

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

Form 10-Q

(Mark One)

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

For the quarterly period ended **March 31, 2025**

OR

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

Commission file number: **001-37918**

iRhythm Technologies, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

20-8149544
(I.R.S. Employer
Identification No.)

699 8th Street Suite 600
San Francisco, California
(Address of Principal Executive Offices)

94103
(Zip Code)

(415) 632-5700

(Registrant's Telephone Number, Including Area Code)
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 \$0.001 Per Share	IRTC	The Nasdaq Stock Market LLC

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 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 definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of April 24, 2025, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 31,925,267.

IRHYTHM TECHNOLOGIES, INC.
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q other than statements of historical fact, including statements concerning our plans, objectives, and expectations for our business, operations, and financial performance and condition, are 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 global business, political, and macroeconomic conditions, including inflation, interest rate volatility, cybersecurity events, potential instability in the global banking system, volatile market conditions, the impact of tariffs, the impact of any significant political and regulatory developments, global events, including public health crises, and ongoing geopolitical conflicts, such as the war in Ukraine and conflict in the Middle East, 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 compliance with all applicable laws, rules, and regulations, including those of the U.S. Food and Drug Administration;
- 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, general and administrative expenses and gross margin;
- 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;
- the outcome of any litigation or investigations;
- 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q. We assume no obligation to update or revise these forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q to conform these statements to actual results or to changes in our expectations, 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.

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

IRHYTHM TECHNOLOGIES, INC. Condensed Consolidated Balance Sheets (In thousands, except par value)

	March 31, 2025	December 31, 2024
(unaudited)		
Assets		
Current assets:		
Cash and cash equivalents	\$ 375,278	\$ 419,597
Marketable securities	145,311	115,956
Accounts receivable, net	80,639	79,941
Inventory	14,336	14,039
Prepaid expenses and other current assets	20,449	16,286
Total current assets	636,013	645,819
Property and equipment, net	130,850	125,092
Operating lease right-of-use assets	46,171	47,564
Restricted cash	8,358	8,358
Goodwill	862	862
Long-term strategic investments	62,745	61,902
Other assets	41,099	41,852
Total assets	\$ 926,098	\$ 931,449
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 11,946	\$ 7,221
Accrued liabilities	79,976	84,900
Deferred revenue	3,282	2,932
Operating lease liabilities, current portion	16,140	15,867
Total current liabilities	111,344	110,920
Long-term senior convertible notes	647,237	646,443
Other noncurrent liabilities	8,727	8,579
Operating lease liabilities, noncurrent portion	72,125	74,599
Total liabilities	839,433	840,541
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value – 5,000 shares authorized; none issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Common stock, \$0.001 par value – 100,000 shares authorized; 32,144 shares issued and 31,915 shares outstanding at March 31, 2025, respectively; and 31,621 shares issued and 31,392 shares outstanding at December 31, 2024, respectively	32	31
Additional paid-in capital	901,085	874,607
Accumulated other comprehensive income	143	165
Accumulated deficit	(789,595)	(758,895)
Treasury stock, at cost; 229 shares at March 31, 2025 and December 31, 2024	(25,000)	(25,000)
Total stockholders' equity	86,665	90,908
Total liabilities and stockholders' equity	\$ 926,098	\$ 931,449

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

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

	Three Months Ended March 31,	
	2025	2024
(unaudited)		
Revenue, net	\$ 158,677	\$ 131,929
Cost of revenue	49,461	44,413
Gross profit	109,216	87,516
Operating expenses:		
Research and development	21,519	16,994
Acquired in-process research and development	296	—
Selling, general and administrative	119,957	108,660
Total operating expenses	141,772	125,654
Loss from operations	(32,556)	(38,138)
Interest and other income (expense), net:		
Interest income	4,919	3,057
Interest expense	(3,273)	(2,860)
Loss on extinguishment of debt	—	(7,589)
Other income (expense), net	875	(105)
Total interest and other income (expense), net	2,521	(7,497)
Loss before income taxes	(30,035)	(45,635)
Income tax provision	665	32
Net loss	\$ (30,700)	\$ (45,667)
Net loss per common share, basic and diluted	\$ (0.97)	\$ (1.47)
Weighted-average shares, basic and diluted	31,590	31,033

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

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

	Three Months Ended March 31,	
	2025	2024
(unaudited)		
Net loss	\$ (30,700)	\$ (45,667)
Other comprehensive income (loss):		
Net change in unrealized gain (loss) from marketable securities	10	(54)
Cumulative translation adjustment	(32)	77
Comprehensive loss	<u>\$ (30,722)</u>	<u>\$ (45,644)</u>

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

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

	Three Months Ended March 31,	
	2025	2024
(unaudited)		
Cash flows from operating activities		
Net loss	\$ (30,700)	\$ (45,667)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,210	5,131
Stock-based compensation	23,344	20,991
Amortization of premium and accretion of discounts, net	(619)	(908)
Amortization of operating lease right-of-use assets	1,393	1,244
Amortization of debt discount	794	578
Change in fair value of strategic investments	(843)	—
Provision for credit losses and contractual allowances	29,427	16,289
Acquired in-process research and development	296	—
Loss on extinguishment of debt	—	7,589
Other	103	106
Changes in operating assets and liabilities:		
Accounts receivable	(30,125)	(44,518)
Inventory	(388)	(923)
Prepaid expenses and other current assets	(4,165)	7,813
Other assets	729	(4,694)
Accounts payable and accrued liabilities	(489)	(12,877)
Deferred revenue	350	(238)
Operating lease liabilities	(2,208)	(1,945)
Net cash used in operating activities	(7,891)	(52,029)
Cash flows from investing activities		
Purchases of property and equipment	(9,419)	(9,776)
Purchases of marketable securities	(34,320)	(2,426)
Maturities of marketable securities	5,600	52,200
Net cash (used in) provided by investing activities	(38,139)	39,998
Cash flows from financing activities		
Payment of SVB term loan and termination costs	—	(37,751)
Proceeds from Braidwell debt	—	75,000
Payments of issuance costs for Braidwell debt	—	(1,803)
Payment of Braidwell debt and termination costs	—	(78,660)
Proceeds from issuance of 2029 Notes	—	661,250
Payments of issuance costs for 2029 Notes	—	(16,592)
Purchases of capped call transactions	—	(72,407)
Purchase of treasury stock	—	(25,000)
Proceeds from issuance of common stock in connection with employee equity incentive plans	1,729	604
Net cash provided by financing activities	1,729	504,641
Effect of exchange rate changes	(18)	(4)
Net increase (decrease) in cash, cash equivalents and restricted cash	(44,319)	492,606
Cash, cash equivalents and restricted cash, beginning of period	427,955	36,173
Cash, cash equivalents and restricted cash, end of period	\$ 383,636	\$ 528,779

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

	Three Months Ended March 31,	
	2025	2024
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	\$ 375,278	\$ 520,421
Restricted cash, long-term	\$ 8,358	\$ 8,358
Total cash, cash equivalents and restricted cash	<u>\$ 383,636</u>	<u>\$ 528,779</u>
Supplemental disclosures of cash flow information:		
Interest paid	\$ 4,959	\$ 1,595
Cash taxes paid	\$ 390	\$ 11
Cash paid for operating lease liabilities	\$ 3,864	\$ 3,732
Non-cash investing and financing activities:		
Property and equipment costs included in accounts payable and accrued liabilities	\$ 132	\$ 23
Capitalized stock-based compensation in property and equipment	\$ 1,406	\$ 1,649

