by increases to materials and electronics components pricing, labor rates, shipping rates, depreciation and amortization of investments, and increases in the general level of inflation.

Research and Development Expenses

We expense research and development costs as they are incurred. Research and development expenses include payroll-related costs, including stock-based compensation, consulting services, clinical studies, laboratory supplies and allocated facility overhead costs. In addition, we expense milestone payments, when probable, for the development agreement with Verily. We expect our research and development costs to increase in absolute dollars as we hire additional personnel to develop new product and service offerings, product enhancements, and clinical evidence.

Selling, General and Administrative Expenses

Our sales and marketing expenses consist of payroll-related costs, including stock-based compensation, sales commissions, travel expenses, consulting, public relations costs, direct marketing, tradeshow and promotional expenses, and allocated facility overhead costs.

Our general and administrative expenses consist primarily of payroll-related costs for executive, finance, legal and administrative personnel, including stock-based compensation. Other significant expenses include professional fees for legal and accounting services, consulting fees, recruiting fees, bad debt expense, third-party patient claims processing fees, and travel expenses. In addition, we incurred transformation costs to scale our organization during the year and expect to incur additional transformation costs throughout 2023 with the restructuring activities to be substantially complete by mid-2024. Upon completion, we expect to achieve operational efficiencies in our administrative expenses.

Interest expense is attributable to borrowings under our loan agreements. See Note 9, Debt, in the Notes to our consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K (the "Consolidated Financial Statements") for further information on our loan agreements.

Other Income (Expense), Net

Other income, net consists primarily of interest income which consists of interest received on our cash and cash equivalents and short-term investments and foreign exchange gain or loss from our UK subsidiary.

Results of Operations

The following table sets forth, for the years indicated, certain Consolidated Statements of Income information (in thousands, except percentages):

	Year Ended December 31,					
	2022	% Revenue	2021	% Revenue	2020	% Revenue
	(dollars in thousands, except percentages)					
Revenue	$ 410,921	100 %	$ 322,825	100 %	$ 265,166	100 %
Cost of revenue	129,289	31 %	109,258	34 %	70,277	27 %
Gross profit	281,632	69 %	213,567	66 %	194,889	73 %
Operating expenses:						
Research and development	46,610	11 %	38,671	12 %	41,329	16 %
Selling, general and administrative	322,198	78 %	274,839	85 %	197,233	74 %
Impairment and restructuring charges	26,608	6 %	—	— %	—	— %
Total operating expenses	395,416	96 %	313,510	97 %	238,562	90 %
Loss from operations	(113,784)	(28)%	(99,943)	(31)%	(43,673)	(16)%
Interest expense	(4,138)	(1)%	(1,169)	— %	(1,519)	(1)%
Other income (expense), net	2,036	— %	118	— %	1,591	1 %
Loss before income taxes	(115,886)	(28)%	(100,994)	(31)%	(43,601)	(16)%
Income tax provision	269	— %	367	— %	229	— %
Net loss	$ (116,155)	(28)%	$ (101,361)	(31)%	$ (43,830)	(17)%

Comparison of the Years Ended December 31, 2021, and 2020

For discussion related to the results of operations and changes in financial condition for fiscal 2021 compared to fiscal 2020 refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of our 2021 Annual Report on Form 10-K, which was filed with the SEC on February 28, 2022.

Comparison of the Years Ended December 31, 2022, and 2021

	Year Ended December 31,			
	2022	2021	Change	% Change
	(dollars in thousands, except percentages)			
Revenue	$ 410,921	$ 322,825	$ 88,096	27 %
Cost of revenue	129,289	109,258	20,031	18 %
Gross profit	281,632	213,567	68,065	32 %
Operating expenses:				
Research and development	46,610	38,671	7,939	21 %
Selling, general and administrative	322,198	274,839	47,359	17 %
Impairment and restructuring charges	26,608	—	26,608	100 %
Total operating expenses	395,416	313,510	81,906	26 %
Loss from operations	(113,784)	(99,943)	(13,841)	14 %
Interest expense	(4,138)	(1,169)	(2,969)	254 %
Other income (expense), net	2,036	118	1,918	1625 %
Loss before income taxes	(115,886)	(100,994)	(14,892)	15 %
Income tax provision	269	367	(98)	(27)%
Net loss	$ (116,155)	$ (101,361)	$ (14,794)	15 %

Revenue

Revenue increased $88.1 million, or 27%, to $410.9 million during the year ended December 31, 2022 from $322.8 million during the year ended December 31, 2021. The increase in revenue was primarily attributable to the increase in volume of the Zio Services provided as a result of increased demand and improved CMS reimbursement rates, partially offset by an increase in contractual allowance with contracted and non-contracted payors.

Cost of Revenue and Gross Margin

Cost of revenue increased $20.0 million, or 18%, to $129.3 million during the year ended December 31, 2022 from $109.3 million during the year ended December 31, 2021. The increase in cost of revenue was primarily due to higher volume of Services provided, higher material and freight costs, and an increase in amortization for capitalized internal-use software.

Gross margin for the year ended December 31, 2022 increased to 69%, compared to 66% for the year ended December 31, 2021. The increase in gross margin was primarily due to higher per unit average selling prices and lower fixed costs per unit driven by higher unit volumes, partially offset by higher material and freight costs.

Research and Development Expenses

Research and development expenses increased $7.9 million, or 21%, to $46.6 million during the year ended December 31, 2022 from $38.7 million during the year ended December 31, 2021. The increase was primarily attributable to an increase of $13.6 million in payroll-related costs, including stock-based compensation, an increase of $1.8 million in consulting fees, partially offset by an increase of $6.8 million in costs capitalized for internal-use software and a decrease of $3.0 million from a milestone payment pursuant to the Development Agreement with Verily incurred during the year ended December 31, 2021 and none incurred during the year ended December 31, 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $47.4 million, or 17%, to $322.2 million during the year ended December 31, 2022 from $274.8 million during the year ended December 31, 2021. The increase was primarily attributable to an increase of $16.7 million in professional service fees, an increase of $13.6 million in payroll related costs, including employee stock-based compensation as a result of increased headcount and executive hires to support the growth in our operations, an increase of $7.6 million of bad debt expense related to revenue growth.$7.5 million of travel, and general office expenses and an increase of $1.8 million related to software and hardware costs.

Impairment and Restructuring Charges

In February 2022, our board of directors (the “Board”) approved reducing our leased space for our headquarters in San Francisco, California. As a result, we recognized an impairment of our right-of-use ("ROU") asset and related leasehold improvements and furniture and fixtures in the amount of $23.2 million during the year ended December 31, 2022. Also in February 2022, the Board approved a restructuring plan to allow the Company to effectively and efficiently scale its business, which resulted in severance and other employment related costs of $3.4 million during the year ended December 31, 2022.

Interest expense and other income (expense), net

Interest expense increased by $3.0 million to $4.1 million during the year ended December 31, 2022 from $1.2 million during the year ended December 31, 2021 due to the additional financing fees of $1.75 million related to the payment of the original loans as well as higher interest expense from the higher term loans balance in 2022 and due to higher interest rates.

Other income (expense), net increased by $1.9 million to $2.0 million for the year ended December 31, 2022, compared to $0.1 million for the year ended December 31, 2021. The increase is primarily due to higher interest earned because of rising interest rates from our cash and cash equivalents and short-term investments during the year ended December 31, 2022.

Liquidity and Capital Expenditures

Overview

As of December 31, 2022, we had cash and cash equivalents of $78.8 million, short-term investments of $134.3 million, and accounts receivable of $49.9 million. In addition, we have term loans facility of $40.0 million and a revolving credit line of $25.0 million available. We are continuously reviewing our liquidity and anticipated capital requirements in light of the significant uncertainty created by the current macroeconomic environment, including inflation and rising interest rates, and the COVID-19 global pandemic. We believe that our current cash, cash equivalents, short-term investment balances, and term loans facility, together with income to be derived from the sales of our Zio Services, will be sufficient to meet our liquidity requirements for the foreseeable future.

Our expected future capital requirements may depend on many factors, including the expansion of our customer base, the expansion of our sales force, and the timing and extent of spending on the development of our technology to increase our service offerings. We expect the next Verily milestone payment of $1.75 million to be due in 2023.

The following table summarizes our cash flows for the years indicated (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Net cash (used in) provided by:			
Operating activities	$ (23,012)	$ (37,753)	$ (13,759)
Investing activities	(52,434)	105,264	(132,391)
Financing activities	26,716	(28,577)	214,316
Net (decrease) increase in cash and cash equivalents	$ (48,730)	$ 38,934	$ 68,166

Operating Activities

During the year ended December 31, 2022, cash used in operating activities was $23.0 million and consisted of a net loss of $116.2 million, adjusted by non-cash charges of $158.7 million and a net change of $65.5 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of stock-based compensation expense of $57.7 million, a change in allowance for doubtful accounts and contractual allowance of $58.3 million, depreciation and amortization expense of $13.4 million and amortization of ROU assets of $6.2 million. The change in our net operating assets and liabilities was primarily due to an increase of $61.8 million in accounts receivable, an increase of $5.1 million in inventory, and a decrease in accounts payable of $3.0 million, partially offset by an increase in accrued liabilities of $14.5 million due to increased compensation and benefit accruals as a result of increased head count.

During the year ended December 31, 2021, cash used in operating activities was $37.8 million and consisted of a net loss of $101.4 million, adjusted by non-cash charges of $109.8 million and a net change of $46.2 million in our net operating assets and liabilities. The non-cash charges are primarily comprised of stock-based compensation expense of $54.5 million, a change in allowance for doubtful accounts and contractual allowance of $37.1 million, depreciation and amortization expense of $9.8 million, and amortization of ROU assets of $6.8 million. The change in our net operating assets and liabilities was primarily due to an increase of $53.6 million in accounts receivable, an increase of $5.0 million in inventory and an increase of $4.1 million in prepaid assets and other assets, partially offset by a decrease of $7.9 million in accrued liabilities and a decrease of $6.1 million in accounts payable.

Investing Activities

During the year ended December 31, 2022, cash used in investing activities was $52.4 million, and consisted primarily of $188.6 million in purchases of short-term investments and $29.8 million of capital expenditures to purchase property and equipment, partially offset by $166.0 million received from the sale and maturities of short-term investments.

During the year ended December 31, 2021, cash provided by investing activities was $105.3 million, which consisted primarily of $255.5 million in maturities of short-term investments, partially offset by $122.2 million in purchases of short-term investments and $28.1 million of capital expenditures to purchase property and equipment.

Financing Activities

During the year ended December 31, 2022, cash provided by financing activities was $26.7 million, primarily due to $35.0 million proceeds of a term loans and $13.2 million in proceeds from the issuance of common stock in connection with employee option exercises and our Employee Stock Purchase Plan, partially offset by a $21.4 million repayment of a long-term debt.

During the year ended December 31, 2021, cash used in financing activities was $28.6 million, primarily due to $25.9 million in tax withholding upon the vesting of restricted stock units (“RSUs”) and $11.7 million in repayment of long-term debt, partially offset by $8.9 million in proceeds from the issuance of common stock in connection with employee option exercises and our Employee Stock Purchase Plan.

Indebtedness

Bank Debt

In October 2018, we entered into the Third Amended and Restated Loan and Security Agreement with SVB. Under the SVB Loan Agreement, we had borrowed $35.0 million and had made repayments through March 2022, at which time the outstanding balance was $18.5 million.

On March 28, 2022, we entered into a Second Amendment (the "2022 Amendment") to our SVB Loan Agreement which provided for a term loans facility in the aggregate principal amount of up to $75.0 million (the "2022 Term Loans"), of which $35.0 million was borrowed at closing and a portion of the proceeds was used to pay in full the outstanding balance of $18.5 million under the SVB Loan Agreement. The remaining $40.0 million of 2022 Term Loans may be borrowed from time to time at our option, in increments of at least $10.0 million, through December 31, 2023. We will pay interest only on the 2022 Term Loans until April 1, 2025, when we will commence repaying the 2022 Term Loans in 24 equal consecutive monthly installments, with all obligations under the 2022 Term Loans maturing on March 1, 2027. Interest charged on the 2022 Term Loans will accrue at a floating per annum rate equal to the greater of: (A) the Prime Rate plus 0.25%; and (B) 3.50%. We are also required to pay fees on any prepayment of the 2022 Term Loans, ranging from 3.0% to 1.0% depending on the date of prepayment, and a final payment equal to 5.0% of the principal amount of the 2022 Term Loans drawn. Once repaid or prepaid, the 2022 Term Loans may not be reborrowed.

The 2022 Amendment also amended the terms of the revolving credit line under the SVB Loan Agreement, which provided for an aggregate principal amount of $25.0 million, to: (i) extend the maturity date from August 1, 2023 to March 1, 2027, (ii) increase the letters of credit sublimit to $15.0 million and (iii) increase the cash management services sublimit to $15.0 million. Interest charged on the principal amount outstanding under the revolving credit line will accrue at a floating per annum rate equal to the greater of (A) the Prime Rate plus 0.25% and (B) 3.50%. We are required to pay an annual fee equal to 0.15% of the revolving credit line. As of December 31, 2022, no loans were outstanding under the revolving credit line.

The 2022 Amendment also amended the SVB Loan Agreement to require us to comply, as of the last day of each fiscal quarter, with a quick ratio of at least 1.15 to 1.0 or minimum adjusted EBITDA trailing six months of at least $15.0 million We were in compliance with its loan covenants as of December 31, 2022.

Critical Accounting Policies and Estimates

Our Consolidated Financial Statements are prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"), which requires us to make judgments, estimates, and assumptions. See Note 2, Summary of Significant Accounting Policies, in the Notes to the Consolidated Financial Statements, which describes our significant accounting policies and methods used in the preparation of our Consolidated Financial Statements. The methods, estimates, and judgments that we use in applying our accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates regarding matters that are inherently uncertain. Our most critical accounting estimates include:

- Revenue recognition;
- Assessment of collectability of accounts receivable which results in uncollectible allowance for doubtful accounts and contractual allowances;
- How many times a PCBA can be used for testing in research and development, loss rates, product obsolescence, and the amount of time it takes the device to go through the manufacturing, shipping, customer shelf, and patient wear time and upload process;
- Stock-based compensation; and
- Lease impairment.

Revenue Recognition

We have developed a proprietary system that combines an FDA-cleared and CE-marked wire-free, patch-based, 14-day wearable biosensor that continuously records ECG data, with a proprietary cloud-based data analytic platform to help physicians monitor patients and diagnose arrhythmias. We currently offer three Zio System options—the Zio XT System, the Zio AT System, and the Zio Monitor System.

The Zio XT System is a prescription-only, remote ECG monitoring system that consists of the Zio XT patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio XT patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm. The final step in the Zio Services is the delivery of an electronic Zio report to the prescribing physician with a summary of findings. Our Zio XT services are generally billable when the Zio report is issued to the physician.

The Zio Monitor System is the next generation of the Zio XT System, and is a prescription-only, remote ECG monitoring system that consists of the Zio Monitor patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio Monitor patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm.

The Zio AT System is a prescription-only, remote ECG monitoring system that similarly consists of the Zio AT patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, but which also incorporates the Zio AT wireless gateway that provides connectivity between the patch and the ZEUS System during the patient wear period. The wireless gateway, slightly larger than a smart phone, is provided to the patient at the time of Zio AT patch application and collects and transmits data from the Zio AT patch to the cloud via a LTE protocol. The Zio AT service revenue is recognized over the patient wear period and delivery of electronic Zio reports with two performance obligations.

We account for contract revenue with a customer when there is a legally enforceable contract between us and the customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. Our revenue is measured based on consideration specified in the contract with each customer. A unique aspect of healthcare is the involvement of multiple parties to the service transaction. In addition to the patient, often a third-party, for example a commercial or governmental payor or healthcare institution, like a hospital or clinic, will pay us for some or all of the service on the patient's behalf. Separate contractual arrangements exist between us and many third-party payors that establish amounts the third-party payor will pay on behalf of a patient for covered services rendered and should be considered in determining collectability and the transaction price for services provided to a patient covered by that third-party payor.

We recognize revenue on an accrual basis based on estimates of the amount that will ultimately be realized, which is the difference between the amount submitted for payment and the amount received. Revenue recognition is subject to uncertainty because these estimates require significant judgment by management. In determining the amount to accrue for a delivered Zio report, we consider factors such as claim payment history from both payors and patient out-of-pocket costs, payor coverage, whether there is a contract between the payor or healthcare institution and us, historical amount received for the service, and any current developments or changes that could impact reimbursement and healthcare institution payments.

A summary of the payment arrangements with third-party payors and healthcare institutions is as follows:

- Contracted third-party payors – We have contracts with negotiated prices for services provided for patients with commercial healthcare insurance carriers.

- Centers for Medicare and Medicaid Services – We have received IDTF approval from regional Medicare Administrative Contractors and will receive reimbursement per the relevant CPT code rate for the services rendered to the patient covered by CMS.

- Healthcare institutions – Healthcare institutions are typically hospitals or physician practices in which we have negotiated amounts for our monitoring services, including certain governmental agencies such as the Veteran's Administration and Department of Defense.