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

IRHYTHM TECHNOLOGIES, INC.
Condensed Consolidated Statements of Stockholders' Equity
(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders' Equity
	Shares	Amount					
(unaudited)							
Balances at December 31, 2024	31,392	\$ 31	\$ 874,607	\$ (758,895)	\$ 165	\$ (25,000)	\$ 90,908
Issuance of common stock in connection with employee equity incentive plans, net	523	1	1,728	—	—	—	1,729
Stock-based compensation	—	—	24,750	—	—	—	24,750
Net loss	—	—	—	(30,700)	—	—	(30,700)
Net change in unrealized gain on marketable securities	—	—	—	—	10	—	10
Cumulative translation adjustment	—	—	—	—	(32)	—	(32)
Balances at March 31, 2025	31,915	\$ 32	\$ 901,085	\$ (789,595)	\$ 143	\$ (25,000)	\$ 86,665

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholders' Equity
	Shares	Amount					
(unaudited)							
Balances at December 31, 2023	30,954	\$ 31	\$ 855,784	\$ (645,606)	\$ (112)	\$ —	\$ 210,097
Issuance of common stock in connection with employee equity incentive plans, net	372	—	604	—	—	—	604
Purchase of capped call transactions	—	—	(72,407)	—	—	—	(72,407)
Purchase of treasury stock	(229)	—	—	—	—	(25,000)	(25,000)
Stock-based compensation	—	—	22,640	—	—	—	22,640
Net loss	—	—	—	(45,667)	—	—	(45,667)
Net change in unrealized loss on marketable securities	—	—	—	—	(54)	—	(54)
Cumulative translation adjustment	—	—	—	—	77	—	77
Balances at March 31, 2024	31,097	\$ 31	\$ 806,621	\$ (691,273)	\$ (89)	\$ (25,000)	\$ 90,290

The accompanying notes are an integral part of these unaudited condensed 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 ambulatory cardiac monitoring services from its Medicare-enrolled independent diagnostic testing facilities ("IDTFs") and with its qualified technicians. The Company has provided the Zio ambulatory cardiac monitoring services, including long-term continuous monitoring ("LTCM"), short-term continuous monitoring, and mobile cardiac telemetry ("MCT") monitoring services (collectively, the "Zio Services"), using 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"). LTCM services (the "Zio LTCM Service") and MCT services (the "Zio MCT Service") 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.

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, a manufacturing facility in Cypress, California and corporate office space in Solana Beach, California.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying financial statements include the accounts of the Company and its wholly owned subsidiaries, and have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") and applicable rules and regulations of the Securities and Exchange Commission (the "SEC") regarding interim financial reporting. As permitted under those rules, the condensed consolidated financial statements and related disclosures as of December 31, 2024, have been derived from the audited consolidated financial statements but do not include all of the information required by GAAP for complete consolidated financial statements. These unaudited condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for the fair statement of the Company's unaudited condensed consolidated financial information. The results of operations for the three months ended March 31, 2025, are not necessarily indicative of the results to be expected for the year ending December 31, 2025, or for any other interim period or for any other future year.

The accompanying unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2024, included in the Company's Annual Report on Form 10-K, filed with the SEC on February 20, 2025.

Reclassification

Certain prior period amounts have been reclassified to conform to the current year presentation. These reclassifications have no impact on previously reported results of operations or financial position.

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 ongoing geopolitical conflicts, such as the war in Ukraine and conflict in the Middle East, domestic and global inflationary trends, interest rate volatility, potential instability in the global banking system, global supply shortages, tariffs on imports, and a tightening labor market. 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, or uncertainty surrounding tariffs, 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 hybrid work arrangements and decision to pursue a sublease have previously resulted in an impairment of its right-of-use asset and related leasehold improvements and furniture and fixtures. As the Company continues to evaluate its global real estate footprint, 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 has adequate liquidity over the next 12 months to operate its business and to meet its cash requirements. The Company is in compliance with its convertible debt requirements.

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 Association. These CPT codes are subject to periodic change and update, which will impact the reimbursement rates for the Company's Zio Services.

Based on relative value units, CMS annually updates the reimbursement rates for diagnostic tests performed by IDTFs via the Medicare Physician Fee Schedule. CMS establishes national payment rates for the CPT codes the Company uses to report Zio Services performed by the Company. Because remote cardiac monitoring technology, including the Zio System, is 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 the Company's financial results.

Third-party payors globally are increasingly challenging the utilization and overall cost for medical products and services. The containment of healthcare costs has become a priority of governments on a global basis. Third-party payors may decline to cover and reimburse for claims or portions of claims.

Use of Estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with 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 periods presented. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, contractual allowances, provision for credit losses, 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, fair value of strategic loan investments, accounting for income taxes, impairment of ROU assets, contingent consideration liabilities, and various inputs used in estimating stock-based compensation. Actual results may differ from those estimates.

Significant Accounting Policies

During the three months ended March 31, 2025, there were no changes to the Company's significant accounting policies as described in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

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. During the first quarter of 2024, the Company experienced a temporary delay in the billing of the Company's contracted and non-contracted payer customers, performed by the Company's third-party claims processing vendor. The delay was due to a cybersecurity incident experienced by Change Healthcare, a division of UnitedHealth Group, in which the Company's third-party vendor did engage for services relating to billing and collections. While the Company substantially cleared the billing backlog as of the end of the first quarter of 2024, the delay in billing resulted in a temporary delay in the Company's cash collections. The Company has received the majority of its cash collections from the delayed billings.

The Company records a provision for credit losses 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. CMS accounted for 18% and 15% of accounts receivable at March 31, 2025 and December 31, 2024, respectively. One commercial customer accounted for approximately 14% and 13% of the Company's accounts receivable as of March 31, 2025, and December 31, 2024, respectively. As presented in Note 3, CMS accounted for approximately 24% of the Company's revenue for the three months ended March 31, 2025, and 2024.

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.

Recently adopted accounting pronouncements

In November 2023, the FASB issued Accounting Standards Update ("ASU") 2023-07 ("ASU 2023-07"), *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which updates reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. The amendments are effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. The Company adopted ASU 2023-07 during the year ended December 31, 2024.

Recently issued accounting pronouncements not yet adopted

In December 2023, the FASB issued ASU No. 2023-09 ("ASU 2023-09"), *Income Taxes (Topic 740): Improvement to Income Tax Disclosures* to enhance the transparency and decision usefulness of income tax disclosures. Two primary enhancements related to this ASU include disaggregating existing income tax disclosures relating to the effective tax rate reconciliation and income taxes paid. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 on a prospective basis. The Company is currently evaluating this ASU to determine its impact on the Company's financial statement disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures*, which requires disclosure about the types of costs and expenses included in certain expense captions presented on the income statement. The new disclosure requirements are effective for the Company's annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently in the process of evaluating the impact of this pronouncement on its related disclosures.

3. BUSINESS SEGMENT AND REVENUE

Reportable Segments

Operating segments are defined as components of an enterprise where separate financial information is evaluated regularly by the chief operating decision maker ("CODM"). The Company has one reportable and one operating segment, its global ambulatory cardiac monitoring business. The Company's Chief Executive Officer, who is the Company's CODM, reviews financial information presented on a consolidated basis for purposes of making operating decisions, allocating resources, and assessing financial performance.

The key measure of the Company's segment profit or loss is consolidated net loss, which is reported on the Company's unaudited condensed consolidated statements of operations. Consolidated net loss is used to measure actual results versus expectations. The measure of segment assets is reported on the unaudited condensed consolidated balance sheets as total assets.

Significant segment expenses within loss from operations, as well as within net loss, include cost of revenue, research and development, acquired in-process research and development, selling, general and administrative expenses, and impairment and restructuring charges which are each separately presented on the Company's unaudited condensed consolidated statements of operations. Other segment items within net loss include interest and other income (expense), net, and income tax provision.

IRHYTHM TECHNOLOGIES, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements (Continued)

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 three months ended March 31, 2025, and 2024 were as follows (in thousands, except percentages)

	Three Months Ended March 31,			
	2025		2024	
	Amount	% of Revenue	Amount	% of Revenue
Contracted third-party payors	\$ 83,802	53%	\$ 71,773	54%
Centers for Medicare and Medicaid	38,112	24%	31,786	24%
Healthcare institutions	26,673	17%	19,571	15%
Non-contracted third-party payors	10,090	6%	8,799	7%
Total	\$ 158,677		\$ 131,929	

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 the three months ended March 31, 2025, and 2024.

Accounts Receivable, Provision for Credit Losses 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 unaudited condensed consolidated balance sheets net of an estimated provision for credit losses and contractual allowances.

The Company establishes a provision for credit losses 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, as a reduction of revenue, based on the estimated differences between contracted amounts and expected collection rates for services performed. Such provisions are based on the Company's historical experience and expected future claims denials. The Company updates the estimate for this provision each reporting period.

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 provision for credit losses (in thousands):

	Three Months Ended March 31, 2025	Year Ended December 31, 2024	Three Months Ended March 31, 2024
Balance, beginning of period	\$ 16,248	\$ 20,289	\$ 20,289
Provision for credit losses	8,883	22,583	6,037
Write-offs	(14,202)	(26,624)	(6,337)
Balance, end of period	\$ 10,929	\$ 16,248	\$ 19,989

IRHYTHM TECHNOLOGIES, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements (Continued)

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

	Three Months Ended March 31, 2025	Year Ended December 31, 2024	Three Months Ended March 31, 2024
Balance, beginning of period	\$ 50,961	\$ 52,689	\$ 52,689
Add: provision for contractual adjustments	20,544	50,880	10,252
Less: contractual adjustments	(21,005)	(52,608)	(10,870)
Balance, end of period	<u>\$ 50,500</u>	<u>\$ 50,961</u>	<u>\$ 52,071</u>

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 LTCM Service upon patient registration or shipment of devices. Such advance payments are recognized as deferred revenue and are recorded as revenue when Zio reports are delivered to the healthcare provider. During the three months ended March 31, 2025, and 2024, \$2.7 million and \$3.0 million related to the contract liability balance at the beginning of 2025 and 2024 was recognized as revenue, respectively. The deferred revenue liability was \$3.3 million and \$2.9 million as of March 31, 2025, and December 31, 2024, respectively.

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 maintains short-term sales incentive compensation programs. 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.

IRHYTHM TECHNOLOGIES, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements (Continued)

4. CASH EQUIVALENTS AND MARKETABLE SECURITIES

The fair value of cash equivalents and marketable securities as of March 31, 2025, and December 31, 2024, were as follows (in thousands):

	March 31, 2025			
	Amortized Cost	Gross Unrealized		Fair Value
		Gains	Losses	
Money market funds	\$ 55,226	\$ —	\$ —	\$ 55,226
U.S. government securities	264,983	50	(3)	265,030
Total cash equivalents and marketable securities	<u>\$ 320,209</u>	<u>\$ 50</u>	<u>\$ (3)</u>	<u>\$ 320,256</u>
Classified as:				
Cash equivalents				\$ 174,945
Marketable securities				145,311
Total cash equivalents and marketable securities				<u>\$ 320,256</u>

	December 31, 2024			
	Amortized Cost	Gross Unrealized		Fair Value
		Gains	Losses	
Money market funds	\$ 40,654	\$ —	\$ —	\$ 40,654
U.S. government securities	276,467	57	—	276,524
Total cash equivalents and marketable securities	<u>\$ 317,121</u>	<u>\$ 57</u>	<u>\$ —</u>	<u>\$ 317,178</u>
Classified as:				
Cash equivalents				\$ 201,222
Marketable securities				115,956
Total cash equivalents and marketable securities				<u>\$ 317,178</u>

5. FAIR VALUE MEASUREMENTS

Assets and Liabilities Measured at Fair Value on a Recurring Basis

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.

IRHYTHM TECHNOLOGIES, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements (Continued)

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 U.S. 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 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):

March 31, 2025				
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	\$ 55,226	\$ —	\$ —	\$ 55,226
U.S. government securities	—	265,030	—	265,030
Strategic investments	—	—	62,745	62,745
Total	<u>\$ 55,226</u>	<u>\$ 265,030</u>	<u>\$ 62,745</u>	<u>\$ 383,001</u>
Liabilities				
Contingent consideration	—	—	17,667	17,667
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 17,667</u>	<u>\$ 17,667</u>

December 31, 2024				
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	\$ 40,654	\$ —	\$ —	\$ 40,654
U.S. government securities	—	276,524	—	276,524
Strategic investments	—	—	61,902	61,902
Total	<u>\$ 40,654</u>	<u>\$ 276,524</u>	<u>\$ 61,902</u>	<u>\$ 379,080</u>
Liabilities				
Contingent consideration	—	—	17,371	17,371
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 17,371</u>	<u>\$ 17,371</u>

Fair Value of Strategic Investments

The Company holds strategic investments upon which it measures the fair value on a recurring basis. The carrying value of these investments are \$62.7 million and \$61.9 million as of March 31, 2025, and December 31, 2024, respectively.

The Company's strategic investments are with privately held companies, and as such, limited information is available. On a quarterly basis, the Company monitors information that becomes available and adjusts the carrying values of these investments if there are identified events or changes in circumstances that have a significant effect on their fair values. The strategic investments are categorized as Level 3 investments within the fair value hierarchy due to the uncertainty of the fair value measurement with respect to the use of significant unobservable inputs and included within long-term strategic investments in the Company's unaudited condensed consolidated balance sheets.

IRHYTHM TECHNOLOGIES, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements (Continued)

During the year ended December 31, 2024, the Company made an aggregate of \$55.0 million in strategic loan investments in BioIntelliSense, Inc. ("BioIS"), a privately-held company. The loan investments have maturity dates ranging from April 2029 through August 2029. The loan investments can convert into preferred shares of BioIS based upon certain qualifying financing events. The aggregate fair value of the strategic loan investments is \$57.2 million and \$56.4 million as of March 31, 2025, and December 31, 2024, respectively. In accordance with ASC 820, *Fair Value Measurement*, the Company elected to apply the fair value option to these strategic loan investments, with changes in fair value reported within other income (expense), net in the Company's unaudited condensed consolidated statements of operations at each reporting period. During the three months ended March 31, 2025, and the year ended December 31, 2024, the Company increased the fair value of the strategic loan investments by \$0.8 million and \$1.4 million, respectively. The fair value of the loan investments in BioIS is determined by using a probability-weighted expected return model ("PWERM") and a discounted cash flow valuation model with scenarios that correspond to the contractual settlement events. The determination of fair value involves significant assumptions such as discount rates, volatility rates, and expected years. These unobservable inputs represent a Level 3 measurement, as they are supported by little or no market activity and reflect the Company's own assumptions in measuring fair value.

The following table sets forth the recurring Level 3 fair value measurements of the loan investment including the significant unobservable inputs:

	March 31, 2025	December 31, 2024
Discount rate	12.0 %	12.0 %
Equity volatility	67.0 %	67.0 %
Expected years (range)	2025 - 2029	2025 - 2029

During the year ended December 31, 2024, the Company made a \$2.0 million strategic loan investment in a separate privately-held company. The fair value of the strategic loan investment is \$2.0 million as of March 31, 2025, and December 31, 2024.

During the year ended December 31, 2023, the Company made a \$3.0 million strategic equity investment in a separate privately-held company. During the year ended December 31, 2024, the Company increased the fair value of the strategic equity investment by \$0.5 million. The carrying value of the strategic equity investment is \$3.5 million as of March 31, 2025, and December 31, 2024. The change in fair value is recorded within other income (expense), net in the Company's unaudited condensed consolidated statements of operations.