- Non-contracted third-party payors – Non-contracted commercial and government payors often reimburse out-of-network rates provided under the relevant CPT codes on a case-by-case basis. The transaction price used for determining revenue recognition is based on factors including an average of our historical collection experience for our non-contracted services. This rate is reviewed at least quarterly.

We are utilizing the portfolio approach practical expedient under Accounting Standard Codification ("ASC") 606, *Revenue from Contracts with Customers*. We account for the contracts within each portfolio as a collective group, rather than individual contracts. Based on history with these portfolios and the similar nature and characteristics of the patients within each portfolio, we have concluded that the financial statement effects are not materially different than if accounting for revenue on a contract-by-contract basis.

For contracted and CMS portfolios, we are providing an implicit price concession because, while we have a contract with the underlying payor, we expect to accept a lower amount of consideration when claims are adjudicated and allowable claims are determined by the commercial payor. The implicit price concession is recorded as variable consideration to the transaction price and recorded as an adjustment to revenue as a contractual allowance. Historical cash collection indicates that it is probable that substantially all of the contracted claim amount will be received. We provide for estimates of uncollectible patient accounts receivable, based upon historical experience, at the time revenue is recognized, with such provisions presented as bad debt expense within the selling, general and administrative line item of the consolidated statement of operations. Adjustments to these estimates for actual experience are also recorded as an adjustment to bad debt expense.

For the healthcare institutions, we have historical experience of collecting substantially all of the negotiated contractual rates and determined at contract inception that these customers, and or their related third-party payor that pays us on their behalf, have the intention and ability to pay the promised consideration. As such, we have not provided an implicit price concession but, rather, have chosen to accept the risk of default, and adjustments to the transaction price are recorded as bad debt expense.

For non-contracted portfolios, we are providing an implicit price concession because we do not have a contract with the underlying payor, the result of which requires us to estimate transaction price based on historical cash collections utilizing the expected value method. Subsequent adjustments to the transaction price are recorded as an adjustment to revenue and not as bad debt expense.

Accounts Receivable, Allowance for Doubtful Accounts and Contractual Allowances

Accounts receivable includes amounts due to us from healthcare institutions, third-party payors, and government payors and our related patients as a result of our normal business activities. Accounts receivable is reported on the consolidated balance sheets net of an estimated allowance for doubtful accounts and contractual allowances.

We establish an allowance for doubtful accounts for estimated uncollectible receivables based on our assessment of the collectability of customer accounts and recognize the provision as a component of selling, general and administrative expenses. We record a provision for contractual allowances based on the estimated differences between contracted amounts and expected collection rates. Such provisions are based on our historical experience and are reported as a reduction of revenue.

We regularly review the allowances by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer’s ability to pay.

PCBA Valuation

We use PCBAs in each wearable Zio AT patch, Zio XT patch and the Zio Monitor, as well as the wireless gateway used in conjunction with the Zio AT patch. The PCBAs are used numerous times and have useful lives beyond one year. Each time a PCBA is used in a wearable Zio AT patch, the Zio XT patch, or the Zio Monitor or a wireless gateway is used with a Zio AT patch a portion of the cost of the PCBA and/or gateway is recorded as a cost of revenue. We have based our estimate of how many times a PCBA can be used in testing in research and development, loss rates, product obsolescence, and the amount of time it takes the device to go through the manufacturing, shipping, customer shelf, and patient wear time and upload process. We periodically evaluate the use of these estimates. The fair value of our PCBAs is included in Other Assets on the Consolidated Balance Sheets.

Stock-Based Compensation

We measure the estimated fair values of our restricted stock units based on the closing price of our stock on the grant date. For performance-based restricted stock units, we estimate the fair value based on the closing price of our stock on the grant date and, if the award includes a market condition, a Monte Carlo simulation model. In addition, for performance-based restricted stock units, we apply a probability assessment to determine the probable achievement of the performance-based metrics.

Stock-based compensation expense is recognized over the requisite service period using the straight-line method and is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, our stock-based compensation is reduced for the estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. For restricted stock, the compensation cost for these awards is based on the closing price of the Company’s common stock on the date of grant, and recognized as compensation expense on a straight-line basis over the requisite service period.

We recognize compensation expense related to the Employee Stock Purchase Plan based on the estimated fair value of the options on the date of grant, net of estimated forfeitures. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option pricing model for each purchase period. The grant date fair value is expensed on a straight-line basis over the offering period.

Lease Impairment

We account for the impairment of long-lived assets in accordance with ASC 360, *Impairment or Disposal of Long-Lived Assets*. An impairment loss is recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying value. If an asset is determined to be impaired, the impairment is measured by the amount that the carrying value of the asset exceeds its fair value.

We estimated undiscounted future cash flows from our vacant office lease based on our intent and ability to sub-lease the vacant office space which we had ceased using and estimated future sub-lease income considering the local real estate market conditions. We also factored into the estimate the amount of time to identify a tenant and to enter into an agreement. We estimated the fair value of the ROU asset related to the vacant office lease by discounting the estimated undiscounted future cash flows using the average lease capitalization rate, plus average inflation rate, for other lease transactions in the local area during the year.

Material Cash Requirements

Our material cash requirements include the following contractual and other obligations.

- Purchase commitments - From time to time in the ordinary course of business, we enter into a variety of purchase arrangements including but not limited to, purchase arrangements related to components used in manufacturing our products. See Note 8, Commitments and Contingencies, to the Consolidated Financial Statements for more information.

- Operating leases - We lease our facilities under non-cancelable operating leases. See Note 8, Commitments and Contingencies, to the Consolidated Financial Statements for more information.

- Debt interest and principal payments - On March 28, 2022, we entered into the 2022 Amendment to our SVB Loan Agreement which provided for a term loans facility in the aggregate principal amount of up to $75.0 million, of which $35.0 million was borrowed at closing. See Note 9, Debt, to the Consolidated Financial Statements for more information.

Recent Accounting Guidance

For a description of recently issued accounting guidance that is applicable to our financial statements, see Note 2 Significant Accounting Policies, to the Consolidated Financial Statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are exposed to market risks in the ordinary course of our business. These risks primarily include risk related to interest rate sensitivities and foreign currency exchange rate sensitivity.

Interest Rate Sensitivity

We had cash, cash equivalents and short-term investments of $213.1 million and $239.1 million as of December 31, 2022 and 2021, respectively; which consisted of bank deposits, money market funds and U.S. government securities. Such interest-earning instruments carry a degree of interest rate risk.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates would have had a $0.5 million and an immaterial impact to interest income for the years ended December 31, 2022 and 2021, respectively.

For the years ended December 31, 2022 and 2021, we had total outstanding debt of $34.9 million and $21.4 million, respectively, net of debt issuance costs. The SVB Loan Agreement Note carries a variable interest rate based on the "Prime Rate" published by The Wall Street Journal. A hypothetical 10% change in interest rates during the years ended December 31, 2022 and 2021 would have resulted in an immaterial impact on our Consolidated Financial Statements.

Foreign Currency Exchange Rate Sensitivity

We face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars, particularly in British Pound Sterling. As of December 31, 2022 and 2021, we do not consider this risk to be material. We do not utilize any forward foreign exchange contracts, although may choose to do so in the future. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made. The volatility of exchange rates depends on many factors that we cannot forecast with reliable accuracy. In the event our foreign currency denominated assets, liabilities, sales, or expenses increase, our operating results may be more greatly affected by fluctuations in the exchange rates of the currencies in which we do business.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

IRHYTHM TECHNOLOGIES, INC.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of iRhythm Technologies, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of iRhythm Technologies, Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations, of comprehensive loss, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2022, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other

procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Contractual Allowance – Contracted Third-Party Payors

As described in Note 2 to the consolidated financial statements, a large portion of the Company's transactions are covered by third-party payors with whom there is a contractual agreement or established amount the third-party payor will pay (contracted third-party payors). These contracts impose a number of obligations regarding billing and other matters, and the Company's noncompliance with a material term of such contracts may result in a denial of the claim. The Company recognizes revenue from contracted third-party payors, net of contractual allowances. As of December 31, 2022, the Company's contractual allowance balance was $41 million, a significant portion of which relates to revenue from services provided to patients where contracted third-party payors pay for the service on the patient's behalf. As disclosed by management, management accounts for denied claims as a form of variable consideration that is included as a reduction to the transaction price and records as an adjustment to revenue as a contractual allowance. The contractual allowance requires judgment by management and is based on historical collections, review of specific outstanding claims and consideration of relevant qualitative factors.

The principal considerations for our determination that performing procedures relating to the contractual allowance for contracted third-party payors is a critical audit matter are (i) the significant judgment by management when developing the estimate of the contractual allowance;

and (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating audit evidence related to the contractual allowance based on historical collections, review of specific outstanding claims and consideration of relevant qualitative factors.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's estimate of the contractual allowance for contracted third party payors. These procedures also included, among others (i) testing management's process for developing the estimate of the contractual allowance; (ii) testing the completeness and accuracy of the underlying data used in the estimate; (iii) testing, on a sample basis, the accuracy of revenue transactions and collections from the historical billing and collection data used in management's analysis; and (iv) evaluating the reasonableness of adjustments made by management to contractual allowances.

/s/ PricewaterhouseCoopers LLP

San Jose, California
February 23, 2023

We have served as the Company's auditor since 2009.

IRHYTHM TECHNOLOGIES, INC.
Consolidated Balance Sheets
(In thousands, except par value and share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 78,832	$ 127,562
Short-term investments	134,312	111,569
Accounts receivable, net	49,918	46,430
Inventory	15,155	10,268
Prepaid expenses and other current assets	10,555	9,693
Total current assets	288,772	305,522
Property and equipment, net	75,670	55,944
Operating lease right-of-use assets	60,666	84,587
Goodwill	862	862
Other assets	22,252	16,052
Total assets	$ 448,222	$ 462,967
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,517	$ 10,509
Accrued liabilities	65,497	51,486
Deferred revenue	3,051	3,049
Debt, current	—	11,667
Operating lease liabilities, current	13,031	11,142
Total current liabilities	89,096	87,853
Debt, noncurrent	34,935	9,690
Other noncurrent liabilities	1,307	697
Operating lease liabilities, noncurrent	83,072	85,212
Total liabilities	208,410	183,452
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value – 5,000,000 shares authorized at December 31, 2022 and 2021; and none issued and outstanding at December 31, 2022 and 2021, respectively	—	—
Common stock, $0.001 par value – 100,000,000 shares authorized at December 31, 2022 and 2021; 30,193,101 and 29,493,726 shares issued and outstanding at December 31, 2022 and 2021, respectively	28	27
Additional paid-in capital	762,380	685,594
Accumulated other comprehensive income (loss)	(396)	(61)
Accumulated deficit	(522,200)	(406,045)
Total stockholders' equity	239,812	279,515
Total liabilities and stockholders' equity	$ 448,222	$ 462,967

The accompanying notes are an integral part of these consolidated financial statements.

IRHYTHM TECHNOLOGIES, INC.
Consolidated Statements of Operations
(In thousands, except share and per share data)

	Year Ended December 31,		
	2022	**2021**	**2020**
Revenue, net	$ 410,921	$ 322,825	$ 265,166
Cost of revenue	129,289	109,258	70,277
Gross profit	281,632	213,567	194,889
Operating expenses:			
Research and development	46,610	38,671	41,329
Selling, general and administrative	322,198	274,839	197,233
Impairment and restructuring charges	26,608	—	—
Total operating expenses	395,416	313,510	238,562
Loss from operations	(113,784)	(99,943)	(43,673)
Interest expense	(4,138)	(1,169)	(1,519)
Other income (expense), net	2,036	118	1,591
Loss before income taxes	(115,886)	(100,994)	(43,601)
Income tax provision	269	367	229
Net loss	$ (116,155)	$ (101,361)	$ (43,830)
Net loss per common share, basic and diluted	$ (3.88)	$ (3.46)	$ (1.58)
Weighted-average shares, basic and diluted	29,915,720	29,331,010	27,754,404

The accompanying notes are an integral part of these consolidated financial statements.

IRHYTHM TECHNOLOGIES, INC.
Consolidated Statements of Comprehensive Loss
(In thousands)

	Year Ended December 31,		
	2022	**2021**	**2020**
Net loss	$ (116,155)	$ (101,361)	$ (43,830)
Other comprehensive income (loss):			
Net change in unrealized losses on short-term investments	(335)	(72)	(71)
Comprehensive loss	$ (116,490)	$ (101,433)	$ (43,901)

The accompanying notes are an integral part of these consolidated financial statements.

IRHYTHM TECHNOLOGIES, INC.
Consolidated Statements of Stockholders' Equity
(In thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2019	26,682,720	$ 25	$ 395,695	$ (260,393)	$ 82	$ 135,409
Issuance of common stock in connection with employee equity incentive plans, net	1,079,488	—	20,244	—	—	20,244
Issuance of common stock in connection with follow-on public offering, net of issuance costs	1,257,142	2	206,023	—	—	206,025
Tax withholding upon vesting of restricted stock awards	—	—	(10,009)	—	—	(10,009)
Stock-based compensation	—	—	34,305	—	—	34,305
Accounting Standards Codification 326 cumulative effect adjustment upon adoption	—	—	—	(461)	—	(461)
Net loss	—	—	—	(43,830)	—	(43,830)
Net change in unrealized loss on short-term investments	—	—	—	—	(71)	(71)
Balances at December 31, 2020	29,019,350	$ 27	$ 646,258	$ (304,684)	$ 11	$ 341,612
Issuance of common stock in connection with employee equity incentive plans, net	474,376	—	8,943	—	—	8,943
Tax withholding upon vesting of restricted stock awards	—	—	(25,853)	—	—	(25,853)
Stock-based compensation	—	—	56,246	—	—	56,246
Net loss	—	—	—	(101,361)	—	(101,361)
Net change in unrealized loss on short-term investments	—	—	—	—	(72)	(72)
Balances at December 31, 2021	29,493,726	$ 27	$ 685,594	$ (406,045)	$ (61)	$ 279,515
Issuance of common stock in connection with employee equity incentive plans, net	699,375	1	13,182	—	—	13,183
Stock-based compensation	—	—	63,604	—	—	63,604
Net loss	—	—	—	(116,155)	—	(116,155)
Net change in unrealized loss on short-term investments	—	—	—	—	(335)	(335)
Balances at December 31, 2022	30,193,101	$ 28	$ 762,380	$ (522,200)	$ (396)	$ 239,812

The accompanying notes are an integral part of these consolidated financial statements.

IRHYTHM TECHNOLOGIES, INC.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2022	2021	2020
Cash flows from operating activities			
Net loss	$ (116,155)	$ (101,361)	$ (43,830)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	13,405	9,842	6,900
Stock-based compensation	57,740	54,527	41,515
Amortization of premium and accretion of discounts on investments, net	(474)	1,641	430
Provision for doubtful accounts and contractual allowances	58,349	37,074	31,431
Amortization of operating lease right-of-use assets	6,204	6,752	6,030
Impairment charges	23,164	—	—
Other	264	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(61,837)	(53,572)	(37,957)
Inventory	(5,108)	(4,960)	(1,389)
Prepaid expenses and other current assets	(862)	(2,329)	(3,027)
Other assets	(6,200)	(1,831)	(6,149)
Accounts payable	(2,993)	6,135	(3,881)
Accrued liabilities	14,473	7,946	1,308
Deferred revenue	2	2,119	(321)
Operating lease liabilities	(6,263)	(2,087)	(4,819)
Reimbursement of tenant improvement allowance	3,279	2,351	—
Net cash used in operating activities	(23,012)	(37,753)	(13,759)
Cash flows from investing activities			
Purchases of property and equipment	(29,830)	(28,067)	(13,551)
Purchases of short-term investments	(188,569)	(122,184)	(277,510)
Sales of short-term investments	34,965	—	14,525
Maturities of short-term investments	131,000	255,515	144,145
Net cash (used in) provided by investing activities	(52,434)	105,264	(132,391)
Cash flows from financing activities			
Payment of loans	(21,389)	(11,667)	(1,944)
Proceeds from term loans	35,000	—	—
Issuance of common stock in connection with follow-on public offering, net	—	—	206,025
Proceeds from issuance of common stock in connection with employee equity incentive plans	13,182	8,943	20,244
Tax withholding upon vesting of restricted stock awards	—	(25,853)	(10,009)
Payment of issuance costs for long-term debt	(77)	—	—
Net cash provided by (used in) financing activities	26,716	(28,577)	214,316
Net (decrease) increase in cash and cash equivalents	(48,730)	38,934	68,166
Cash and cash equivalents, beginning of year	127,562	88,628	20,462
Cash and cash equivalents, end of year	$ 78,832	$ 127,562	$ 88,628
Supplemental disclosures of cash flow information:			
Interest paid	$ 3,317	$ 1,194	$ 1,502
Cash taxes paid	$ 287	$ —	$ —
Non-cash investing and financing activities:			
Property and equipment costs included in accounts payable and accrued liabilities	$ 160	$ 9	$ 3
Right-of-use assets obtained in exchange for operating lease liabilities	$ 7,686	$ 6,625	$ 621
Capitalized stock-based compensation	$ 5,863	$ 3,593	$ 1,129

The accompanying notes are an integral part of these consolidated financial statements.