The following table sets forth the changes in the estimated fair value of the Company's strategic investments measured on a recurring basis (in thousands):

	Three Months Ended March 31, 2025	Year Ended December 31, 2024	Three Months Ended March 31, 2024
Balance, beginning of period	\$ 61,902	\$ 3,000	\$ 3,000
Additions during the period	—	57,000	—
Changes in estimated fair value	843	1,902	—
Balance, end of period	<u>\$ 62,745</u>	<u>\$ 61,902</u>	<u>\$ 3,000</u>

Contingent Consideration Liabilities

The Company established contingent consideration liabilities in conjunction with the development milestones associated with the acquisition of certain technology from BioIS. The fair value of contingent consideration liabilities is determined using PWERM, with scenarios that correspond to the contractual settlement events. There are significant inputs of such model that are not observable in the market, such as probability of achievement of stated milestones and expected term. The unobservable inputs represent a Level 3 measurement. Fair value adjustments to contingent consideration liabilities are assessed quarterly and recorded through operating expenses within acquired in-process research and development in the unaudited condensed consolidated statements of operations. Refer to Note 7, Commitments and Contingencies, for further details relating to the BioIS contingent consideration liabilities.

IRHYTHM TECHNOLOGIES, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements (Continued)

The following table sets forth the recurring Level 3 fair value measurements of contingent consideration liabilities associated with the development agreement milestones including the significant unobservable inputs:

	March 31, 2025	December 31, 2024
Probability of achievement (range)	75.0% - 90.0%	75.0% - 90.0%
Expected years	2025 - 2026	2025 - 2026

Contingent consideration liabilities for BiolS at the inception of acquisition of the licensed technology were \$17.0 million. Contingent consideration liabilities were \$17.7 million and \$17.4 million as of March 31, 2025, and December 31, 2024, respectively, with the current portion included within accrued liabilities and the noncurrent portion included within other noncurrent liabilities in the Company's unaudited condensed consolidated balance sheet.

The following table sets forth the changes in the estimated fair value of the Company's contingent consideration liabilities measured on a recurring basis (Level 3) (in thousands):

	Three Months Ended March 31, 2025	Year Ended December 31, 2024
Balance, beginning of period	\$ 17,371	\$ —
Additions during the period	—	16,970
Changes in estimated fair value	296	401
Balance at end of period	<u>\$ 17,667</u>	<u>\$ 17,371</u>

Fair Value of Senior Convertible Notes

The fair value, based on a quoted market price (Level 1), of the Company's senior convertible notes due 2029 (the "2029 Notes") is as follows (in thousands):

	March 31, 2025	December 31, 2024
Senior Convertible Notes due 2029	\$ 689,221	\$ 641,214

6. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
Raw materials and work-in-progress	\$ 5,167	\$ 5,863
Finished goods	9,169	8,176
Total	<u>\$ 14,336</u>	<u>\$ 14,039</u>

Long-term Strategic Investments

Long-term strategic investments consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
Strategic loan investments	\$ 59,250	\$ 58,407
Strategic equity investments	3,495	3,495
Total	<u>\$ 62,745</u>	<u>\$ 61,902</u>

IRHYTHM TECHNOLOGIES, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements (Continued)

Other Assets

Other assets consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
PCBAs	\$ 34,496	\$ 34,698
Cloud computing arrangements	4,758	5,230
Other	1,845	1,924
Total	<u>\$ 41,099</u>	<u>\$ 41,852</u>

The Company reuses PCBAs in each wearable Zio Monitor patch, Zio XT patch, and Zio AT patch, as well as the wireless gateway used in conjunction with the Zio AT patch. As PCBAs are used in a wearable Zio Monitor patch, Zio XT patch, or Zio AT patch, a portion of the cost of the PCBA is recorded as a cost of revenue. Charges to cost of revenue were \$3.9 million and \$2.8 million for the three months ended March 31, 2025, and 2024, respectively. During the three months ended March 31, 2025, PCBAs decreased by \$0.2 million primarily driven by the charges to cost of revenues for PCBA usage, offset by additional purchases of PCBAs for Zio Monitor patch to further support the growth in commercial volumes.

The Company recorded \$0.6 million amortization expense during three months ended March 31, 2025, and 2024, respectively, related to capitalized implementation costs in our cloud computing arrangement balance.

Property and Equipment, Net

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

	Useful life	March 31, 2025	December 31, 2024
Laboratory and manufacturing equipment	2 to 7	\$ 9,543	\$ 9,687
Computer equipment and software	3	4,082	4,227
Furniture and fixtures	2 to 5	4,180	4,181
Leasehold improvements	3 to 12	27,121	27,121
Internal-use software in service	3 to 7	80,191	79,660
Internal-use software in development	—	69,358	60,797
Construction in progress	—	12,284	10,638
Total property and equipment, gross		206,759	196,311
Less: accumulated depreciation and amortization		(75,909)	(71,219)
Total property and equipment, net		<u>\$ 130,850</u>	<u>\$ 125,092</u>

Depreciation and amortization expense for the three months ended March 31, 2025, and 2024 was \$5.2 million and \$5.1 million, respectively, of which amortization related to internal-use software, was \$3.8 million and \$3.7 million for the three months ended March 31, 2025, and 2024, respectively.

During the three months ended March 31, 2025, internal-use software, both in service and in development, increased by \$9.1 million. This increase related to enhancements in the Company's core technology, products and services and artificial intelligence, as well as investment in future technology.

IRHYTHM TECHNOLOGIES, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements (Continued)

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
Accrued payroll and related expenses	\$ 32,605	\$ 42,293
Accrued vacation	7,318	6,914
Accrued expenses	15,178	16,044
Claims payable	1,562	2,011
Accrued employee share purchase plan contributions	2,213	585
Accrued income and other taxes	4,713	4,008
Accrued professional services fees	6,539	3,345
Contingent consideration liabilities	9,848	9,700
Total accrued liabilities	<u>\$ 79,976</u>	<u>\$ 84,900</u>

7. COMMITMENTS AND CONTINGENCIES

Leases

The Company leases office, manufacturing, and clinical centers under non-cancelable operating leases which expire on various dates through 2033. 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 expenses, generally on a straight-line basis over the lease period.

During the three months ended March 31, 2025, there were no material changes to the leases from those described in Note 8, Commitments and Contingencies, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2024.

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

Year Ended December 31:

2025 (remainder of the year)	\$ 11,242
2026	16,683
2027	17,096
2028	17,014
2029	17,121
Thereafter	32,912
Total lease payments	<u>112,068</u>
Less: imputed interest	(23,803)
Total lease liabilities	<u>\$ 88,265</u>

Self-Insured Health Plan

As of January 1, 2025, the Company transitioned from a fully-insured program to a self-insurance program to cover U.S. employees and their dependent health benefits. As part of the program, the Company also has stop-loss coverage from a third party which limits the exposure to large claims. The Company records a liability associated with these benefits by utilizing a third-party actuarial specialist, that includes both an estimate of claims filed and incurred but not yet reported based upon historical claims experience. As of March 31, 2025, the Company's accrued health benefits liability was \$1.9 million which is included within accrued liabilities on the unaudited condensed consolidated balance sheets.

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 6, 2024, a putative class action lawsuit was filed in the United States District Court for the Northern District of California alleging that the Company and its current Chief Executive Officer, Quentin Blackford, its former Chief Financial Officer, Brice Bobzien, and its former Chief Financial Officer and former Chief Operating Officer, Douglas Devine violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder, and seeks unspecified damages purportedly sustained by the class. On July 19, 2024, an amended complaint was filed, naming the Company, Mr. Blackford, Mr. Bobzien, Mr. Devine, its Chief Commercial Officer Chad Patterson, its former Chief Technology Officer Mark Day, and its Chief Medical Officer, Chief Scientific Officer, and Executive Vice President of Product Innovation Mintu Turakhia as defendants. On October 7, 2024, a second amended complaint was filed to include events from the recent FDA inspections, but otherwise included the same claims under the Exchange Act. On December 10, 2024, defendants filed a motion to dismiss. Oral arguments on the motion to dismiss were held in late April.