IRHYTHM TECHNOLOGIES, INC.
Notes to Consolidated Financial Statements

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

iRhythm Technologies, Inc. (the "Company") was incorporated in the state of Delaware in September 2006. The Company is a leading digital healthcare company that creates trusted solutions that detect, predict, and prevent disease. The Company's principal business is the design, development, and commercialization of device-based technology to provide remote cardiac monitoring services that it believes allow clinicians to diagnose certain arrhythmias quicker and with greater efficiency than other services that rely on traditional technology.

Since first receiving clearance from the U.S. Food and Drug Administration ("FDA") for the Company's technology in 2009, the Company has supported physician and patient use of its technology and provided remote cardiac monitoring services from its Medicare-enrolled independent diagnostic testing facilities ("IDTFs") and its qualified technicians. The Company has provided the Zio remote cardiac monitoring services, including extended Holter, traditional Holter, and mobile cardiac telemetry ("MCT") monitoring services ("Zio Services"), using the Zio Systems.

The Company is headquartered in San Francisco, California, which also serves as a clinical center. The Company has additional clinical centers in Deerfield, Illinois and Houston, Texas and a manufacturing facility in Cypress, California. The Company formed wholly-owned subsidiaries in the United Kingdom in March 2016, in Singapore in June 2021 and in Japan in June 2022.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") and include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated. The Company has reclassified certain amounts previously reported in its consolidated financial statements to conform to the current presentation.

Risks and Uncertainties

Macroeconomic Factors and Supply Chain Constraints

The Company's operations and performance may vary based on worldwide economic and political conditions, which have been adversely impacted by continued global economic uncertainty, political instability, and military hostilities in multiple geographies, including the COVID-19 pandemic, the ongoing military conflict between Russia and Ukraine, domestic and global inflationary trends, rising interest rates, global supply shortages, and a tightening labor market. For example, the Company has experienced staff shortages at its contact centers as a result of the COVID-19 pandemic and federal, state and local responses thereto. A severe or prolonged economic downturn or period of global political instability could drive hospitals and other healthcare professionals to tighten budgets and curtail spending, which could in turn negatively impact rates at which physicians prescribe the Company's Zio Services. In addition, higher unemployment rates or reductions in employer-provided benefits plans could result in fewer commercially insured patients, resulting in a reduction in the Company's margins and impairing the ability of uninsured patients to make timely payments. A weak or declining economy could also strain the Company's suppliers, possibly resulting in supply delays and disruptions. There is also a risk that one or more of the Company's current service providers, suppliers, or other partners may not survive such difficult economic times, which could directly affect the Company's ability to attain its goals on schedule and on budget. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. The Company cannot predict the timing, strength, or duration of an economic downturn, instability, or recovery, whether worldwide, in the United States, or within its industry.

The Company's remote work arrangements resulting from the COVID-19 pandemic and subsequent decision to pursue a sublease for its San Francisco headquarters resulted in an impairment of its right of use asset and related leasehold improvements and furniture, and the Company may incur additional impairment charges related to real property lease agreements.

The Company is continuously reviewing its liquidity and anticipated capital requirements. The Company believes it will have adequate liquidity over the next 12 months to operate its business and to meet its cash requirements. As of December 31, 2022, the Company is in compliance with its debt covenants.

Macroeconomic factors have contributed to delays in payments of outstanding receivables, supply chain disruptions, including shortages and inflationary pressure, uncertain or reduced demand, and the impact of any initiatives or programs that the Company has undertaken to address financial and operational challenges faced by the Company's customers. This impact is having a material, adverse impact on liquidity, capital resources, supply chain, operations and business and those of the third parties on which the Company relies, and could worsen over time. In addition, the extent to which macroeconomic conditions, including inflation, increasing interest rates and other effects of the COVID-19 pandemic, impacts the Company's results will depend on future developments, which are highly uncertain and cannot be predicted. The full extent of potential delays or impacts on the business, financial condition, cash flows and results of operations remains unknown.

Reimbursement

The Company receives revenue for the Zio Services primarily from third-party payors, which include commercial payors and government agencies, such as the Centers for Medicare & Medicaid Services ("CMS"). Third-party payors require the Company to identify the service for which it is seeking reimbursement by using a Current Procedural Terminology ("CPT") code set maintained by the American Medical Associations. These CPT codes are subject to periodic change and update, which will impact the reimbursement rates for the Company's Zio Services.

CMS updates the reimbursement rates for diagnostic tests performed by IDTFs annually via the Medicare Physician Fee Schedule, and effective January 1, 2023, CMS established national payment rates for the CPT codes the Company uses to report the long-term Holter monitoring services it performs with its Zio XT System: CPT codes 93247 (for wear-time of greater than 7 days and up to 15 days) and 93243 (for wear-time of greater than 48 hours and up to 7 days). Based on the relative value units CMS assigned to CPT codes 93247 and 93243, the national reimbursement rates for these services in 2023 are $243.65 and $231.79, respectively, and range from $247.59 to $334.46 and $235.54 to $318.17 for the Company's Medicare-enrolled IDTF locations in Deerfield, Illinois, Houston, Texas, and San Francisco, California, when considering the geographic practice cost index for these locations. Because remote cardiac monitoring technology, including the Zio System, are rapidly evolving, there is a continuing risk that relative value units assigned, and reimbursement rates set, by CMS may not adequately reflect the value and expense of this technology and related monitoring services, and the Company cannot provide certainty that CMS will not reduce these rates in the future, which would adversely affect the Company's financial results.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the years presented. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, contractual allowances, allowance for doubtful accounts, the useful lives of property and equipment, the recoverability of long-lived assets including the estimated usage of the printed circuit board assemblies ("PCBAs"), the incremental borrowing rate for operating leases, accounting for income taxes, impairment of right-of-use ("ROU") assets, and various inputs used in estimating stock-based compensation. Actual results may differ from those estimates.

For further details on estimates used to calculate the impairment on ROU assets, see Note 7. Impairment and Restructuring Charges, included in the notes to the consolidated financial statements.

Reportable Segment

Operating segments are defined as components of an enterprise where separate financial information is evaluated regularly by the chief operating decision maker, which the Company has identified as being the chief executive officer, in deciding how to allocate resources and assessing performance. The Company operates as one operating segment. The Company's chief operating decision maker allocates resources and assesses performance at the consolidated level.

Fair Value of Financial Instruments

The carrying amounts of certain of the Company's financial instruments, which include cash equivalents, short-term investments, accounts receivable, accounts payable, accrued liabilities and debt, approximate fair value due to their short maturities.

Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less from the date of purchase.

Short-term Investments

The Company's short-term investments consist primarily of commercial paper, corporate bonds, U.S. agency obligations and U.S. treasury securities. The Company typically invests in highly-rated securities, and its investment policy generally limits the amount of credit exposure to any one issuer. The Company's policy generally requires investments to be investment grade, with the primary objective of minimizing the potential risk of principal loss. The Company classifies investments as available-for-sale at the time of purchase and re-evaluates such classification as of each balance sheet date. Available-for-sale debt securities with an amortized cost basis in excess of the estimated fair value are assessed to determine what amount of that difference, if any, is caused by expected credit losses. Allowance for credit losses on available-for-debt securities are recognized as a charge in other income (expense), net on the Company's consolidated statements of operations and any remaining unrealized losses, net of taxes, are included in accumulated other comprehensive loss in accumulated deficit on the consolidated balance sheets. There were no impairment charges for any unrealized losses during the years ended December 31, 2022, 2021, and 2020.

Accounts Receivable, Allowance for Doubtful Accounts and Contractual Allowances

Accounts receivable includes amounts due to the Company from healthcare institutions, third-party payors, and government payors and their related patients, as a result of the Company's normal business activities. Accounts receivable is reported on the consolidated balance sheets net of an estimated allowance for doubtful accounts and contractual allowances.

The Company establishes an allowance for doubtful accounts for estimated uncollectible receivables based on its assessment of the collectability of customer accounts and recognizes the provision as a component of selling, general and administrative expenses. The Company records a provision for contractual allowances based on the estimated differences between contracted amounts and expected collection rates. Such provisions are based on the Company's historical experience and are reported as a reduction of revenue.

The Company regularly reviews the allowances by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay.

The following table presents the changes in the allowance for doubtful accounts (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Balance, beginning of year	$ 14,012	$ 12,711	$ 9,049
Add: adoption of ASC 326, *Financial Instruments - Credit Losses*	—	—	461
Add: provision for doubtful accounts	17,191	9,615	10,515
Less: write-offs, net of recoveries and other adjustments	(12,728)	(8,314)	(7,314)
Balance, end of year	$ 18,475	$ 14,012	$ 12,711

The following table presents the changes in the contractual allowance (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Balance, beginning of year	$ 31,274	$ 21,281	$ 15,433
Add: allowance for contractual adjustments	41,158	27,459	20,916
Less: contractual adjustments	(31,043)	(17,466)	(15,068)
Balance, end of year	$ 41,389	$ 31,274	$ 21,281

Concentrations of Risk

Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents, investments and accounts receivable. Cash balances are deposited in financial institutions which, at times, may be in excess of federally insured limits. Cash equivalents are invested in highly rated money market funds. The Company invests in a variety of financial instruments, such as, but not limited to, U.S. government securities, corporate notes, commercial paper and, by policy, limits the amount of credit exposure with any one financial institution or commercial issuer. The Company has not experienced any material losses on its deposits of cash and cash equivalents or investments.

Concentrations of credit risk with respect to accounts receivable are limited due to the large number of customers comprising the Company's customer base and their dispersion across many geographies. The Company does not require collateral. The Company records an allowance for doubtful accounts based on the assessment of the collectability of customer accounts, considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. The Centers for Medicare and Medicaid Services ("CMS"), accounted for approximately 25%, 14% and 27% of the Company's revenue for the years ended December 31, 2022, 2021, and 2020, respectively. CMS accounted for 22% and 8% of accounts receivable as of December 31, 2022 and 2021, respectively.

Inflationary Risk

The Company continuously monitors the effects of inflationary factors, such as increases in cost of goods sold and selling and operating expenses, which may adversely affect its results of operations. Specifically, the Company may experience inflationary pressure affecting freight costs, the cost of the components for the Company's Zio Services, overhead costs relating to maintenance of the Company's facilities, and in the wages paid to its employees due to challenging labor market conditions. Competitive and regulatory conditions may restrict the Company's ability to fully recover these costs through price increases. As a result, it may be difficult to fully offset the impact of persistent inflation. The Company's inability or failure to do so could have a material adverse effect on its business, financial condition and results of operations or cause the Company to need to obtain additional capital in future earlier than anticipated.

Supply Risk

The Company relies on single-source vendors to supply some of its disposable housings, instruments and other materials used to manufacture the Zio patches and the adhesive that binds the Zio patch to a patient's body. These components and materials are critical, and there could be a considerable delay in finding alternative sources of supply.

A global semiconductor supply shortage is having wide-ranging effects across multiple industries. The supply shortage has impacted multiple suppliers that provide the PCBAs to the Company. The semiconductor supply shortage may have an impact on the Company until global supply is sufficient for global demand.

Inventory

Inventory owned by the Company is valued at cost, on the first in, first out ("FIFO") basis, or the lower of cost or net realizable value. The Company records write-downs of inventory that is obsolete or in excess of anticipated demand. The Company also records market value based write-downs in consideration of product lifecycle stage, technology trends, product development plans and assumptions about future demand and market conditions. Actual demand may differ from forecasted demand, and such differences may have a material effect on recorded inventory values. Inventory write-downs are charged to cost of revenue and establish a new cost basis for the inventory.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization is computed using the straight-line method over the estimated useful lives of the assets, ranging from three to five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the assets. Maintenance and repairs are charged to expense as incurred, and improvements and betterment are capitalized.

The Company classifies internal-use software in property and equipment. Internal-use software costs are capitalized during the application development stage. Costs related to planning and post implementation activities are expensed as incurred. Capitalized internal-use software is amortized, and recognized as cost of revenue, on a straight-line basis over the estimated useful life of three years.

PCBAs

The Company uses PCBAs in each wearable Zio XT patch, Zio AT patch and the Zio Monitor as well as the wireless gateway used in conjunction with the Zio AT patch. The PCBAs are used numerous times and have useful lives beyond one year. Each time a PCBA is used in a wearable Zio XT patch, Zio AT patch, or the Zio Monitor or a wireless gateway is used with a Zio AT patch a portion of the cost of the PCBA and/or gateway is recorded as a cost of revenue. The Company periodically evaluates and has based its estimates of how many times a PCBA can be used on testing in research and development, loss rates, product obsolescence, and the amount of time it takes the device to go through the manufacturing, shipping, customer shelf and patient wear time and upload process. The fair value of the Company's PCBAs is included in Other Assets on the Consolidated Balance Sheets.

Implementation Costs in Cloud-Computing Arrangements

The Company capitalizes qualified implementation costs incurred in a hosting arrangement that is a service contract for which it is the customer in accordance with the requirements for cloud computing arrangements ("CCA") to the extent it is incurred in the course of developing internal-use software. These capitalized implementation costs are generally amortized over the fixed, non-cancellable term of the associated hosting arrangement on a straight-line basis are recorded in prepaid expenses and other current assets or in other noncurrent assets. The Company amortizes capitalized implementation costs in a CCA on a straight-line basis over the terms of the associated hosting arrangement. The Company recorded an immaterial amount of amortization expense during the years ended December 31, 2022, 2021, and 2020.

Goodwill

Goodwill represents the excess of the purchase price of an acquired business over the fair value of the underlying net tangible and intangible assets. Goodwill amounts are not amortized, but rather tested for impairment at least annually, and more frequently when changes in circumstances indicate that the carrying value may not be recoverable. The Company has determined that it operates its business as one reporting unit and the Company completes its annual impairment test in the fourth quarter. In the event that the Company determines that the fair value of the reporting unit is less than the reporting unit's carrying value, goodwill impairment charge will be incurred for the amount of the difference during the quarter in which the determination is made. The Company did not record any goodwill impairment charges in the years ended December 31, 2022, 2021, and 2020.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment annually or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future net cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset.

Any impairments to ROU assets, leasehold improvements, or other assets as a result of a sublease or other similar action are initially recognized when a decision to take such action is made and recorded as an operating expense. Similar to other long-lived assets, management tests ROU assets for impairment whenever events or changes in circumstances occur that could impact the recoverability of these assets. For ROU assets, such circumstances may include subleases that do not fully recover the costs of the associated leases or commitments to sublease a property. For the year ended December 31, 2022, the Company recorded $23.2 million of long-lived asset impairment charges in the consolidated statement of operations. In addition, see Note 7, Impairment and Restructuring Charges, included in the notes to the consolidated financial statements.

Comprehensive Loss

Comprehensive loss represents all changes in stockholders' equity during the year from non-owner sources. The Company's unrealized gains and losses on short-term investments represent the only component of other comprehensive loss that are excluded from the reported net loss and that are presented in the consolidated statements of comprehensive loss.

Revenue Recognition

The Company has developed a proprietary system that combines an FDA-cleared and CE-marked wire-free, patch-based, 14-day wearable biosensor that continuously records ECG data, with a proprietary cloud-based data analytic platform to help physicians monitor patients and diagnose arrhythmias. The Company currently offers three Zio System options—the Zio XT System, the Zio AT System, and the Zio Monitor System.

The Zio XT System is a prescription-only, remote ECG monitoring system that consists of the Zio XT patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio XT patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm. The final step in the Zio Services is the delivery of an electronic Zio report to the prescribing physician with a summary of findings. The Company's Zio XT services are generally billable when the Zio report is issued to the physician.

The Zio Monitor System is the next generation of the Zio XT System, and is a prescription-only, remote ECG monitoring system that consists of the Zio Monitor patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, which supports the capture and analysis of ECG data recorded by the Zio Monitor patch at the end of the wear period, including specific arrhythmia events detected by the ZEUS algorithm.

The Zio AT System is a prescription-only, remote ECG monitoring system that similarly consists of the Zio AT patch that records the electric signal from the heart continuously for up to 14 days and the ZEUS System, but which also incorporates the Zio AT wireless gateway that provides connectivity between the patch and the ZEUS System during the patient wear period. The wireless gateway, slightly larger than a smart phone, is provided to the patient at the time of Zio AT patch application and collects and transmits data from the Zio AT patch to the cloud via a LTE protocol. The Zio AT service revenue is recognized over the patient wear period and delivery of electronic Zio reports with two performance obligations.

The Company recognizes as revenue the amount of consideration to which it expects to be entitled in exchange for performing the service. The consideration the Company is entitled to varies by portfolio, as further defined below, and includes estimates that require significant judgment by management. A unique aspect of healthcare is the involvement of multiple parties to the service transaction. In addition to the patient, often a third-party, for example a commercial or governmental payor or healthcare institution, will pay the Company for some or all of the service on the patient's behalf. Separate contractual arrangements exist between the Company and third-party payors that establish amounts the third-party payor will pay on behalf of a patient for covered services rendered.

A small portion of the Company's transactions are covered by third-party payors with whom there is neither a contractual agreement nor an established amount that the third-party payor will pay. In determining the collectability and transaction price for its service, the Company considers factors such as insurance claims which are adjudicated as allowable under the applicable policy and payment history from both payors and patient out-of-pocket costs, payor coverage, whether there is a contract between the payor or healthcare institution and the Company, historical amount received for the service, and any current developments or changes that could impact reimbursement and healthcare institution payments. Certain of these factors are forms of variable consideration which are only included in the transaction price to the extent it is probable that a significant reversal of cumulative revenue will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

A summary of the payment arrangements with third-party payors and healthcare institutions is as follows:

- Contracted third-party payors – The Company has contracts with negotiated prices for services provided to patients with commercial healthcare insurance coverage.

- CMS – The Company has received IDTF approval from regional Medicare Administrative Contractors and will receive reimbursement per the relevant CPT code rates for the services rendered to the patient covered by CMS.

- Healthcare institutions – Healthcare institutions are typically hospitals or physician practices in which the Company has negotiated amounts for its monitoring services, including certain governmental agencies such as the Veterans Administration and Department of Defense.

- Non-contracted third-party payors – Non-contracted commercial and government payors often reimburse out-of-network rates provided under the relevant CPT codes on a case-by-case basis. The transaction price used for determining revenue recognition is based on factors including an average of the Company's historical collection experience for its non-contracted services. This rate is reviewed at least quarterly.

The Company is utilizing the portfolio approach practical expedient under ASC 606, *Revenue from Contracts with Customers,* whereby services provided under each of the above payor types form a separate portfolio. The Company accounts for the contracts within each portfolio as a collective group, rather than individual contracts. Based on history with these portfolios and the similar nature and characteristics of the patients within each portfolio, the Company has concluded that the financial statement effects are not materially different than if accounting for revenue on a contract-by-contract basis.

For contracted and CMS portfolios, the Company recognizes revenue, net of contractual allowances, and recognizes an allowance for doubtful accounts for uncollectible patient accounts receivable. The transaction price is determined based on negotiated rates, and the Company has historical experience of collecting substantially all of these contracted rates. These contracts also impose a number of obligations regarding billing and other matters, and the Company's noncompliance with a material term of such contracts may result in a denial of the claim. The Company accounts for denied claims as a form of variable consideration that is included as a reduction to the transaction price recognized as revenue. The Company estimates the denied claims which require management judgment. The estimated denied claims are based on historical information and judgement includes the historical period utilized. The Company monitors the estimated denied claims against the latest available information, and subsequent changes to the estimated denied claims are recorded as an adjustment to revenue in the periods during which such changes occur. Delays in claims submissions could lead to an increase in denials if the Company misses the payors' filing deadlines and could result in a reduction in the Company's receipt of payments. Historical cash collection indicates that it is probable that substantially all of the transaction price, less the estimate of denied claims, will be received. Contracted payors may require that the Company bills patient co-payments and deductibles and from time to time the Company may not be able to collect such amounts due to credit risk. The Company provides for estimates of uncollectible patient accounts receivable, based upon historical experience where judgment includes the historical period utilized, at the time revenue is recognized, with such provisions presented as bad debt expense within the selling, general and administrative line item of the consolidated statement of operations. Adjustments to these estimates for actual experience are also recorded as an adjustment to bad debt expense.

As discussed in the *Accounts Receivable, Allowance for Doubtful Accounts and Contractual Allowances* section above, the inherent uncertainty caused by the longer collection cycle and claims adjudication process related to delays in submission because of the CPT code transition in 2021 could result in additional provisions for contractual allowances and doubtful accounts which would negatively impact the Company's results of operations in future periods.

For healthcare institutions, the transaction price is determined based on negotiated rates, and the Company has historical experience collecting substantially all of these contracted rates. Historical cash collections indicate that it is probable that substantially all of the transaction price will be received. As such, the Company is not providing an implicit price concession but, rather, has chosen to accept the risk of default, and any subsequent uncollected amounts are recorded as bad debt expense to selling, general and administrative expense in the consolidated statements of operations.

For non-contracted portfolios, the Company provides an implicit price concession due to the lack of a contracted rate with the underlying payor. As a result, the Company estimates the transaction price based on historical cash collections utilizing the expected value method. All subsequent adjustments to this transaction price are recorded to revenue.

Leases

The Company determines if an arrangement is a lease at inception. The Company's lease agreements generally contain lease and non-lease components. Payments under its lease arrangements are primarily fixed. Non-lease components primarily include payments for maintenance and utilities. The Company combines fixed payments for non-lease components with lease payments and accounts for them together as a single lease component which increases the amount of the Company’s ROU assets and lease liabilities.

Certain lease agreements contain variable payments, which are expensed as incurred and not included in the ROU assets and lease liabilities.

ROU assets and lease liabilities are recognized at the present value of the future lease payments at the lease commencement date. The interest rate used to determine the present value of the future lease payments is the Company's incremental borrowing rate, because the interest rate implicit in its leases is not readily determinable. The Company's incremental borrowing rate is estimated to approximate the interest rate on a collateralized basis with similar terms and payments, and in economic environments where the leased asset is located. The Company's lease terms include periods under options to extend or terminate the lease when it is reasonably certain that it will exercise that option. The Company generally uses the base, non-cancelable, lease term when determining the ROU assets and lease liabilities. ROU assets are adjusted for any prepaid lease payments and lease incentives.

Cost of Revenue

Cost of revenue includes direct labor, material costs, overhead, data analysis, customer care, equipment and infrastructure expenses, amortization of internal-use software, and shipping and handling. Direct labor includes payroll and personnel-related costs involved in manufacturing. Material costs include both the disposable costs of the device and amortization of the PCBAs. Each time the PCBA is used in a wearable Zio XT System, a portion of the cost of the PCBA is charged to cost of revenue.

Research and Development

The Company’s research and development costs are expensed as incurred. Research and development costs include, but are not limited to personnel costs, laboratory supplies, consulting costs and overhead charges. In addition, the Company expenses milestone payments, when probable, for the development agreement with Verily.

Selling, General and Administrative Expenses

The Company's sales and marketing expenses consist of personnel costs, including stock-based compensation, and sales commissions. Other significant costs include travel expenses, consulting, public relations costs, direct marketing, tradeshow and promotional expenses and allocated facility overhead costs.

The Company incurred an immaterial amount of advertising expense during each of the years ended December 31, 2022, 2021, and 2020, which is included in selling, general and administrative expenses.

The Company's general and administrative expenses consist primarily of personnel costs for executive, finance, legal and administrative personnel, including stock-based compensation. Other significant expenses include professional fees for legal and accounting services, consulting fees, recruiting fees, bad debt expense, third-party patient claims processing fees and travel expenses. In addition, the Company incurred transformation costs to scale its organization during the year and expect to incur additional transformation costs throughout 2023 with the restructuring activities to be substantially complete by mid-2024. Upon completion, the Company expects to achieve operational efficiencies in its administrative expenses.

Income Taxes

The Company uses the asset and liability method to account for income taxes in accordance with the authoritative guidance for income taxes. Under this method, deferred tax assets and liabilities are determined based on future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and tax loss and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that has a greater than 50% likelihood of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company records interest and penalties related to unrecognized tax benefits in income tax expense. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Stock-Based Compensation

The Company measures the estimated fair values of its restricted stock units based on the closing price of the Company's stock on the grant date. For performance-based restricted stock units, the Company estimates the fair value based on the closing price of its stock on the grant date and, if the award includes a market condition, a Monte Carlo simulation model. In addition, for performance-based restricted stock units, the Company applies a probability assessment to determine the probable achievement of the performance-based metrics.

Stock-based compensation expense is recognized over the requisite service period using the straight-line method and is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, the Company's stock-based compensation is reduced for the estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. For restricted stock, the compensation cost for these awards is based on the closing price of the Company’s common stock on the date of grant, and recognized as compensation expense on a straight-line basis over the requisite service period.

The Company recognizes compensation expense related to the Employee Stock Purchase Plan (“ESPP”) based on the estimated fair value of the options on the date of grant, net of estimated forfeitures. The Company estimates the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option pricing model for each purchase period. The grant date fair value is expensed on a straight-line basis over the offering period.

Net Loss per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per common share is the same as basic net loss per common share for all periods presented, since the effect of potentially dilutive securities are anti-dilutive.

Recent Accounting Pronouncements

The Company continues to monitor new accounting pronouncements issued by the Financial Accounting Standards Board and does not believe any recently issued accounting pronouncements will have a material impact on the Company's consolidated financial statements.

3. REVENUE

Disaggregation of Revenue

The Company disaggregates revenue from contracts with customers by payor type. The Company believes these categories aggregate the payor types by nature, amount, timing and uncertainty of its revenue streams. Disaggregated revenue by payor type and major service line for the years ended December 31, 2022, 2021, and 2020 were as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Contracted third-party payors	$ 223,984	$ 193,871	$ 135,939
Centers for Medicare and Medicaid	103,032	44,529	72,536
Healthcare institutions	59,772	57,496	41,396
Non-contracted third-party payors	24,133	26,929	15,295
Total	$ 410,921	$ 322,825	$ 265,166

Revenue generated from the United States comprised substantially all of the Company's revenue. No other country comprised 10% or greater of the Company's revenue during each of the years ended December 31, 2022, 2021, and 2020.

Contract Liabilities

ASC 606, *Revenue from Contracts with Customers,* requires an entity to present a revenue contract as a contract liability when the Company has an obligation to transfer goods or services to a customer for which the Company has received consideration from the customer, or an amount of consideration from the customer is due and unconditional (whichever is earlier).

Certain of the Company’s customers pay the Company directly for the Zio XT service upon shipment of devices. Such advance payments are contract liabilities and are recorded as deferred revenue and revenue is recognized when reports are delivered to the healthcare provider. During the year ended December 31, 2022, $3.0 million relating to the contract liability balance at the beginning of 2022 was recognized as revenue. Total revenue recognized during the year ended December 31, 2021 that was included in the contract liability balance at the beginning of 2021 was $0.9 million.

Contract Costs

Under ASC 340, *Other Assets and Deferred Costs* ("ASC 340"), the incremental costs of obtaining a contract with a customer are recognized as an asset. Incremental costs of obtaining a contract are those costs that an entity incurs to obtain a contract with a customer that it would not have incurred if the contract had not been obtained.

The Company’s current commission programs are considered incremental. However, as a practical expedient, ASC 340 permits the Company to immediately expense contract acquisition costs, because the asset that would have resulted from capitalizing these costs will be amortized in one year or less.

4. CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

The fair value of cash equivalents and short-term investments at December 31, 2022 and 2021, were as follows (in thousands):

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 24,263	$ —	$ —	$ 24,263
U.S. government securities	134,709	12	(409)	134,312
Total cash equivalents and short-term investments	$ 158,972	$ 12	$ (409)	$ 158,575
Classified as:				
Cash equivalents				$ 24,263
Short-term investments				134,312
Total cash equivalents and short-term investments				$ 158,575

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 110,137	$ —	$ —	$ 110,137
U.S. government securities	50,490	—	(46)	50,444
Corporate notes	31,158	—	(15)	31,143
Commercial paper	29,982	—	—	29,982
Total cash equivalents and short-term investments	$ 221,767	$ —	$ (61)	$ 221,706
Classified as:				
Cash equivalents				$ 110,137
Short-term investments				111,569
Total cash equivalents and short-term investments				$ 221,706

Unrealized losses during the years ended December 31, 2022, 2021, and 2020 were not material. As of December 31, 2022, the weighted average maturity for the Company's short-term investments was 114 days.

5. FAIR VALUE MEASUREMENTS

The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

Level 1—Inputs are unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted market prices included in Level 1) are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument’s anticipated life.

Level 3—Inputs reflect management’s best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The corporate notes, commercial paper and government securities are classified as Level 2 as they were valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets.

The Company's interest-bearing obligation is classified as Level 1 input. As of December 31, 2022, the fair value of the Company's outstanding interest-bearing obligation approximated the carrying value of $34.9 million. As of December 31, 2021, the fair value of the Company's outstanding interest-bearing obligations approximated the carrying value of $21.4 million.

The Company had no transfers between levels of the fair value hierarchy of its assets measured at fair value.

The following tables present the fair value of the Company's financial assets determined using the inputs defined above (in thousands):

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 24,263	$ —	$ —	$ 24,263
U.S. government securities	—	134,312	—	134,312
Total	$ 24,263	$ 134,312	$ —	$ 158,575

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 110,137	$ —	$ —	$ 110,137
U.S. government securities	—	50,444	—	50,444
Corporate notes	—	31,143	—	31,143
Commercial paper	—	29,982	—	29,982
Total	$ 110,137	$ 111,569	$ —	$ 221,706

6. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2022	2021
Raw materials	$ 9,338	$ 5,101
Finished goods	5,817	5,167
Total	$ 15,155	$ 10,268

Other Assets

Other assets consisted of the following (in thousands):

	December 31,	
	2022	2021
PCBAs	$ 18,599	$ 13,863
Cloud computing arrangements	2,523	1,427
Other	1,130	762
	$ 22,252	$ 16,052

The Company uses PCBAs in each wearable Zio XT patch and Zio AT patch, as well as the wireless gateway used in conjunction with the Zio AT patch. The PCBAs are used numerous times and have useful lives beyond one year. Each time a PCBA is used in a wearable Zio XT patch or Zio AT patch, a portion of the cost of the PCBA is recorded as a cost of revenue. Each time a wireless gateway is used with a Zio AT patch, a portion of the gateway is recorded as a cost of revenue. PCBAs, which are recorded as other assets, were $18.6 million and $13.9 million as of December 31, 2022 and 2021, respectively. The amortization was $5.2 million, $4.4 million and $3.0 million for the years ending December 31, 2022, 2021, and 2020, respectively.

Property and Equipment

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2022	2021
Laboratory and manufacturing equipment	$ 4,911	$ 3,192
Computer equipment and software	2,315	2,269
Furniture and fixtures	4,119	4,174
Leasehold improvements	23,144	20,401
Internal-use software	44,877	30,922
Internal-use software in development	28,069	15,739
Construction in progress	3,451	1,951
Total property and equipment, gross	110,886	78,648
Less: accumulated depreciation and amortization	(35,216)	(22,704)
Total property and equipment, net	$ 75,670	$ 55,944

Depreciation and amortization expense for the years ended December 31, 2022, 2021 and 2020 was $13.4 million, $9.8 million and $6.9 million, respectively.

During the year ended December 31, 2022, internal-use-software increased by $26.3 million. This increase relates to the enhancements to the Company’s core technology, products and services and artificial intelligence, as well as investment in future technology, such as the Zio Monitor System, the Company's new biosensor technology platform, and the clinically-integrated ZEUS System for the Zio Watch.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued payroll and related expenses	$ 34,752	$ 34,484
Accrued vacation	8,608	7,431
Accrued professional services fees	7,234	1,724
Accrued expenses	7,006	3,112
Claims payable	4,464	2,988
Accrued state and foreign income and sales taxes	2,388	745
Accrued employee share purchase plan contributions	1,045	1,002
Total accrued liabilities	$ 65,497	$ 51,486

7. IMPAIRMENT AND RESTRUCTURING CHARGES

In February 2022, the Company's board of directors (the “Board”) approved a restructuring plan ("Restructuring Plan") to allow it to effectively and efficiently scale its business, which resulted in severance and other employment related costs of $3.4 million during the year ended December 31, 2022. Also in February 2022, the Board approved reducing the Company's leased space for its headquarters in San Francisco, California, by a total amount of leased square footage of approximately 50%. As a result, the Company recognized an impairment of its ROU asset and related leasehold improvements and furniture and fixtures in the amount of $23.2 million during the year ended December 31, 2022. The Company's restructuring and impairment charges are described below (in thousands):

	Year Ended December 31, 2022
Restructuring charges	$ 3,444
Impairment charges	23,164
Total	$ 26,608

Restructuring

The following table provides a summary of changes in the restructuring liabilities associated with the Restructuring Plan (in thousands):

	December 31, 2021	Charges	Cash Payments	December 31, 2022
Employee severance	$ —	$ 3,444	$ (3,050)	$ 394
Total	$ —	$ 3,444	$ (3,050)	$ 394

Impairment

On February 15, 2022, the Board agreed to pursue a sublease of one floor (approximately 50%) of the San Francisco Lease. The Company recorded $20.5 million in impairment charges on its ROU asset during the year ended December 31, 2022 and $2.7 million for the impairment of related leasehold improvements and furniture and fixtures. The impairment was recorded to restructuring and impairment expenses within the consolidated statement of operations.

The Company accounts for the impairment of long-lived assets in accordance with ASC 360, *Impairment or Disposal of Long-Lived Assets*. An impairment loss is recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying value. If an asset is determined to be impaired, the impairment is measured by the amount that the carrying value of the asset exceeds its fair value.

The Company estimated undiscounted future cash flows from its vacant office lease based on the Company's intent and ability to sub-lease the vacant office space, based on the facts and circumstances discussed below, which it had ceased using and estimated future sub-lease income considering the local real estate market conditions. The Company also factored into its estimate the amount of time to identify a tenant and to enter into an agreement. The Company estimated the fair value of the ROU asset related to the vacant office lease by discounting the estimated undiscounted future cash flows using the average lease capitalization rate, plus average inflation rate, for other lease transactions in the local area during the year.