The Company's board members and certain of its current and former executives were named as defendants in two complaints filed as stockholder derivative actions in the United States District Court for the District of Delaware and the United States District Court for the Northern District of California, respectively. iRhythm is named as a nominal defendant in both complaints. The cases make similar allegations to those in the securities class action complaint described above and both cases have both been stayed pending the resolution of motion to dismiss briefing in the securities class action.

The Company believes the above securities class action and derivative lawsuits to be without merit and plans to continue 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 FDA and its products and services. On September 13, 2021, the Company received a second subpoena requesting additional information. On April 4, 2023, the Company received a Subpoena Duces Tecum from the Consumer Protection Branch, Civil Division of the U.S. Department of Justice (the "DOJ"), requesting production of various documents regarding our products and services. The Company is cooperating fully on these matters.

On July 1, 2024, the DOJ filed with the United States District Court for the Northern District of California a Petition for Order to Show Cause and Application for Enforcement with respect to the production of certain documentary materials which the Company asserts are protected by legal privileges. The Company continues to defend its privilege assertions over such materials in its response to the DOJ's petition. The matter has been briefed, and oral argument has been rescheduled for May 1, 2025. Regardless of the outcome, it is not clear what, if any, action the DOJ may take following resolution of the dispute over legal privileges.

On February 20, 2024, Welch Allyn, a subsidiary of Hill-Rom Holdings, Inc. now part of Baxter International, Inc., filed a lawsuit against the Company in the United States District Court for the District of Delaware, alleging that its Zio devices infringe certain of Welch Allyn's patents and that the Company's infringement was willful. The Company filed a motion to dismiss Welch Allyn's willful infringement claims on April 11, 2024. Welch Allyn filed an amended complaint on April 24, 2024 that continued to allege that the Company's devices infringe certain of its patents and that the Company's infringement was willful. The Company filed a motion to dismiss Welch Allyn's willful infringement allegations found in the amended complaint on May 22, 2024 and a hearing on the motion to dismiss was held on January 28, 2025. After hearing arguments, the Court granted the Company's motion and the willful infringement claims in the amended complaint were dismissed without prejudice. Welch Allyn filed a second amended complaint adding additional patent claims on February 14, 2025. The Company filed a response to the allegations found in the second amended complaint on March 21, 2025 denying all allegations of patent infringement and asserting defenses including patent invalidity. Welch Allyn seeks money damages and attorneys' fees. The Company believes this lawsuit is without merit and plans to defend itself vigorously.

On December 10, 2024, Bardy Diagnostics, Inc. ("BardyDx"), a subsidiary of Hill-Rom Holdings, Inc. now part of Baxter International, Inc., filed a lawsuit against the Company in the United States District Court for the District of Delaware, alleging that our Zio Monitor patch infringes one of its patents. On December 26, 2024, BardyDx filed an amended complaint alleging that the Company's Zio Monitor patch infringes two of BardyDx's patents. The Company filed a response to the allegations found in the amended complaint on March 3, 2025 denying all allegations of patent infringement, asserting defenses including patent invalidity, and asserting patent infringement counterclaims, and filed an amended counterclaims and answer asserting infringement of two additional patents by BardyDx on March 24, 2025. On March 27, 2025, BardyDx filed an answer and counterclaims to the Company's most recent filing asserting their own counterclaims for declaratory judgment for non-infringement and invalidity of the patents asserted by the Company. BardyDx seeks money damages and attorneys' fees. The Company believes this lawsuit is without merit and plans to defend itself vigorously.

Technology License Agreement

On August 30, 2024, the Company entered into a Technology License Agreement (the "License Agreement") with BioIS, pursuant to which (i) the Company will receive a perpetual fully paid up license to certain of BioIS' intellectual property, technology and products for research, development and commercialization of potential next generation products and services in certain fields of use, including an exclusive license to develop and commercialize pulse oximetry, accelerometry, and trending non-invasive blood pressure technologies for use within the Company's ambulatory cardiac monitoring products and services, and (ii) the Company and BioIS agreed to negotiate in good faith a supply agreement for pulse oximetry hardware.

Under the terms of the License Agreement, during the third quarter of 2024 the Company paid BioIS an upfront fee of \$15.0 million in cash consideration in acceptance of the initial transfer of certain licensed technologies and data following the execution of the License Agreement. In connection with the License Agreement, the Company also purchased an aggregate of \$40.0 million of convertible promissory notes from BioIS (the "Convertible Notes"), of which \$20.0 million of the convertible promissory notes ("Milestone Notes") were designated for satisfaction of the Company's regulatory milestone payment obligations. The Milestone Notes, plus accrued and unpaid interest, if any, shall be cancelled, if outstanding, upon the achievement of the regulatory milestones up through December 31, 2026. During the three months ended March 31, 2025, the Company has recorded a charge for \$0.3 million for acquired IPR&D in the Company's unaudited condensed consolidated statements of operations for contingent considerations related to regulatory milestones. Additionally, BioIS is eligible to receive low single digit royalty payments on annual net sales of certain products in the home sleep testing field, subject to certain adjustments specified in the License Agreement.

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*.

Pursuant to the Development Agreement, the Company and Verily agreed to develop certain next-generation atrial fibrillation ("Afib") screening, detection, or monitoring products, which products will involve combining Verily's 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 milestone payments to Verily up to an aggregate of \$12.75 million upon achievement of various development and regulatory milestones over the term of the Development Agreement. The Company and Verily have achieved milestones tied to payments totaling \$11.0 million to date and the Company is obligated to make additional payments over the term of the Development Agreement of \$1.75 million, subject to the achievement of specified milestones.

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 not 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.

8. DEBT

1.50% Senior Convertible Notes due 2029

The carrying amounts of the Company's 2029 Notes were as follows (in thousands):

	March 31, 2025	December 31, 2024
Principal amount	\$ 661,250	\$ 661,250
Unamortized debt issuance costs	(14,013)	(14,807)
Carrying amount of senior convertible notes due 2029	<u>\$ 647,237</u>	<u>\$ 646,443</u>

IRHYTHM TECHNOLOGIES, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements (Continued)

The following table summarizes the components of interest expense and the effective interest rate for the 2029 Notes for the periods shown (in thousands):

	Three Months Ended March 31,	
	2025	2024
Contractual coupon interest	\$ 2,480	\$ 689
Amortized debt issuance costs	793	399
Total interest expense recognized on senior convertible notes due 2029	<u>\$ 3,273</u>	<u>\$ 1,088</u>
Effective interest rate	2.0 %	2.0 %

On March 7, 2024, the Company completed an offering of \$661.3 million aggregate principal amount of unsecured senior convertible notes with a stated interest rate of 1.50% and a maturity date of September 1, 2029. The proceeds include the full exercise of the option granted by the Company to the initial purchasers of the 2029 Notes to purchase up to an additional \$86.3 million aggregate principal amount of notes. Interest on the 2029 Notes is payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2024. The net proceeds from the offering, after deducting initial purchasers' discounts and costs directly related to the offering, were approximately \$643.8 million. The initial conversion rate of the 2029 Notes is 6.7927 shares per \$1,000 principal amount of notes, which is equivalent to a conversion price of approximately \$147.22 per share, subject to adjustments. The 2029 Notes may be settled in cash, stock, or a combination thereof, solely at the Company's discretion.