The Company has engaged a leasing broker and has formalized a marketing plan for the San Francisco office market. The sublease market for commercial office space is currently very challenging in the San Francisco area due to lower demand for leased office space as most companies have adjusted to allowing their employees to work from home during and after the COVID-19 pandemic that persisted throughout 2020 and 2021. The Company believes that it is likely to be able to sublease a portion of its existing office space, but at a rate below the amount that it is currently paying.

Significant judgment and estimates are required in assessing impairment of ROU assets, including identifying whether events or changes in circumstances require an impairment assessment, estimating future cash flows, and determining appropriate discount rates.

The following table presents impairment charges recorded during the year ended December 31, 2022:

	Year Ended December 31, 2022
ROU asset	$ 20,451
Leasehold improvements	2,211
Furniture and fixtures	502
Total	$ 23,164

For further details on the Company's leases, refer to Note 8. Commitments and Contingencies.

8. COMMITMENTS AND CONTINGENCIES

Purchase Commitments

The Company is party to various purchase arrangements related to its manufacturing and research and development activities. As of December 31, 2022, the Company' purchase commitments during the years ended December 31, 2023 and 2024 are $62.0 million and $1.5 million, respectively, primarily to purchase the Zio Monitor patch and inventory.

Leases

The Company leases office, manufacturing, and clinical centers under non-cancelable operating leases which expire on various dates through 2031. These leases generally contain scheduled rent increases or escalation clauses and renewal options. Operating lease ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The operating lease ROU assets also include any lease payments made to the lessor at or before the commencement date as well as variable lease payments which are based on a consumer price index. The Company is also subject to variable lease payments related to janitorial services and electricity which are not included in the operating lease ROU asset as they are based on actual usage. The Company recognizes operating lease expense on a straight-line basis over the lease period.

Contractual obligations under operating lease liabilities were as follows (in thousands):

Year Ended December 31:	
2023	$ 20,826
2024	20,586
2025	20,379
2026	20,131
2027	19,731
Thereafter	31,003
Total lease payments	132,656
Less: imputed interest	(36,553)
Total lease liabilities	$ 96,103

Other information related to the operating leases were as follows:

	Year Ended December 31,		
	2022	**2021**	**2020**
Operating lease costs (in thousands)	$ 13,524	$ 13,500	$ 12,800
Weighted average remaining lease term (years)	8.75	9.62	10.59
Weighted average discount rate (percentage)	7.3 %	7.3 %	7.4 %

Operating lease costs include an immaterial amount of non-operating lease rent expense for each of the years ended in December 31, 2022, 2021, and 2020.

Legal Proceedings

From time to time, the Company is involved in claims and legal proceedings or investigations, that arise in the ordinary course of business. Such matters could have an adverse impact on the Company's reputation, business, and financial condition and divert the attention of its management from the operation of the Company's business. These matters are subject to many uncertainties and outcomes that are not predictable.

On February 1, 2021, a putative class action lawsuit was filed in the United States District Court for the Northern District of California (the “Court”) alleging that the Company and its former Chief Executive Officer, Kevin M. King, violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder (“Securities Class Action Lawsuit”). On August 2, 2021, the lead plaintiff filed an amended complaint, and filed a further amended complaint on September 24, 2021. The amended complaint names as defendants, in addition to the Company and Mr. King, its former Chief Executive Officer, Michael J. Coyle, and former Chief Financial Officer and current Chief Operating Officer, Douglas J. Devine. The purported class in the amended complaint includes all persons who purchased or acquired the Company's common stock between August 4, 2020 and July 13, 2021, and seeks unspecified damages purportedly sustained by the class. On October 27, 2021, the Company filed a motion to dismiss the amended complaint. The motion to dismiss was fully briefed and the Court held a hearing on the motion on February 4, 2022, after which the Court took the matter under submission. On March 31, 2022, the Court issued an order granting the Company's motion to dismiss the Securities Class Action Lawsuit, without allowing plaintiff further leave to amend, and entered judgment in favor of the Company and the other defendants. On April 29, 2022, the plaintiff that filed the initial complaint in the action filed a notice of appeal. On September 7, 2022, the plaintiff-appellant filed its opening brief, and the Company filed a motion to dismiss for lack of standing to appeal and Article III standing on September 27, 2022. On October 17, 2022, the plaintiff filed its response to the Company's motion to dismiss, and the Company filed its reply in support of the motion to dismiss on November 3, 2022. The Company's motion to dismiss the appeal was denied without prejudice on December 8, 2022. The Company filed its responding brief on the appeal on February 16, 2023. The Company believes the Securities Class Action Lawsuit to be without merit and plan to defend itself vigorously.

On March 26, 2021, the Company received a grand jury subpoena from the U.S. Attorney’s Office for the Northern District of California requesting information related to communications with the Food and Drug Administration and the Company's products. On September 14, 2021, the Company received a second subpoena requesting additional information. The Company is cooperating fully and is providing the requested information.

Development Agreement

On September 3, 2019, the Company entered into a Development Collaboration Agreement with Verily Life Sciences LLC, an Alphabet company ("VLS") and Verily Ireland Limited ("VIL" And together with VLS, "Verily") (such Development Collaboration Agreement, as amended by Amendment No.1 dated April 26, 2021 and Amendment No.2 dated January 24, 2022, the "Development Agreement"). The Development Agreement involves joint development and production of intellectual property between the Company and Verily. Each participant has primary responsibility for certain aspects of development and approval, with all processes to be performed at each respective party's own cost. Costs incurred by the Company in connection with the Development Agreement will be expensed as research and development expense in accordance with ASC 730, *Research and Development*.

The Company and Verily will develop certain next-generation atrial fibrillation ("Afib") screening, detection, or monitoring products pursuant to the Development Agreement, which products will involve combining Verily and the Company's technology platforms and capabilities. Under the terms of the Development Agreement, the Company paid Verily an upfront fee of $5.0 million in 2019. In addition, the Company agreed to make additional cash payments to Verily up to an aggregate of $12.75 million in milestone payments upon achievement of various development and regulatory milestones over the term of the Development Agreement. The Company has achieved milestones tied to payments totaling $11.0 million to date and expects to make additional payments over the term of the Development Agreement of $1.75 million, subject to the achievement of certain development and regulatory milestones including provisioning of the Zio Watch to enable market evaluation scheduled to begin in 2023.

No payment-triggering milestones were achieved during the year ended December 31, 2022.

The Development Agreement provides each party with licenses to use certain intellectual property of the other party for development activities in the field of Afib screening, detection, or monitoring. Ownership of developed intellectual property will be allocated to the Company or Verily depending on the subject matter of the underlying developed intellectual property, and, for certain subject matter, shall be jointly owned.

Indemnifications

In the ordinary course of business, the Company enters into agreements pursuant to which it agrees to indemnify customers, vendors, lessors, business partners, and other parties with respect to certain matters, including losses arising out of the breach of such agreements, services to be provided by the Company, or from intellectual property infringement claims made by third parties. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by applicable law. The Company currently has directors' and officers' insurance. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions, and believes that the estimated fair value of these indemnification obligations is not material and it has not accrued any amounts for these obligations.

9. DEBT

In October 2018, the Company entered into the Third Amended and Restated Loan and Security Agreement with the Silicon Valley Bank ("SVB Loan Agreement"). Under the SVB Loan Agreement, the Company had borrowed $35.0 million and had made repayments through March 2022, at which time the outstanding balance was $18.5 million.

On March 28, 2022, the Company entered into a Second Amendment ("2022 Amendment") to its SVB Loan Agreement which provided for a term loans facility in the aggregate principal amount of up to $75.0 million (the "2022 Term Loans"), of which $35.0 million was borrowed at closing and a portion of the proceeds was used to pay in full the outstanding balance of $18.5 million under the SVB Loan Agreement. The remaining $40.0 million of 2022 Term Loans may be borrowed from time to time at the Company's option, in increments of at least $10.0 million, through December 31, 2023. The Company will pay interest only on the 2022 Term Loans until April 1, 2025, when it will commence repaying the 2022 Term Loans in 24 equal consecutive monthly installments, with all obligations under the 2022 Term Loans maturing on March 1, 2027. Interest charged on the 2022 Term Loans will accrue at a floating per annum rate equal to the greater of: (A) the Prime Rate plus 0.25%; and (B) 3.50%. The Company is also required to pay fees on any prepayment of the 2022 Term Loans, ranging from 3.0% to 1.0% depending on the date of prepayment, and a final payment equal to 5.0% of the principal amount of the 2022 Term Loans drawn. Once repaid or prepaid, the 2022 Term Loans may not be reborrowed. The Company accounted for the refinancing as an extinguishment of the original loans and paid a fee of $1.8 million, which was included in interest expense on the Consolidated Statement of Operations and recorded the 2022 Term Loans, net of issuance costs. The issuance costs on the new loans are amortized over the term of the loan.

The 2022 Amendment also amended the terms of the revolving credit line under the SVB Loan Agreement, which provided for an aggregate principal amount of $25.0 million, to: (i) extend the maturity date from August 1, 2023 to March 1, 2027, (ii) increase the letters of credit sublimit to $15.0 million and (iii) increase the cash management services sublimit to $15.0 million. Interest charged on the principal amount outstanding under the revolving credit line shall accrue at a floating per annum rate equal to the greater of (A) the Prime Rate plus 0.25% and (B) 3.50%. The Company is required to pay an annual fee equal to 0.15% of the revolving credit line. As of December 31, 2022, no loans were outstanding under the revolving credit line.

The 2022 Amendment also amended the SVB Loan Agreement to require the Company to comply, as of the last day of each fiscal quarter, with a quick ratio of at least 1.15 to 1.0 or minimum adjusted EBITDA trailing 6 months of at least $15.0 million. The Company was in compliance with its loan covenants as of December 31, 2022.

Future minimum payments

Contractual obligations, which comprises of principal payments included in Debt, noncurrent, in the Consolidated Balance Sheets and interest payments under the 2022 Term Loans were as follows (in thousands):

Year Ended December 31,		
2023	$	2,337
2024		2,313
2025		15,142
2026		18,412
2027		4,424
Total		42,628
Less: Amount representing interest		(7,628)
Less: Debt issuance costs		(65)
Principal payments	$	34,935

10. INCOME TAXES

The following table presents components of the Company's provision for income taxes (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Current expense:			
Federal	$ —	$ —	$ —
State	160	223	181
Foreign	111	150	59
Total current tax expense	271	373	240
Deferred tax benefit:			
Federal	—	—	—
State	—	—	—
Foreign	(2)	(6)	(11)
Total deferred tax benefit	(2)	(6)	(11)
Total tax expense	$ 269	$ 367	$ 229

The following table presents a reconciliation of the tax expense computed at the statutory federal rate and the Company's tax expense (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Tax at statutory federal rate	$ (24,323)	$ (21,198)	$ (9,172)
State income taxes, net of federal benefit	160	223	181
Stock-based compensation	(3,492)	(7,049)	(20,762)
Meals and entertainment	348	182	177
Section 162(m) limitation - officers compensation	2,498	4,856	544
Other	526	(347)	89
Tax credits	(2,695)	(381)	(1,426)
Foreign rate differential	(40)	(30)	(9)
Change in valuation allowance	27,287	24,111	30,607
Provision for income taxes	$ 269	$ 367	$ 229

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 111,236	$ 114,856
Tax credit carryforwards	29,455	9,174
Stock-based compensation	11,942	9,812
Capital research expenditures	15,997	—
Allowances and other	19,399	20,988
Lease obligation	24,232	23,868
Total deferred tax assets	212,261	178,698
Valuation allowance	(188,070)	(154,734)
Net deferred tax assets	24,191	23,964
Deferred tax liabilities:		
Depreciation and amortization	(9,402)	(3,212)
ROU assets	(14,731)	(20,696)
Total deferred tax liabilities	(24,133)	(23,908)
Total deferred tax assets	$ 58	$ 56

Due to the uncertainties surrounding the realization of deferred tax assets through future taxable income, the Company has provided a full valuation allowance against its U.S. deferred tax assets, and, therefore, no benefit has been recognized for the net operating loss carryforwards and other deferred tax assets. The U.S. valuation allowance increased by $33.3 million, $30.9 million and $35.4 million for the years ended December 31, 2022, 2021, and 2020, respectively. The current year change in the U.S. valuation allowance is primarily related to the increase in reserves and research and development not currently deductible. The Company recorded an immaterial deferred tax asset related to the Company's foreign operations in the United Kingdom.

The valuation allowance for deferred tax assets consisted of the following activity for the years ended December 31, 2022, 2021, and 2020 (in thousands):

	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
Year Ended December 31, 2022	$ 154,734	$ 33,336	$ —	$ 188,070
Year Ended December 31, 2021	$ 123,803	$ 30,931	$ —	$ 154,734
Year Ended December 31, 2020	$ 88,433	$ 35,370	$ —	$ 123,803

As of December 31, 2022, the Company had approximately $445.0 million of federal and $285.5 million of state net operating loss carryforwards available to offset future taxable income which expires in varying amounts beginning in 2027 and 2022, respectively. Federal losses incurred from 2019 can be carried forward indefinitely.

As of December 31, 2022, the Company had research tax credit carryforwards of approximately $10.7 million, and $8.6 million available to reduce future taxable income, if any, for both federal and state purposes, respectively. The federal tax credit carryforwards expire beginning in 2028 and the state tax credits can be carried forward indefinitely.

The Tax Reform Act of 1986, and similar state provisions, limits the use of net operating loss and tax credit carryforwards in certain situations where equity transactions result in a change of ownership as defined by Internal Revenue Code Section 382. In the event the Company should experience an ownership change, as defined, utilization of its net operating loss carryforwards and tax credits could be limited.

A reconciliation of the Company's unrecognized tax benefit amount is as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Balance at beginning of year	$ 3,310	$ 2,302	$ 1,842
Additions for tax positions taken in current year	996	772	488
Increases in balance related to prior year tax positions	426	236	—
Decreases in balance related to prior year tax positions	—	—	(28)
Balance at end of year	$ 4,732	$ 3,310	$ 2,302

The total amount of gross unrecognized tax benefits was $4.7 million, $3.3 million, and $2.3 million as of December 31, 2022, 2021, and 2020 respectively. None of the Company's unrecognized tax benefits that, if recognized, would affect its effective tax rate. The Company does not anticipate the total amounts of unrecognized tax benefits will significantly increase or decrease in the next 12 months. The Company's policy is to include interest and penalties related to unrecognized tax benefits within the provision for taxes. The Company determined that no accrual for interest or penalties was required as of December 31, 2022, 2021, and 2020.

The Company files income tax returns in the U.S. and UK jurisdictions. All of the Company's tax years are open to examination by the US federal and state tax authorities. The UK is open to examination for tax years starting 2017 and forward. The Company currently has no federal, state or foreign tax examinations in progress, nor has it had any federal or state examinations since inception.

11. STOCKHOLDERS' EQUITY

Common Stock

The Company's amended and restated certificate of incorporation dated October 25, 2016, as amended, authorizes the Company to issue 100,000,000 shares of common stock with a par value of $0.001 per share and 5,000,000 shares of preferred stock with a par value of $0.001 per share. The holders of common stock are entitled to receive dividends whenever funds and assets are legally available and when declared by the Board, subject to the prior rights of holders of all series of convertible preferred stock outstanding. No dividends were declared through December 31, 2022.

The Company had reserved shares of common stock for issuance as follows:

	December 31,	
	2022	2021
Options issued and outstanding	328,193	504,106
Unvested restricted stock units and performance-based restricted stock units	2,025,755	1,649,561
Shares available for grant under future stock plans	7,822,637	9,011,213
Shares available for future issuance	10,176,585	11,164,880

12. EMPLOYEE BENEFIT PLANS

401(k) Plan

The Company has a defined contribution 401(k) retirement plan (the 401(k) Plan) covering substantially all employees in the United States. Employees who participate in the 401(k) Plan may contribute up to 10% of eligible compensation each year, subject to Internal Revenue Service limitations and the terms and conditions of the plan. Under the terms of the 401(k) Plan, the Company may elect to match a discretionary percentage of contributions. The Company matches contributions up to 50% and a maximum of $5,000 per year. Total matching contributions were $5.1 million, $3.3 million and $2.2 million for the years ended December 31, 2022, 2021, and 2020, respectively.

13. EQUITY INCENTIVE PLANS

2016 Plan

In October 2016, the Company adopted the 2016 Equity Incentive Plan, (the "2016 Plan"). The 2016 Plan was approved by the Company's stockholders and became effective on October 19, 2016. On the first day of each fiscal year starting from the 2017 fiscal year, the 2016 Plan authorizes an annual increase in the number of shares available for issuance equal to the least of (i) 3,865,000 shares, (ii) 5% of the shares of the Company's common stock outstanding on the last day of the immediately preceding fiscal year or (iii) such number of shares determined by the Board. As of December 31, 2022, the Company has reserved 7,822,637 shares of common stock for issuance under the 2016 Plan.

Pursuant to the 2016 Plan, stock options, restricted stock, restricted stock units, performance units, performance shares, and stock appreciation rights may be granted to employees, consultants and directors of the Company. Options were not granted during the years ended December 31, 2022, 2021 and 2020.

Employee Stock Purchase Plan

In October 2016, the Board and stockholders approved the 2016 Employee Stock Purchase Plan ("ESPP"). Under the ESPP, the Company initially reserved 483,031 shares of common stock for issuance as of its effective date of October 19, 2016. On the first day of each fiscal year starting from the 2017 fiscal year, the number of shares reserved for the ESPP increases by the least of (i) 966,062 shares, (ii) 1.5% of the shares of the Company's common stock outstanding on the last day of the immediately preceding fiscal year, or (iii) such number of shares determined by the Board. The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their eligible compensation, subject to any plan limitations. The ESPP provides for 12 month offering periods that each contain two 6-month purchase periods. At the end of each purchase period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock on (i) the first trading day of the offering period or (ii) the last trading day of the purchase period.

Equity Incentive Plan

A summary of awards available for grant under the 2016 Plan is as follows:

	Shares Available for Grant
Balance as of December 31, 2020	**6,505,390**
Additional awards authorized	1,450,967
Awards granted	(1,289,567)
Awards forfeited	356,999
Awards withheld for tax purposes	135,886
Balance as of December 31, 2021	**7,159,675**
Additional awards authorized	1,476,018
Awards granted	(1,036,109)
Awards forfeited	223,053
Balance as of December 31, 2022	**7,822,637**

Restricted Stock Units and Performance-Based Restricted Stock Units

The fair value of restricted stock units (“RSUs”) and performance-based restricted stock units ("PRSUs") are based on the Company’s closing stock price on the date of grant. The fair value of market based PRSUs were estimated at the date of grant using the Monte-Carlo option pricing model. A summary is as follows:

	Restricted Stock Units		Performance Based Restricted Stock Units and Market-Based Units	
	Shares Underlying RSUs	Weighted Average Grant Date Fair Value	Shares Underlying PRSUs [1]	Weighted Average Grant Date Fair Value
Balance as of December 31, 2020	837,204	$ 82.82	276,955	$ 128.54
Granted	1,009,457	88.67	280,110	135.31
Vested	(285,335)	78.10	(126,671)	165.39
Forfeited	(201,079)	104.19	(142,144)	127.95
Balance as of December 31, 2021	1,360,247	84.99	288,250	119.21
Granted	691,128	147.94	344,981	138.99
Vested	(390,238)	85.55	(46,934)	257.61
Forfeited	(196,471)	110.22	(25,208)	109.82
Balance as of December 31, 2022	1,464,666	111.16	561,089	120.22

[1]Based on the maximum number of performance based restricted stock units in the key executive grant agreements, the actual number of units granted will be based on the annual unit volume CAGR as described below.

As of December 31, 2022, there was total unamortized compensation costs of $112.5 million, net of estimated forfeitures, related to unrecognized RSU expense, which the Company expects to recognize over a weighted average period of 1.9 years. Aggregate intrinsic value of the RSUs was $137.2 million, $160.1 million and $198.6 million as of December 31, 2022, 2021, and 2020, respectively.

As of December 31, 2022, 1.4 million shares of RSUs were expected to vest with an aggregate intrinsic value of $128.2 million. Total vest date fair value of RSUs was $33.4 million, $22.3 million, and $16.3 million during the years ended December 31, 2022, 2021, and 2020, respectively.

As of December 31, 2022, there was total unamortized compensation costs of $28.2 million, net of estimated forfeitures, related to unrecognized PRSU expense, which the Company expects to recognize over a weighted average period of 2.1 years. Aggregate intrinsic value of the PRSUs was $52.6 million, $33.9 million and $65.7 million as of December 31, 2022, 2021, and 2020, respectively.

As of December 31, 2022, 0.5 million shares of PRSUs were expected to vest with an aggregate intrinsic value of $49.9 million. The vest date fair value of PRSUs was $12.1 million, $20.9 million, and $0.0 million during the years ended December 31, 2022, 2021, and 2020, respectively.

PRSUs and Market-based RSUs

The Company grants PRSUs to key executives of the Company. PRSUs can be earned in accordance with the performance equity program for each respective grant:

In February 2020, the Company granted PRSUs (“February 2020 awards”) to be earned based on compound annual growth rate (“CAGR”) of fiscal year 2022's annual unit volume compared to fiscal year 2019's annual unit volume CAGR, measuring a minimum performance threshold of 19.7% to earn 50.0% of target, and a maximum threshold of 29.0% achieved to earn 200.0% of target. These February 2020 awards are subject to the recipient's continued employment through the vesting date of March 15, 2023.

In January 2021, the Company granted PRSUs ("January 2021 awards") to be earned based on fiscal year 2021's annual consolidated revenue compared to fiscal year 2020's annual consolidated revenue, measuring a performance threshold of 10.0% to earn 100.0% of target. These January 2021 awards were subject to the recipient's continued employment through the vesting date of March 15, 2022.

In February 2021, the Company granted PRSUs ("February 2021 awards") to be earned based on fiscal year 2023's annual unit volume CAGR compared to fiscal year 2020's annual unit volume CAGR, measuring a minimum performance threshold of 19.7% to earn 50.0% of target, and a maximum threshold of 29.0% achieved to earn 200.0% of target. These February 2021 awards are subject to recipient's continued employment through the vesting date of March 15, 2024.

In February 2022, the Company granted PRSUs ("February 2022 awards") to be earned based on fiscal year 2024's annual unit volume CAGR compared to fiscal year 2021's annual unit volume CAGR, measuring a minimum performance threshold of 13.0% to earn 50.0% of target, and a maximum threshold of 23.0% achieved to earn 200.0% of target. These February 2022 awards are subject to the recipient's continued employment through the vesting date of March 15, 2025.

In addition, in February 2022, the Company granted market-based RSUs to its Chief Executive Officer. These RSUs to be earned based on both the fiscal year 2024's annual unit volume CAGR compared to fiscal year 2021's annual unit volume CAGR and a comparison of the S&P Healthcare Index to the Company's total shareholder return ("TSR"). The fair value of the TSR was based on the expected term of 2.9 years, interest risk free rate of 1.7%, implied volatility of 81.2% and no dividend yield. These February 2022 awards are subject to the Chief Executive Officer's continued employment through the vesting date of March 15, 2025.

Options

The following table summarizes stock option activity:

		Options Outstanding		
	Options Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2020	609,881	$ 40.18	6.24	$ 120,163
Options exercised	(90,939)	31.15		
Options forfeited	(14,836)	68.81		
Balance at December 31, 2021	504,106	40.97	5.20	38,675
Options exercised	(174,539)	36.82		
Options forfeited	(1,374)	83.15		
Balance at December 31, 2022	328,193	43.00	4.43	16,635
Options exercisable – December 31, 2022	327,768	42.95	4.43	16,631
Options vested and expected to vest – December 31, 2022	328,191	43.00	4.43	16,635

There have been no options granted since December 31, 2019. As of December 31, 2022, there was an immaterial amount of unamortized compensation costs as the options are fully vested. The total estimated grant date fair value of options vested during the period was $2.4 million, $2.8 million and $4.9 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Employee Stock Purchase Plan

The ESPP provides for 12 month offering periods that each contain two 6-month purchase periods. The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15.0% of their eligible compensation, subject to any plan limitations. At the end of each purchase period, employees purchase shares at 85% of the lower of the fair value of the Company's stock price at the enrollment date and the purchase date. During the year ended December 31, 2022, 87,664 shares of common stock have been issued to employees participating in the ESPP and 2,206,279 shares were available for issuance under the ESPP.

On each purchase date, participating employees will purchase common stock at a price per share equal to 85% of the lesser of the fair market value of the shares of the Company's common stock on (i) the first trading day of the applicable offering period, or (ii) the last trading day of each purchase period in the applicable offering period. If the stock price of the Company's common stock on any purchase date in an offering period is lower than the stock price on the first trading date of that offering period, the offering period will immediately reset after the purchase of shares on such purchase date and automatically roll into a new offering period ("ESPP reset"). During the November 30, 2022 purchase period, there was an ESPP reset that resulted in additional expense of approximately $0.2 million, which will be recognized over an offering period from December 1, 2022 to May 31, 2023.

The ESPP provides for 12 month offering periods that contain two six-month purchase periods. The fair value using the Black-Scholes option pricing model is estimated on the enrollment date. For the offering period which started on June 1, 2022, the assumptions included the expected term ranging from 0.5 year to 1.0 year, expected volatility ranging from 81.4% to 96.3%, risk-free rate ranging from 1.6% to 2.2% and dividend yield of 0.0%. For the offering period which started on December 1, 2022 the assumptions included the expected term ranging from 0.5 year to 1.0 year, expected volatility ranging from 68.1% to 73.4%, risk-free rate ranging from 4.7% to 4.7% and dividend yield of 0.0%.

The fair value of ESPP shares to be purchased during the six-month period from June 1, 2022 to November 30, 2022 was $55.02 per share, for the one-year period from June 1, 2022 to May 31, 2023 was $68.52 per share and the six-month period from December 1, 2022 to May 31, 2023 was $48.34 per share. As of December 31, 2022, the Company had $4.4 million of unrecognized compensation expense that will be recognized over a weighted average period of 0.7 years.

14. STOCK-BASED COMPENSATION

The following table summarizes the total stock-based compensation expense included in the statements of operations and comprehensive loss for all periods presented (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Cost of revenue	$ 2,153	$ 1,896	$ 27
Research and development	6,976	5,565	7,727
Selling, general and administrative	48,611	47,066	33,761
Total stock-based compensation expense	$ 57,740	$ 54,527	$ 41,515

Non-Employee Stock-Based Compensation

On July 3, 2020, the Company's Chief Financial Officer ("CFO") resigned and entered into a Consulting and Professional Services Agreement ("CPSA") with the Company to provide consulting services through July 2, 2021. Pursuant to the original terms of the awards, the CFO continued to vest in outstanding awards as long as services are provided to the Company under the CPSA as a non-employee consultant. In accordance with ASC 718, *Compensation - Stock Compensation (*"ASC 718"*),* the Company recognized expense related to all awards expected to vest over the duration of the CPSA in 2020 as an equity-based severance cost as the consulting services are not substantive. Total expense related to non-employee stock-based compensation recognized for the year ended December 31, 2020, was $1.8 million.

On January 12, 2021, the Company's Chief Executive Officer ("CEO") resigned and entered into a CPSA with the Company. Pursuant to the original terms of the awards, the CEO continued to vest in outstanding awards as long as services are provided to the Company under the CPSA as a non-employee consultant or a member of the Board. In accordance with ASC 718, the Company recognized expense related to all awards expected to vest over the duration of the CPSA in the three months ended March 31, 2021, as an equity-based severance cost as the consulting services are not substantive. Total expense related to non-employee stock-based compensation recognized for the year ended December 31, 2021 was $5.4 million.

In March 2022, the former CEO retired from the Board and as a non-employee consultant. Vesting for all outstanding awards was accelerated upon his retirement. The Company recognized expense of $0.9 million related to the retirement of the former CEO during the year ended December 31, 2022.

On June 3, 2022, the Company's former Chief Clinical Officer ("CCO") retired and entered into a Consulting Agreement ("CA") with the Company. Pursuant to the original terms of the awards, the CCO will continue to vest in her outstanding awards as long as services are provided to the Company under the CA as a non-employee consultant. In accordance with ASC 718, the Company recognized expense related to all awards expected to vest over the duration of the CA in the current period as an equity-based severance cost because the consulting services are not substantive. The former CCO total non-employee stock-based compensation expense recognized $0.4 million for the year ended December 31, 2022.

On July 25, 2022, the Company's former Executive Vice President, Chief Commercial Officer ("EVP") resigned and entered into a CA with the Company. Pursuant to the original terms of the agreement, the EVP outstanding awards will continue to vest during the period of his CA services. In accordance with ASC 718, *Compensation - Stock Compensation,* the Company will continue to record stock-based compensation expense related to the awards expected to vest over the duration of the CA, because the consulting services are substantive. The EVP's total expense related to non-employee stock-based compensation recognized for the year ended December 31, 2022 was $0.1 million.

15. NET LOSS PER COMMON SHARE

As the Company had net losses for the years ended December 31, 2022, 2021, and 2020, all potential common shares were determined to be anti-dilutive. The following table sets forth the computation of the basic and diluted net loss per share during the years ended December 31, 2022, 2021, and 2020 (in thousands, except share and per share data):

	Year Ended December 31,		
	2022	2021	2020
Numerator:			
Net loss	$ (116,155)	$ (101,361)	$ (43,830)
Denominator:			
Weighted-average shares used to compute net loss per common share, basic and diluted	29,915,720	29,331,010	27,754,404
Net loss per common share, basic and diluted	$ (3.88)	$ (3.46)	$ (1.58)

The following outstanding shares of potentially dilutive securities have been excluded from diluted net loss per common share for the years ended December 31, 2022, 2021, and 2020 because their inclusion would be anti-dilutive:

	Year Ended December 31,		
	2022	2021	2020
Options to purchase common stock	328,193	504,106	609,881
RSUs and PRSUs issued and unvested	2,025,755	1,649,561	1,114,159
Total	2,353,948	2,153,667	1,724,040

16. SUBSEQUENT EVENT

On February 21, 2023, the Company's Board of Directors approved a restructuring plan that will result in the transition or augmentation of staff of certain operations to the Philippines. In addition, the restructuring plan contemplates the potential use of third-party service providers to transform certain aspects of the Company's revenue cycle management organization. The Company estimates that it will incur total pre-tax charges and costs of approximately $15.0 million to $20.0 million primarily for consulting services from third party service providers to plan and support the transition, legal expenses, as well as employee severance and retention benefits under both ongoing and one-time benefit arrangements and $8.0 million to $10.0 million of capital expenditures. The Company expects to incur these costs throughout 2023 and expects the restructuring activities to be substantially complete by mid-2024.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer ("CEO") (principal executive officer) and Chief Financial Officer ("CFO") (principal financial officer), as appropriate to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a under the Exchange Act, our management, including our CEO and CFO, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15e under the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our CEO and our CFO have concluded that our disclosure controls and procedures are effective at the reasonable assurance level as of December 31, 2022.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2022, using the criteria described in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on their evaluation, as of December 31, 2022, our management concluded that our internal control over financial reporting was effective based on these criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2022 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included in Part II, Item 8 of this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There have been no changes in internal control over financial reporting during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting can also be circumvented by collusion or improper management override of the controls. Projections of any evaluation of controls effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or deterioration in the degree of compliance with policies or procedures.

ITEM 9B. OTHER INFORMATION.

None.

ITEM 9C. DISCLOSURES REGARDING FOREIGN JURISDICTIONS THE PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2023 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2022.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2023 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2022.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT RELATED STOCKHOLDER MATTERS.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2023 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2022.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2023 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2022.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

Our independent registered public accounting firm is PricewaterhouseCoopers LLP, San Jose, CA, PCAOB ID: 238.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2023 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2022.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

The financial statements filed as part of this Annual Report on Form 10-K are listed in the "Index to Financial Statements" under Part II, Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

Financial statement schedules have been omitted in this Annual Report on Form 10-K because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or related notes thereto.

(3) Exhibits

The following is a list of exhibits filed with this Annual Report on Form 10-K incorporated herein by reference (numbered in accordance with Item 601 of Regulation S-K.