The Company used net proceeds from the offering to purchase capped calls, as well as repayment of the Company's outstanding debt which is described below. In addition, the Company also used net proceeds from the offering to repurchase shares of the Company's common stock. Refer to Note 10, Stockholders' Equity for further details relating to the Company's shares repurchase.

No principal payments are due on the 2029 Notes prior to maturity. Other than restrictions relating to certain fundamental changes and consolidations, mergers or asset sales and customary anti-dilution adjustments, the indenture relating to the 2029 Notes (the "Indenture") includes customary terms and covenants, including certain events of default after which the 2029 Notes may be due and payable immediately. The Company uses the if-converted method for assumed conversion of the 2029 Notes to compute the weighted-average shares of common stock outstanding for diluted earnings per share, when applicable.

Conversion Rights at the Option of the Holders

Holders of the 2029 Notes who convert their notes in connection with a make-whole fundamental change (as defined in the Indenture) or convert their 2029 Notes called (or deemed called) for redemption in connection with any optional redemption are, under certain circumstances, entitled to an increase in the conversion rate. Additionally, in the event of a fundamental change (as defined in the Indenture), holders of the 2029 Notes may require the Company to repurchase for cash all or a portion of their notes at a price equal to 100% of the principal amount of notes, plus any accrued and unpaid interest to, but excluding, the repurchase date.

Holders of the 2029 Notes may convert all or a portion of their notes prior to the close of business on the business day immediately preceding June 1, 2029, in multiples of \$1,000 principal amount, only under the following circumstances:

(1) during any calendar quarter commencing after the calendar quarter ending on June 30, 2024 (and only during such calendar quarter), if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price of the 2029 Notes on each applicable trading day;

(2) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price (as defined in the Indenture) per \$1,000 principal amount of the 2029 Notes for each trading day of that measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate of the 2029 Notes on such trading day;

(3) if the Company calls any or all 2029 Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date, but only with respect to the 2029 Notes called (or deemed called) for redemption; or

(4) upon the occurrence of specified corporate events as specified in the Indenture.

On or after June 1, 2029, until 5:00 p.m., New York City time, on the second scheduled trading day immediately preceding September 1, 2029, holders of the notes may convert the 2029 Notes, in multiples of \$1,000 principal amount, at their option regardless of the foregoing circumstances.

Conversion Rights at the Company's Option

The Company may not redeem the 2029 Notes prior to September 5, 2027. On or after September 5, 2027 and prior to June 1, 2029, the Company may redeem at its option for cash all or any portion of the 2029 Notes, at the redemption price, if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company provides the redemption notice. The redemption price will be equal to 100% of the principal amount of the 2029 Notes, plus accrued and unpaid interest, if any, to, but excluding, the redemption date.

2029 Capped Call Transactions

On March 4, 2024, in connection with the offering of the 2029 Notes, the Company entered into privately negotiated capped call transactions (the "2029 Capped Calls") with certain financial institutions. The 2029 Capped Calls will cover, subject to anti-dilution adjustments substantially similar to those applicable to the 2029 Notes, the number of shares of the Company's common stock that will initially underlie the 2029 Notes. The 2029 Capped Calls are expected generally to reduce potential dilution to the Company's common stock upon conversion of the 2029 Notes and/or offset any cash payments that the Company could be required to make in excess of the principal amount of converted 2029 Notes, as the case may be, with such reduction and/or offset subject to a cap. The 2029 Capped Calls have an initial cap price of \$218.10 per share, subject to adjustments, which represents a premium of 100% over the closing price of the Company's common stock of \$109.05 per share on the Nasdaq Global Select Market on March 4, 2024. The Company completed the purchase of the 2029 Capped Calls on March 7, 2024, for the amount of \$72.4 million. The cost to purchase the 2029 Capped Calls was recorded as a reduction to additional paid-in capital in the Company's consolidated balance sheets, as the 2029 Capped Calls met the criteria for classification within stockholders' equity.

Braidwell Debt

On January 3, 2024 (the "Closing Date"), the Company entered into the Credit, Security and Guaranty Agreement (the "Braidwell Credit Agreement") with Braidwell Transactions Holdings LLC – Series 5 ("Braidwell"), which provided for a senior secured term loan in an aggregate principal amount of up to \$150.0 million (the "Braidwell Term Loan Facility"). An initial tranche of \$75.0 million ("Initial Loan") was funded on the Closing Date. In addition to the Initial Loan, the Braidwell Term Loan Facility included an additional tranche of \$75.0 million, which was accessible by the Company through the one year anniversary of the Closing Date, so long as the Company satisfied certain customary conditions. The Braidwell Term Loan Facility had a maturity date of January 3, 2029 (the "Maturity Date") and provided, at the Company's election, for the option to have a portion of interest added to principal rather than paid in cash during the term of the loan, with principal and accrued interest due at the Maturity Date.

On March 7, 2024, in connection with the offering of the 2029 Notes, the Company used approximately \$80.2 million of the net proceeds for the repayment in full of the \$75.0 million outstanding Initial Loan, as well as interest, fees and expenses associated with terminating the agreement. Interest expense for the three months ended March 31, 2024, was \$1.8 million, consisting of contractual coupon interest and amortized debt issuance costs of \$1.6 million and \$0.2 million, respectively. The Company incurred \$5.6 million of fees and expenses relating to the repayment of the Initial Loan and the termination of the Braidwell Credit Agreement, inclusive of unamortized debt origination costs, which has been recorded within loss on extinguishment of debt in the Company's unaudited condensed consolidated statements of operations for the three months ended March 31, 2024.

IRHYTHM TECHNOLOGIES, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements (Continued)

SVB Term Loan

In October 2018, the Company entered into the Third Amended and Restated Loan and Security Agreement ("SVB Loan Agreement") with Silicon Valley Bank ("SVB"). 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. None of the remaining \$40.0 million of the 2022 Term Loans was borrowed up through December 31, 2023.

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.

On January 3, 2024, in connection with the entry into the Braidwell Credit Agreement, the Company used approximately \$37.8 million of the net proceeds for the repayment in full of the \$35.0 million outstanding principal balance as well as interest, fees and expenses associated with terminating the agreement. Upon termination of the SVB Loan Agreement, SVB's security interest in the Company's assets and property was released.

In connection with the termination of the SVB term loan, interest expense, contractual coupon interest, and amortized debt issuance costs for the three months ended March 31, 2024, were de minimis. The Company incurred \$2.0 million of fees and expenses relating to the termination of the SVB Loan Agreement, which has been recorded within loss on extinguishment of debt in the Company's unaudited condensed consolidated statements of operations during the three months ended March 31, 2024.

9. INCOME TAXES

The Company recorded a tax provision related to its U.S. state taxes and its foreign subsidiaries during the three months ended March 31, 2025, and 2024. Due to the uncertainties surrounding the realization of the U.S. deferred tax assets through future taxable income, the Company has provided a full valuation allowance and, therefore, no benefit has been recognized for the net operating loss carryforwards and other deferred tax assets.

10. STOCKHOLDERS' EQUITY

Treasury Shares

On March 7, 2024, the Company used approximately \$25.0 million of the net proceeds from the 2029 Notes offering to repurchase 229,252 shares of the Company's common stock at a purchase price of \$109.05 per share via privately negotiated transactions effected through one of the initial purchasers or its affiliate. Repurchased shares of the Company's common stock are held as treasury shares until they are reissued or retired.

11. STOCK-BASED COMPENSATION

The following table summarizes the total stock-based compensation expense included in the unaudited condensed consolidated statements of operations for the three months ended March 31, 2025, and 2024 (in thousands):

	Three Months Ended March 31,	
	2025	2024
Cost of revenue	\$ 783	\$ 846
Research and development	4,185	3,596
Selling, general and administrative	18,376	16,549
Total stock-based compensation expense	<u>\$ 23,344</u>	<u>\$ 20,991</u>

Restricted Stock Units and Performance-Based Restricted Stock Units

As of March 31, 2025, there were a total of 1.6 million awards outstanding and total unamortized compensation cost of \$136.3 million, net of estimated forfeitures, related to restricted stock units ("RSUs"), which the Company expects to recognize over a weighted average period of 1.8 years.

As of March 31, 2025, there were a total of 0.9 million awards outstanding and total unamortized compensation cost of \$38.1 million, net of estimated forfeitures, related to performance based RSUs ("PRSUs"), which the Company expects to recognize over a weighted average remaining period of 1.8 years. PRSUs are based on the maximum number of PRSUs issuable in the key executive grant agreements. The actual number of PRSUs awarded will be based on company performance criteria.

Market-based PRSUs

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

In February 2025, the Company granted market-based PRSUs to senior executive officers with a grant date fair value of \$15.5 million. These PRSUs to be earned will be based on the cumulative annual growth rate ("CAGR") of annual unit volume calculated between fiscal year 2027 and fiscal year 2024 and measured against performance thresholds, as well as a relative comparison of the S&P Healthcare Equipment Select Industry Index to the Company's Total Shareholder Return ("TSR"). The grant date fair value of the TSR was based on the expected term of 2.8 years, interest risk free rate of 4.0%, implied volatility of 56.02% and no dividend yield. These February 2025 awards are subject to the recipient senior executive officer's continued employment through the vesting date of March 15, 2028.

Options

As of March 31, 2025, the Company had a total of 0.2 million options outstanding. As of March 31, 2025, the options were fully vested.

Employee Stock Purchase Plan

As of March 31, 2025, the Company had \$0.7 million of unrecognized compensation expense that will be recognized over a weighted average period of 0.3 years.

12. NET LOSS PER COMMON SHARE

As the Company had net losses for the three months ended March 31, 2025 and 2024, 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 three months ended March 31, 2025, and 2024 (in thousands, except per share data):

	Three Months Ended March 31,	
	2025	2024
Numerator:		
Net loss	\$ (30,700)	\$ (45,667)
Denominator:		
Weighted-average shares used to compute net loss per common share, basic and diluted	31,590	31,033
Net loss per common share, basic and diluted	\$ (0.97)	\$ (1.47)

IRHYTHM TECHNOLOGIES, INC.
Notes to the Unaudited Condensed Consolidated Financial Statements (Continued)

The Company applies the if-converted method in computing the effect of the Company's senior convertible notes on diluted net income per share. For periods in which the Company reports net income, the numerator of the diluted per share computation is adjusted for interest expense and amortization of debt issuance costs, net of tax, and the denominator is adjusted for the weighted average number of shares into which each of the Company's senior convertible notes could be converted. The effect is only included in the calculation of diluted net income per share for those senior convertible notes which reduce net income per share.

The following outstanding shares of potentially dilutive securities have been excluded from diluted net loss per common share for the three months ended March 31, 2025, and 2024 because their inclusion would be anti-dilutive (in thousands):

	Three Months Ended March 31,	
	2025	2024
Options to purchase common stock	236	298
RSUs and PRSUs ¹	2,477	2,699
Senior convertible notes	4,492	4,492
Total	7,205	7,489

¹PRSUs are based on the maximum number of PRSUs in the key executive grant agreements. The actual number of PRSUs granted will be based on Company performance criteria and relative TSR, as discussed in Note 11, Stock-Based Compensation.

ITEM 2. 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 unaudited condensed consolidated financial statements and related notes included elsewhere in Item 1 of Part I of this Quarterly Report on Form 10-Q. This discussion and other parts of this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q entitled "Risk Factors."

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 an FDA-cleared, CE-marked and Japan PMDA-approved wire-free, patch-based, 14-day wearable biosensor that continuously records ECG data with a proprietary, FDA-cleared, CE-marked, and Japan PMDA-approved 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 eight million patients and have collected over 2 billion hours of curated heartbeat data.

Since first receiving clearance from 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 IDTFs and with 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 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:

	Three Months Ended March 31,	
	2025	2024
Contracted third-party payors	53%	54%
Centers for Medicare and Medicaid	24%	24%
Healthcare institutions	17%	15%
Non-contracted third-party payors	6%	7%

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 operational performance 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 before income tax provision, depreciation and amortization, interest expense, interest income and as further adjusted for stock-based compensation expense, changes in fair value of strategic investments, impairment and restructuring charges, business transformation costs, certain intellectual property litigation expenses and settlements, and loss on extinguishment of debt. Business transformation costs include costs associated with professional services, employee termination and relocation, third-party merger and acquisition, integration, and other costs to augment and restructure the organization, inclusive of both outsourced and offshore resources. Beginning in the first quarter of 2025, we have excluded third-party attorneys' fees and expenses associated with patent litigation brought against the Company by Welch Allyn, Inc. and Bardy Diagnostics, Inc., subsidiaries of Baxter International, Inc. Factors we considered in arriving at this determination to exclude these patent litigation costs from our Adjusted EBITDA include frequency and complexity of the patent litigation, the counterparty involved, and the expected magnitude of patent litigation costs for this matter.

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 unaudited condensed consolidated statements of operations that are necessary to run our business. We may identify additional charges and gains to exclude from Adjusted EBITDA that are significant in nature which may impact period to period comparability and do not represent the ongoing results of the business. Other companies, including other companies in our industry, may not use this measure or may calculate this measure differently than as presented in this Quarterly Report on Form 10-Q, limiting its 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):

	Three Months Ended March 31,	
	2025	2024
Net loss ¹	\$ (30,700)	\$ (45,667)
Interest expense	3,273	2,860
Interest income	(4,919)	(3,057)
Changes in fair value of strategic investments	(843)	—
Income tax provision	665	32
Depreciation and amortization	5,210	5,131
Stock-based compensation	23,344	20,991
Business transformation costs	503	—
Intellectual property litigation expenses	832	—
Loss on extinguishment of debt	—	7,589
Adjusted EBITDA	\$ (2,635)	\$ (12,121)

¹ Net loss for the three months ended March 31, 2025, includes \$0.3 million of acquired in-process research and development expense.

Macroeconomic Factors

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, tariffs on imports, 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.

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, interest rate volatility make access to credit more expensive, and unrealized losses decrease available cash reserves. 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. Private and government payers around the world are increasingly challenging the utilization and overall cost charged for medical products and services. The containment of healthcare costs has become a priority of governments on a global basis. Private and government payors may decline to cover and reimburse for claims or portions of claims. Climate-related events, including the increasing frequency of extreme weather events, natural disasters, or other catastrophic events may cause damage or disruption to our domestic or global customers or our operations, which could have an adverse effect on our business, operating results, and financial condition.

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.

Our hybrid work arrangements and decision to pursue a sublease have previously resulted in an impairment of our right-of-use asset and related leasehold improvements and furniture and fixtures. As we continue to evaluate our global real estate footprint, we may incur additional impairment charges related to real property lease agreements.

Revenue, net

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 considers 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 that are updated annually.

Cost of Revenue

Cost of revenue includes direct labor, material costs, equipment and infrastructure expenses, amortization of internal-use software, allocated overhead, royalties, 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 PCBAs. Each Zio XT patch and Zio Monitor patch includes a PCBA, and each Zio AT patch includes a PCBA and gateway board, the cost of which is amortized over the expected useful life 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, as well as amortization of internal-use software, partially offset by economies of scale in relation to fixed costs such as overhead and facilities costs.