Exhibit Index

Exhibit Number	Exhibit Title	Incorporated by Reference				Provided Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-37918	3.1	October 26, 2016	
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-37918	3.2	October 26, 2016	
4.1	Specimen Common Stock Certificate of the Registrant.	S-1	333-213773	4.1	September 23, 2016	
4.2	Amended and Restated Investors' Rights Agreement dated May 16, 2014 by and among the Registrant and certain stockholders.	S-1/A	333-213773	4.2	October 7, 2016	
4.3	Description of the Registrant's securities registered pursuant to Section 12 of the Exchange Act.	10-K	001-37918	4.3	March 2, 2020	
4.4	Warrant to Purchase Stock issued to Life Science Loans, LLC dated as of June 3, 2014.	S-1	333-213773	4.8	September 23, 2016	
10.1±	Services Agreement dated December 24, 2013 between the Registrant and XIFIN, Inc.	S-1	333-213773	10.20	September 23, 2016	
10.2±	Development Collaboration Agreement by and among the Registrant, Verily Life Sciences LLC and Verily Ireland Limited.	10-Q	001-37918	10.3	December 23, 2019	
10.3±	First Amendment to Development Collaboration Agreement by and among the Registrant, Verily Life Sciences LLC and Verily Ireland Limited.	10-K	001-37918	10.43	February 28, 2022	
10.4±	Second Amendment to Development Collaboration Agreement by and among the Registrant, Verily Life Sciences LLC and Verily Ireland Limited.	10-K	001-37918	10.44	February 28, 2022	
10.5	Second Amended and Restated Loan and Security Agreement dated December 4, 2015 between the Registrant and Silicon Valley Bank.	S-1/A	333-213773	10.21	October 7, 2016	
10.6	Third Amended and Restated Loan and Security Agreement, dated as of October 23, 2018, between Silicon Valley Bank, a California corporation, and iRhythm Technologies, Inc., a Delaware corporation.	8-K	001-37918	10.1	October 29, 2018	
10.7	First Amendment to Third Amended and Restated Loan and Security Agreement between the Registrant and Silicon Valley Bank.	10-K	001-37918	4.4	March 2, 2020	
10.8	Office Lease dated October 4, 2018 between the Registrant and Big Dog Holdings LLC.	10-K	001-37918	10.35	March 2, 2020	
10.9	Multi-Tenant Office/Industrial Lease by and between iRhythm Technologies, Inc. and Katella/Holder Street LLC dated March 18, 2021.	10-Q	001-37918	10.42	May 10, 2021	
10.10+	2016 Equity Incentive Plan and related form agreements.	S-1/A	333-213773	10.3	October 7, 2016	
10.11+	2016 Employee Stock Purchase Plan, as amended February 26, 2019, and related form agreements.	10-Q	001-37918	10.1	December 23, 2019	
10.12+	Executive Incentive Compensation Plan.	S-1/A	333-213773	10.5	October 7, 2016	
10.13+	Form of Indemnification Agreement for directors and executive officers.	S-1	333-213773	10.1	September 23, 2016	
10.14+	Executive Change in Control and Severance Policy	10-Q	001-37918	10.1	August 7, 2020	
10.15+	Form of Change of Control and Severance Agreement.	10-Q	001-37918	10.29	November 14, 2017	
10.16+	Offer Letter, dated September 8, 2021, by and between the Registrant and Quentin S. Blackford.	8-K	001-37918	10.1	September 13, 2021	
10.17+	Employment Letter to Mark Day dated September 3, 2007 between the Registrant and Mark Day.	10-Q	001-37918	10.2	December 23, 2019	

10.18+	Offer Letter, dated June 3, 2020, by and between the Registrant and Douglas J. Devine.	8-K	001-37918	10.1	June 4, 2020	
10.19+	Offer Letter, dated November 15, 2021, by and between the Registrant and Patrick Murphy.					X
10.20+	Offer Letter, dated April 24, 2022, by and between the Registrant and Minang Pravin Turakhia, MD.					X
10.21+	Offer Letter, dated July 18,2022, by and between the Registrant and Chad Patterson.					X
10.22+	Offer Letter, dated July 22, 2022, by and between the Registrant and Brice Bobzien.					X
10.23	Note Purchase Agreement dated November 16, 2012, as amended, by and between the Registrant and California HealthCare Foundation, exhibits related thereto and related Promissory Note	S-1/A	333-213773	10.24	October 7, 2016	
10.24	Note and Warrant Purchase Agreement dated November 1, 2012, by and among the Registrant and the persons and entities listed on the Schedule of Investors attached thereto as Exhibit A and exhibits related thereto.	S-1/A	333-213773	10.31	October 7, 2016	
21.1	List of Subsidiaries of Registrant.					X
23.1	Consent of Independent Registered Public Accounting Firm (PricewaterhouseCoopers LLP, San Jose, CA, PCAOB ID: 238)					X
31.1†	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2†	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1†	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document					
101.SCH	Inline XBRL Taxonomy Extension Schema Document					
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					

† The certifications attached as Exhibit 31.1, 31.2 and 32.1 that accompany this Annual Report on Form 10-K, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of iRhythm Technologies, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

+ Indicates management contract or compensatory plan.

± Confidential treatment has been requested for portions of this exhibit. These portions have been omitted and have been filed separately with the Securities and Exchange Commission.

ITEM 16. FORM 10-K SUMMARY.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

iRhythm Technologies, Inc.

Date: February 23, 2023

By: /s/ Quentin S. Blackford

Quentin S. Blackford
President and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Quentin S. Blackford Quentin S. Blackford	President, Chief Executive Officer and Director (Principal Executive Officer)	February 23, 2023
/s/ Brice Bobzien Brice Bobzien	Chief Financial Officer (Principal Financial Officer)	February 23, 2023
/s/ Abhijit Y. Talwalkar Abhijit Y. Talwalkar	Director and Chairman of the Board	February 23, 2023
/s/ Bruce G. Bodaken Bruce G. Bodaken	Director	February 23, 2023
/s/ Ralph Snyderman M.D. Ralph Snyderman M.D.	Director	February 23, 2023
/s/ C. Noel Bairey Merz, M.D. C. Noel Bairey Merz, M.D.	Director	February 23, 2023
/s/ Mark J. Rubash Mark J. Rubash	Director	February 23, 2023
/s/ Karen Ling Karen Ling	Director	February 23, 2023
/s/ Renee Budig Renee Budig	Director	February 23, 2023

Exhibit 10.19

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November 15, 2021

Patrick Michael Murphy

via email: patrickmmurphy78@gmail.com

Dear Patrick:

We are pleased to offer you the position of General Counsel of iRhythm Technologies, Inc. (the "Company"). If you decide to join us, you will receive a salary and certain employee benefits as explained in Exhibit A. You should note that the Company may modify job titles, salaries, and benefits from time to time as it deems necessary.

If you decide to join the Company, it will be recommended to the Compensation Committee of the Board (the "Compensation Committee") that the Company grant you equity awards with an aggregate value of four million dollars ($4,000,000), consisting of the following:

1. An award of restricted stock units ("RSUs") in December 2021 covering a number of shares of the Company's common stock with an aggregate value of $2,000,000 which will vest annually over four years at the rate of twenty-five percent (25%) per year, subject to your continuing employment through each vesting date.

2. An award of performance stock units ("PSUs") in February 2022 covering a number of shares of the Company's common stock with an aggregate value of $2,000,000 which will vest pursuant to the performance-based metrics applicable to the Company's management team generally as set forth in the Company's 2022 PSU incentive program as approved by the Board, subject to your continuing employment through the applicable vesting date.

Each equity award will be subject to the terms and conditions of the Company's 2016 Equity Incentive Plan (as amended from time to time, the "2016 Plan") and, as applicable, a PSU agreement or RSU agreement thereunder.

For purposes of this letter, the aggregate value of each award will be determined in accordance with the Company's standard equity grant practice, which typically means, with respect to Company equity awards, the number of shares subject to the award will be calculated based on the twenty (20) day average closing price of the Company's common stock as reported on the Nasdaq Global Select Market (the "Average Closing Price") prior to and including the date of approval, or such other methodology the Board or Compensation Committee may determine prior to the

grant of the awards becoming effective; provided that with respect to your PSUs, the number of shares subject to the award will be calculated based on the Average Closing Price prior to and including the date of grant of the RSUs.

No right to any stock is earned or accrued until such time that vesting occurs, nor does the grant of the equity awards confer any right to continue vesting or employment.

The Company is excited about your joining and looks forward to a beneficial and productive relationship. Nevertheless, you should be aware that your employment with the Company is for no specified period and constitutes at-will employment. As a result, you are free to resign at any time, for any reason or for no reason. Similarly, the Company is free to conclude its employment relationship with you at any time, with or without cause, and with or without notice. We request that, in the event of resignation, you give the Company at least two weeks' notice.

The Company reserves the right to conduct background investigations and/or reference checks on all of its potential employees. Your job offer, therefore, is contingent upon a clearance of such a background investigation and/or reference check, if any.

For purposes of federal immigration law, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated.

We also ask that, if you have not already done so, you disclose to the Company any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed. It is the Company's understanding that any such agreements will not prevent you from performing the duties of your position and you represent that such is the case. Moreover, you agree that, during the term of your employment with the Company, you will not engage in any other employment, occupation, consulting or other business activity directly related to the business in which the Company is now involved or becomes involved during the term of your employment, nor will you engage in any other activities that conflict with your obligations to the Company. Similarly, you agree not to bring any third party confidential information to the Company, including that of your former employer, and that in performing your duties for the Company you will not in any way utilize any such information.

As a Company employee, you will be expected to abide by the Company's rules and standards. As a condition of your employment, you are also required to sign and comply with an At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement ("CIIAA") which requires, among other provisions, the assignment of patent rights to any invention made during your employment at the Company, and non-disclosure of Company proprietary information. In the event of any dispute or claim relating to or arising out of our employment relationship, you and the Company agree that (i) any and all disputes between you and the Company will be fully and finally resolved by binding arbitration, (ii) you are waiving any and all rights to a jury trial but all court remedies will be available in arbitration, (iii) all disputes will be resolved by a neutral arbitrator who will issue a written opinion, (iv) the arbitration will provide for adequate discovery, and (v) the Company will pay all the arbitration fees, except an amount equal to the filing fees you would have paid had you filed a complaint in a court of law. Please note that we must receive your signed CIIAA before your first day of employment.

To accept the Company's offer, please sign and date this letter in the space provided below. If you accept our offer, we anticipate your first day of employment will be November 29, 2021. This letter, along with any agreements relating to proprietary rights between you and the Company, set forth the terms of your employment with the Company and supersede any prior representations or agreements including, but not limited to, any representations made during your recruitment, interviews or pre-employment negotiations, whether written or oral. This letter, including, but not limited to, its at-will employment provision, may not be modified or amended except by a written agreement signed by the Chairman of the Board of the Company and you. This offer of employment will terminate if it is not accepted, signed and returned by November 18, 2021. An At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement will follow in a separate communication should you decide to accept.

We look forward to your favorable reply and to working with you at iRhythm Technologies, Inc.

Sincerely,

/s/ Quentin Blackford
President & Chief Executive Officer

Agreed to and accepted:

Signature: /s/ Patrick Murphy

Printed Name: Patrick Murphy

Date: 11/17/2021

Exhibit A

Services and Benefits for Patrick Michael Murphy

Position: General Counsel

Base Pay Rate: You will be a full-time employee, with a base rate of $440,000 annually, which will be earned and payable in substantially equal installments in accordance with the Company's payroll policy.

Bonus: Each calendar year, you will be eligible to earn a bonus of 60% of your annual base salary at the time of bonus approval. The bonus will be based on achievement of financial targets and/or other performance objectives set by the Company, and the earned bonus will generally be paid within 90 days after the close of a calendar year. The eligible bonus amount will be prorated for any calendar quarter in which you are not employed for an entire quarter, and you must be employed on the date that your bonus, if any, is paid in order to earn and be eligible to receive the bonus.

Signing Bonus: You will receive a one-time signing bonus in the amount of $478,500. This bonus will be paid in one lump sum on the next regularly scheduled pay date after March 1, 2022, assuming you are an active employee on that date, and all regular payroll taxes will be withheld.

In the event your employment with the Company is terminated within 24 months of your date of hire due to (1) your resignation without Good Reason, as defined in our Change of Control and Severance Policy, or (2) your termination for Cause, as defined in our Change of Control and Severance Policy, you will be responsible for reimbursing the Company for a portion of the full amount of the Signing Bonus within 60 days of your employment termination date, with such portion equal to the product (rounded to the nearest whole cent) of: (i) the gross amount of the Signing Bonus multiplied by (ii) a fraction (A) the numerator of which is equal to the difference between (x) 24 minus (y) the number of completed months you have served as the Company's regular, full-time General Counsel as measured immediately prior to your termination date and (B) the denominator of which is 24. By your signature on this offer of employment, you authorize the Company to withhold the portion of the Signing Bonus calculated pursuant to the prior sentence from any separation payments and/or other final pay you receive upon such termination of employment.

Benefits and Expenses: You will be entitled to participate in the benefit plans and programs generally available from time to time to employees of the Company, subject to the terms of such plans and programs. This includes four weeks per year of Paid Time Off, in addition to specified Holidays, among other benefits.

Severance: You may be eligible to receive severance benefits in the event your employment is terminated under certain conditions pursuant to the terms of our Change of Control and Severance Policy and a participation agreement thereunder.

Exhibit 10.20

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April 24, 2022

Minang Pravin Turakhia, MD 1490
Southdown Road
Hillsborough, CA 94010

Dear Dr. Turakhia:

We are pleased to offer you the position of Chief Scientific Officer and Chief Medical Officer with iRhythm Technologies, Inc. (the "Company"). If you decide to join us, you will receive a salary and certain employee benefits as explained in Exhibit A. You should note that the Company may modify job titles, salaries, and benefits from time to time as it deems necessary.

In addition, if you decide to join the Company, it will be recommended at the first meeting of the Compensation and Management Development Committee (the "Compensation Committee") of the Company's Board of Directors (the "Board") following your start date that the Company grant you equity awards with an aggregate grant date fair value of three million dollars ($3,000,000), consisting of the following:

1. An award of performance stock units ("PSUs") covering a number of shares of the Company's common stock with an aggregate grant date fair value of one million five hundred thousand dollars ($1,500,000), which will vest pursuant to the performance-based metrics set forth in the Company's 2022 PSU incentive program, subject to your continuing employment through the vesting date.

2. An award of restricted stock units ("RSUs") covering a number of shares of the Company's common stock with an aggregate grant date fair value of one million five hundred thousand dollars ($1,500,000), which will vest annually over four years at the rate of twenty-five percent (25%) per year, subject to your continuing employment through each vesting date.

Each equity award will be subject to the terms and conditions of the Company's 2016 Equity Incentive Plan (as amended from time to time, the "2016 Plan") and, as applicable, a PSU agreement or RSU agreement thereunder.

For purposes of this letter, the grant date fair value of each award will be determined in accordance with the Company's standard equity grant practice, which typically means, with respect to awards of PSUs and RSUs, the grant date fair value will be calculated based on the twenty (20) day average closing price of the Company's

Common Stock as reported on the Nasdaq Global Select Market prior to and including the date of grant, or such other methodology the Board or Compensation Committee may determine prior to the grant of the awards becoming effective.

No right to any stock is earned or accrued until such time that vesting occurs, nor does the grant of the equity awards confer any right to continue vesting or employment.

The Company is excited about your joining and looks forward to a beneficial and productive relationship. Nevertheless, you should be aware that your employment with the Company is for no specified period and constitutes at-will employment. As a result, you are free to resign at any time, for any reason or for no reason. Similarly, the Company is free to conclude its employment relationship with you at any time, with or without cause, and with or without notice. We request that, in the event of resignation, you give the Company at least two weeks' notice.

The Company reserves the right to conduct background investigations and/or reference checks on all of its potential employees. Your job offer, therefore, is contingent upon a clearance of such a background investigation and/or reference check, if any.

For purposes of federal immigration law, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated.

We also ask that, if you have not already done so, you disclose to the Company the existence of any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed. It is the Company's understanding that any such agreements will not prevent you from performing the duties of your position and you represent that such is the case. You further agree not to disclose any third party confidential information to the Company, including that of your former employer, and that in performing your duties for the Company you will not in any way improperly utilize any such information.

You shall devote your best efforts and full business time, skill and attention to the performance of your duties at iRhythm. Any engagement in outside clinical, academic, advisory and/or board work must not interfere with the performance of your duties at iRhythm and requires advance approval from the Chief Executive Officer, who shall not unreasonably withhold such approval. The outside clinical, academic, advisory and/or board work set forth in Exhibit E to the CIIAA is deemed to have received such approval. Moreover, you agree that, during the term of your employment with the Company, subject to the exceptions set forth in Exhibit E the CIIAA, you will not engage in any other business- or academic-related activity directly related to the business in which the Company is now involved or becomes involved during the term of your employment without prior written approval from the Chief Executive Officer (email sufficing).

As a Company employee, you will be expected to abide by the Company's rules and standards. As a condition of your employment, you are also required to sign and comply with an At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement ("CIIAA") which requires, among other provisions, the assignment of patent rights to any invention made during your employment at the Company (subject to the exceptions described in the CIIAA and California Labor Code Section 2870), and non-disclosure of Company proprietary information. Any dispute or claim relating to or arising out of our employment relationship or the termination of that relationship will be fully and finally resolved by binding arbitration in accordance with Section 12 of the CIIAA. Please note that we must receive your signed CIIAA before your first day of employment.

To accept the Company's offer, please sign and date this letter in the space provided below. If you accept our offer, we anticipate your first day of employment will be Monday, June 6, 2022, or such later date after which your approved leave of absence from Stanford University begins. This letter, along with any agreements relating to proprietary rights between you and the Company and the CIIAA, set forth the terms of your employment with the Company and supersede any prior representations or agreements including, but not limited to, any representations made during your recruitment, interviews or pre-employment negotiations, whether written or oral. This letter, including, but not limited to, its at-will employment provision, may not be modified or amended except by a written agreement signed by the President of the Company and you.

We look forward to your favorable reply and to working with you at iRhythm Technologies, Inc.

Sincerely,

/s/ Quentin Blackford
President and CEO

Agreed to and accepted:

Signature: /s/ Minang Turakhia

Printed Name: Minang Turakhia

Date: 4/24/2022

Exhibit A

Services and Benefits for Minang Turakhia

April 24, 2022

Position: EVP, Chief Scientific Officer and Chief Medical Officer

Base Pay Rate: You will be a full-time employee, with a base rate of $425,000 annually, which will be earned and payable in accordance with the Company's payroll policy. This rate is based on your geographical work location at the time of hire, and should your work location change due to relocation, your rate of pay may be reevaluated to align with geographical market rates.

Bonus: Each calendar year, you will be eligible to earn a bonus of 50% of your annual base salary at the time of bonus payment. The bonus will be based on achievement of financial targets and/or other performance objectives set by the Company, and the earned bonus will generally be paid within 90 days after the close of a calendar year. The eligible bonus amount will be prorated for any calendar quarter in which you are not employed for an entire quarter, and you must be employed on the date that your bonus, if any, is paid in order to earn and be eligible to receive the bonus.

Signing Bonus: You will receive a one-time signing bonus in the amount of $500,000. This bonus will be paid in one lump sum on the next regularly scheduled pay date after you start employment with the Company, and all regular payroll taxes will be withheld.

In the event your employment with the Company is terminated within 24 months of your date of hire due to (1) your resignation without Good Reason, as defined in our Change of Control and Severance Policy, or (2) your termination for Cause, as defined in our Change of Control and Severance Policy, you will be responsible for reimbursing the Company for a portion of the full amount of the Signing Bonus within 60 days of your employment termination date, with such portion equal to the product (rounded to the nearest whole cent) of: (i) the gross amount of the Signing Bonus multiplied by (ii) a fraction (A) the numerator of which is equal to the difference between (x) 24 minus (y) the number of completed months you have served as the Company's regular, full-time Chief Scientific Officer and Chief Medical Officer as measured immediately prior to your termination date and (B) the denominator of which is 24. By your signature on this offer of employment, you authorize the Company to withhold the portion of the Signing Bonus calculated pursuant to the prior sentence from any separation payments and/or other final pay you receive upon such termination of employment.

Benefits and Expenses: You will be entitled to participate in the benefit plans and programs generally available from time to time to employees of the Company, subject to the terms of such plans and programs. This includes four weeks per year of Paid Time Off, in addition to specified Holidays, among other benefits.

Severance: You may be eligible to receive severance benefits in the event your employment is terminated under certain conditions pursuant to the terms of our Change of Control and Severance Policy and a participation agreement thereunder.

Exhibit 10.21

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iRhythmTech.com

Dear Chad Patterson,

We are pleased to offer you the position of Chief Commercial Officer with iRhythm Technologies, Inc. (the "Company"). If you decide to join us, you will receive a salary and certain employee benefits as explained in Exhibit A. You should note that the Company may modify job titles, salaries, and benefits from time to time as it deems necessary.

If you decide to join the Company, it will be recommended to the Compensation and Talent Management Committee (the "Compensation Committee") of the Company's Board of Directors (the "Board") that the Company grant you equity awards with an aggregate value of five million five hundred thousand dollars ($5,500,000) following your start date, consisting of the following:

1. An award of restricted stock units ("RSUs") covering a number of shares of the Company's common stock with an aggregate value of $2,750,000 which will vest annually over four years at the rate of twenty-five percent (25%) per year, subject to your continuing employment through each vesting date.

2. An award of performance stock units ("PSUs") covering a number of shares of the Company's common stock with an aggregate value of $2,750,000 which will vest pursuant to the performance-based metrics applicable to the Company's management team generally as set forth in the Company's 2022 PSU incentive program as approved by the Compensation Committee, subject to your continuing employment through the applicable vesting date.

Each equity award will be subject to the terms and conditions of the Company's 2016 Equity Incentive Plan (as amended from time to time, the "2016 Plan") and, as applicable, a PSU agreement or RSU agreement thereunder.

For purposes of this letter, the aggregate value of each award will be determined in accordance with the Company's standard equity grant practice, which typically means, with respect to Company equity awards, the number of shares subject to the award will be calculated based on the twenty (20) day average closing price of the Company's common stock as reported on the Nasdaq Global Select Market (the "Average Closing Price") prior to and including the date of approval, or such other methodology the Board or Compensation Committee may determine prior to the grant of the awards becoming effective.

No right to any stock is earned or accrued until such time that vesting occurs, nor does the grant of the equity awards confer any right to continue vesting or employment.

The Company is excited about your joining and looks forward to a beneficial and productive relationship. Nevertheless, you should be aware that your employment with the Company is for no specified period and constitutes at-will employment. As a result, you are free to resign at any time, for any reason or for no reason. Similarly, the Company is free to conclude its employment relationship with you at any time, with or without cause, and with or without notice. We request that, in the event of resignation, you give the Company at least two weeks' notice.

The Company reserves the right to conduct background investigations and/or reference checks on all of its potential employees. Your job offer, therefore, is contingent upon a clearance of such a background investigation and/or reference check, if any.

For purposes of federal immigration law, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated.

We also ask that, if you have not already done so, you disclose to the Company any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed. It is the Company's understanding that any such agreements will not prevent you from performing the duties of your position and you represent that such is the case. Moreover, you agree that, during the term of your employment with the Company, you will not engage in any other employment, occupation, consulting or other business activity directly related to the business in which the Company is now involved or becomes involved during the term of your employment, nor will you engage in any other activities that conflict with your obligations to the Company. Similarly, you agree not to bring any third-party confidential information to the Company, including that of your former employer, and that in performing your duties for the Company you will not in any way utilize any such information.

As a Company employee, you will be expected to abide by the Company's rules and standards. As a condition of your employment, you are also required to sign and comply with an At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement ("CIIAA") which requires, among other provisions, the assignment of patent rights to any invention made during your employment at the Company, and non-disclosure of Company proprietary information. In the event of any dispute or claim relating to or arising out of our employment relationship, you and the Company agree that (i) any and all disputes between you and the Company will be fully and finally resolved by binding arbitration, (ii) you are waiving any and all rights to a jury trial but all court remedies will be available in arbitration, (iii) all disputes will be resolved by a neutral arbitrator who will issue a written opinion, (iv) the arbitration will provide for adequate discovery, and (v) the Company will pay all the arbitration fees, except an amount equal to the filing fees you would have paid had you filed a complaint in a court of law. Please note that we must receive your signed CIIAA before your first day of employment.

To accept the Company's offer, please sign and date this letter in the space provided below. If you accept our offer, we anticipate your first day of employment will be July 25, 2022. This letter, along with any agreements relating to proprietary rights between you and the Company, set forth the terms of your employment with the Company and supersede any prior representations or agreements including, but not limited to, any representations made during your recruitment, interviews or pre-employment negotiations, whether written or oral. This letter, including, but not limited to, its at-will employment provision, may not be modified or amended except by a written agreement signed by the Chairman of the Board of the Company and you. This offer of employment will terminate if it is not accepted, signed and returned by July 20th, 2022. An At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement will follow in a separate communication should you decide to accept.

We look forward to your favorable reply and to working with you at iRhythm Technologies, Inc.

Regards,		Agreed to and accepted:
/s/Quentin Blackford	Signature	/s/CHAD PATTERSON
Quentin Blackford	Printed Name	CHAD PATTERSON
President and CEO	Date	7/18/2022

Exhibit A

Services and Benefits for Chad Patterson

Position: Chief Commercial Officer

Base Pay Rate: You will be a Full-Time Exempt employee, with a base rate of $450,000.00 annually, which will be earned and payable in accordance with the Company's payroll policy.

Bonus: Each calendar year, you will be eligible to earn a bonus of 60% of your annual base salary. The bonus will be based on the achievement of financial targets and/or other performance objectives set by the Company, and the earned bonus will generally be paid within 90 days after the close of a calendar year. Your bonus (if any) for 2022 will not be prorated and will be paid on a full-year basis, and you must be employed on the date that your bonus, if any, is paid in order to earn and be eligible to receive the bonus.

Eligibility for Equity Award: In addition to your new hire equity grant, you are also annually eligible for an award of equity in the first quarter of each year, currently targeted at the amount of $2,300,000, as follows:

1. An award of restricted stock units ("RSUs") covering a number of shares of the Company's common stock with an aggregate value of $1,150,000 which will vest annually over four years at the rate of twenty-five percent (25%) per year, subject to your continuing employment through each vesting date.

2. An award of performance stock units ("PSUs") covering a number of shares of the Company's common stock with an aggregate value of $1,150,000 which will vest pursuant to the performance- based metrics applicable to the Company's management team generally as set forth in the Company's then current PSU incentive program as approved by the Compensation Committee, subject to your continuing employment through the applicable vesting date.

The granting and amount of the annual equity award (if any) is in the sole discretion of the CEO and Board. Each equity award will be subject to the terms and conditions of the Company's 2016 Equity Incentive Plan (as amended from time to time, the "2016 Plan") and, as applicable, a PSU agreement or RSU agreement thereunder.

Benefits and Expenses: You will be entitled to participate in the benefit plans and programs generally available from time to time to employees of the Company, subject to the terms of such plans and programs. This includes five weeks per year of Paid Time Off to be accrued in 2023 (normal PTO accrual will apply thereafter), in addition to specified Holidays, among other benefits.

Severance: You may be eligible to receive severance benefits in the event your employment is terminated under certain conditions pursuant to the terms of our Change of Control and Severance Policy and a participation agreement thereunder.

Exhibit 10.22

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iRhythmTech.com

Dear Brice Bobzien,

We are pleased to offer you the position of Chief Financial Officer with iRhythm Technologies, Inc. (the "Company"). If you decide to join us, you will receive a salary and certain employee benefits as explained in Exhibit A. You should note that the Company may modify job titles, salaries, and benefits from time to time as it deems necessary.

If you decide to join the Company, it will be recommended to the Compensation and Talent Management Committee (the "Compensation Committee") of the Company's Board of Directors (the "Board") that the Company grant you equity awards with an aggregate value of three million dollars ($3,000,000) following your start date, consisting of the following:

1. An award of restricted stock units ("RSUs") covering a number of shares of the Company's common stock with an aggregate value of $1,500,000 which will vest annually over four years at the rate of twenty-five percent (25%) per year, subject to your continuing employment through each vesting date.

2. An award of performance stock units ("PSUs") covering a number of shares of the Company's common stock with an aggregate value of $1,500,000 which will vest pursuant to the performance-based metrics applicable to the Company's management team generally as set forth in the Company's 2022 PSU incentive program as approved by the Compensation Committee, subject to your continuing employment through the applicable vesting date.

Each equity award will be subject to the terms and conditions of the Company's 2016 Equity Incentive Plan (as amended from time to time, the "2016 Plan") and, as applicable, a PSU agreement or RSU agreement thereunder.

For purposes of this letter, the aggregate value of each award will be determined in accordance with the Company's standard equity grant practice, which typically means, with respect to Company equity awards, the number of shares subject to the award will be calculated based on the twenty (20) day average closing price of the Company's common stock as reported on the Nasdaq Global Select Market (the "Average Closing Price") prior to and including the date of approval, or such other methodology the Board or Compensation Committee may determine prior to the grant of the awards becoming effective.

No right to any stock is earned or accrued until such time that vesting occurs, nor does the grant of the equity awards confer any right to continue vesting or employment.

The Company is excited about your joining and looks forward to a beneficial and productive relationship. Nevertheless, you should be aware that your employment with the Company is for no specified period and constitutes at-will employment. As a result, you are free to resign at any time, for any reason or for no reason. Similarly, the Company is

free to conclude its employment relationship with you at any time, with or without cause, and with or without notice. We request that, in the event of resignation, you give the Company at least two weeks' notice.

The Company reserves the right to conduct background investigations and/or reference checks on all of its potential employees. Your job offer, therefore, is contingent upon a clearance of such a background investigation and/or reference check, if any.

For purposes of federal immigration law, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated.

We also ask that, if you have not already done so, you disclose to the Company any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed. It is the Company's understanding that any such agreements will not prevent you from performing the duties of your position and you represent that such is the case. Moreover, you agree that, during the term of your employment with the Company, you will not engage in any other employment, occupation, consulting or other business activity directly related to the business in which the Company is now involved or becomes involved during the term of your employment, nor will you engage in any other activities that conflict with your obligations to the Company. Similarly, you agree not to bring any third-party confidential information to the Company, including that of your former employer, and that in performing your duties for the Company you will not in any way utilize any such information.

As a Company employee, you will be expected to abide by the Company's rules and standards. As a condition of your employment, you are also required to sign and comply with an At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement ("CIIAA") which requires, among other provisions, the assignment of patent rights to any invention made during your employment at the Company, and non-disclosure of Company proprietary information. In the event of any dispute or claim relating to or arising out of our employment relationship, you and the Company agree that (i) any and all disputes between you and the Company will be fully and finally resolved by binding arbitration, (ii) you are waiving any and all rights to a jury trial but all court remedies will be available in arbitration, (iii) all disputes will be resolved by a neutral arbitrator who will issue a written opinion, (iv) the arbitration will provide for adequate discovery, and (v) the Company will pay all the arbitration fees, except an amount equal to the filing fees you would have paid had you filed a complaint in a court of law. Please note that we must receive your signed CIIAA before your first day of employment.

To accept the Company's offer, please sign and date this letter in the space provided below. If you accept our offer, we anticipate your first day of employment will be August 8, 2022. This letter, along with any agreements relating to proprietary rights between you and the Company, set forth the terms of your employment with the Company and supersede any prior representations or agreements including, but not limited to, any representations made during your recruitment, interviews or pre-employment negotiations, whether written or oral. This letter, including, but not limited to, its at-will employment provision, may not be modified or amended except by a written agreement signed by the Chairman of the Board of the Company and you. This offer of employment will terminate if it is not accepted, signed and returned by July 25, 2022. An At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement will follow in a separate communication should you decide to accept.

We look forward to your favorable reply and to working with you at iRhythm Technologies, Inc.

Regards,		Agreed to and accepted:
/s/Quentin Blackford	Signature	/s/Brice Bobzien
Quentin Blackford	Printed Name	Brice Bobzien
President and CEO	Date	July 22, 2022

Exhibit A

Services and Benefits for Brice Bobzien

Position: Chief Financial Officer

Base Pay Rate: You will be a Full-Time Exempt employee, with a base rate of $400,000.00 annually, which will be earned and payable in accordance with the Company's payroll policy.

Bonus: Each calendar year, you will be eligible to earn a bonus of 60% of your annual base salary. The bonus will be based on the achievement of financial targets and/or other performance objectives set by the Company, and the earned bonus will generally be paid within 90 days after the close of a calendar year. Your bonus (if any) for 2022 will not be prorated and will be paid on a full-year basis, and you must be employed on the date that your bonus, if any, is paid in order to earn and be eligible to receive the bonus.

Eligibility for Equity Award: In addition to your new hire equity grant, you are also annually eligible for an award of equity in the first quarter of each year, currently targeted at the amount of $1,800,000, as follows:

1. An award of restricted stock units ("RSUs") covering a number of shares of the Company's common stock with an aggregate value of $900,000 which will vest annually over four years at the rate of twenty-five percent (25%) per year, subject to your continuing employment through each vesting date.

2. An award of performance stock units ("PSUs") covering a number of shares of the Company's common stock with an aggregate value of $900,000 which will vest pursuant to the performance-based metrics applicable to the Company's management team generally as set forth in the Company's then current PSU incentive program as approved by the Compensation Committee, subject to your continuing employment through the applicable vesting date.

The granting and amount of the annual equity award (if any) is in the sole discretion of the CEO and Board. Each equity award will be subject to the terms and conditions of the Company's 2016 Equity Incentive Plan (as amended from time to time, the "2016 Plan") and, as applicable, a PSU agreement or RSU agreement thereunder.

Benefits and Expenses: You will be entitled to participate in the benefit plans and programs generally available from time to time to employees of the Company, subject to the terms of such plans and programs. This includes five weeks per year of Paid Time Off to be accrued in 2023 (normal PTO accrual will apply thereafter), in addition to specified Holidays, among other benefits.

Severance: You may be eligible to receive severance benefits in the event your employment is terminated under certain conditions pursuant to the terms of our Change of Control and Severance Policy and a participation agreement thereunder.

Exhibit 21.1

List of Subsidiaries

Company Name	Country	Date of Incorporation	Registration No.
iRhythm Technologies Inc.	US (Delaware)	September 14, 2006	4211384
iRhythm Technologies Limited	UK	March 10, 2016	10055682
iRhythm Singapore Pte. Ltd.	Singapore	June 24, 2021	202120787H
iRhythm Japan GK [(1)]	Japan	June 7, 202	#0110-03-014840

(1) Japan is a subsidiary of Singapore

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-263066, 333-256762, 333-236838, 333-233033, 333-223351 and 333-217077) of iRhythm Technologies, Inc. of our report dated February 23, 2023 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
San Jose, California
February 23, 2023

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Quentin S. Blackford, certify that:

1. I have reviewed this Annual Report on Form 10-K of iRhythm Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 23, 2023

By: /s/ Quentin S. Blackford

Quentin S. Blackford,
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Brice Bobzien, certify that:

1. I have reviewed this Annual Report on Form 10-K of iRhythm Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 23, 2023

By: /s/ Brice Bobzien

Brice Bobzien
Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of iRhythm Technologies, Inc. (the "Company") on Form 10-K for the year ending December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 23, 2023

By: /s/ Quentin S. Blackford

Quentin S. Blackford
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Brice Bobzien

Brice Bobzien
Chief Financial Officer
(Principal Financial Officer)