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 increases to the cost of revenues due to increases to materials and electronics components pricing, labor rates, shipping rates, amortization of capitalized internal-use software, along with increases in the general level of inflation and potential tariffs on imports (which may complicate and increase costs associated with our supply chain). We expect to partially offset these increases by reduced costs from 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. We experienced an improvement in our gross margin from 2023 to 2024, and continue to focus on improving annual gross margins in the future, while navigating through the macroeconomic and supply chain headwinds discussed above that we expect to face.

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, milestone payments and allocated facility overhead costs. 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.

Acquired In-Process Research and Development Expenses

Our in-process research and development acquired in an asset acquisition for use in research and development activities with no alternative future use is expensed in the unaudited condensed consolidated statements of operations.

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, business transformation, and travel expenses.

Interest Income

Interest income consists of interest income received on our cash and cash equivalents and marketable securities.

Interest Expense

Interest expense is attributable to borrowings under our loan agreements and 2029 Notes. See Note 8, Debt, in the notes to our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for further information on our debt.

Loss on Extinguishment of Debt

Loss on extinguishment of debt reflects the losses incurred in the early repayment of debt. See Note 8, Debt, in the notes to our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for further information on our loss on extinguishment of debt.

Other Income (Expense), Net

Other income (expense), net consists primarily of changes in fair value of our strategic loan and equity investments, as well as realized and unrealized foreign currency exchange gains or losses.

Results of Operations

Comparison of the Three Months Ended March 31, 2025, and 2024

	Three Months Ended March 31,			
	2025	2024	\$ Change	% Change
	(in thousands, except percentages) *			
Revenue, net	\$ 158,677	\$ 131,929	\$ 26,748	20 %
Cost of revenue	49,461	44,413	5,048	11 %
Gross profit	109,216	87,516	21,700	25 %
Operating expenses:				
Research and development	21,519	16,994	4,525	27 %
Acquired in-process research and development	296	—	296	N/M
Selling, general and administrative	119,957	108,660	11,297	10 %
Total operating expenses	141,772	125,654	16,118	13 %
Loss from operations	(32,556)	(38,138)	5,582	(15)%
Interest and other income (expense), net:				
Interest income	4,919	3,057	1,862	61 %
Interest expense	(3,273)	(2,860)	(413)	14 %
Loss on extinguishment of debt	—	(7,589)	7,589	N/M
Other income (expense), net	875	(105)	980	(933)%
Total interest and other income (expense), net	2,521	(7,497)	10,018	(134)%
Loss before income taxes	(30,035)	(45,635)	15,600	(34)%
Income tax provision	665	32	633	1978 %
Net loss	\$ (30,700)	\$ (45,667)	\$ 14,967	(33)%

N/M - Not meaningful

* Certain numbers expressed may not sum due to rounding.

Revenue, net

Revenue, net increased by \$26.7 million, or 20%, to \$158.7 million during the three months ended March 31, 2025, as compared to \$131.9 million during the three months ended March 31, 2024. The increase in revenue was primarily attributable to an increase in volume of Zio Services resulting from increased demand. In particular, during the first quarter of 2025 Zio AT as a proportion of our total revenue volume grew significantly compared to the prior year primarily as a result of new customer account growth. Offsetting the revenue growth from volume and product mix were higher contractual allowance reserves recognized during the first quarter of 2025, resultant from billing disruptions due to the Change Healthcare cybersecurity incident from the first quarter of 2024, as well as higher payer claims denials. Overall average selling prices for net revenue remained relatively stable period over period.

Cost of Revenue

Cost of revenue increased by \$5.0 million, or 11%, to \$49.5 million during the three months ended March 31, 2025, as compared to \$44.4 million during the three months ended March 31, 2024. The increase in cost of revenue was due to increases in material component costs and headcount-related costs associated with the increase in volume of Zio Services. Additional impacts to cost of revenue include \$0.7 million in amortization costs primarily for Zio Monitor PCBAs in conjunction with the ongoing commercial launch of the Zio Monitor System.

Research and Development Expenses

Research and development expenses increased by \$4.5 million, or 27%, to \$21.5 million during three months ended March 31, 2025, as compared to \$17.0 million during the three months ended March 31, 2024. The increase in research and development expenses was primarily due to higher employee-related costs (including stock based compensation) supporting ongoing FDA remediation and sustaining activities, product development consulting costs, and further development, enhancement, and functionality of our current and future product offerings.

Acquired In-Process Research and Development

Acquired IPR&D expense was \$0.3 million during the three months ended March 31, 2025. The expense was related to the Technology License Agreement (the "License Agreement") we entered into with BioIntelliSense, Inc. ("BioIS") during the third quarter of 2024. See Note 7, Commitments and Contingencies, in the notes to our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for further details.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by \$11.3 million, or 10%, to \$120.0 million during the three months ended March 31, 2025, as compared to \$108.7 million during the three months ended March 31, 2024. The increase in selling, general, and administrative expenses was primarily attributable to increases in headcount-related costs (including stock-based compensation), legal and professional fees, and provisions for credit losses, offset by a reduction in claims processing fees. During the three months ended March 31, 2025, we incurred \$0.5 million of business transformation costs primarily related to professional fees to support the growth in our operations, which were not incurred during the first quarter of 2024.

Interest Income

Interest income increased by \$1.9 million to \$4.9 million during the three months ended March 31, 2025, as compared to \$3.1 million during the three months ended March 31, 2024. The increase was attributable to higher average invested balances during the three months ended March 31, 2025, as compared to the same period in 2024, primarily as a result of the borrowing under the 2029 Notes in March 2024.

Interest Expense

Interest expense increased by \$0.4 million to \$3.3 million during the three months ended March 31, 2025, as compared to \$2.9 million during the three months ended March 31, 2024. The increase in interest expense was primarily attributable to the \$661.3 million 2029 Notes borrowed in March 2024.

Other Income (Expense), Net

Other income (expense), net increased by \$1.0 million to \$0.9 million during the three months ended March 31, 2025, as compared to other income (expense), net of \$(0.1) million during the three months ended March 31, 2024. The increase was primarily attributable to the changes in the fair value of our strategic equity investments recognized during the three months ended March 31, 2025.

Loss on Extinguishment of Debt

Loss on extinguishment of debt was \$7.6 million for the three months ended March 31, 2024. The loss was related to the early extinguishment of both the SVB Loan Agreement and the Braidwell Term Loan Facility during the first quarter of 2024. See Note 8, Debt, in the notes to our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for details of our financing activities.

Liquidity and Capital Resources

Overview

As of March 31, 2025, we had cash and cash equivalents of \$375.3 million, marketable securities of \$145.3 million, and accounts receivable, net of \$80.6 million. We continuously review our liquidity and anticipated capital requirements in light of the significant uncertainty created by the current macroeconomic environment, including inflation, interest rate volatility, and potential instability in the global banking system. 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. During the first quarter of 2024, we experienced a temporary delay in the billing of our contracted and non-contracted payer customers, performed by our third-party claims processing vendor. The delay was due to a cybersecurity incident experienced by Change Healthcare, a division of UnitedHealth Group, in which our third-party vendor did engage for services relating to billing and collections. While we substantially cleared the billing backlog as of the end of the first quarter of 2024, the delay in billing resulted in a temporary delay in our cash collections. We have received the majority of our cash collections from the delayed billings. During the first quarter of 2025, we experienced higher levels of contractual adjustments associated with our gross accounts receivable. Additionally, through our revenue cycle management transformation we have focused our efforts in part to resolve payor claims denials and unpaid portions of patient-responsible balances in a more timely basis.

We believe that our current cash, cash equivalents, and marketable securities balances, together with income to be derived from the sales of our Zio Services, will be sufficient to meet our liquidity requirements for at least the next 12 months.

Under the terms of the Development Agreement with Verily, we agreed to make milestone payments to Verily up to an aggregate of \$12.75 million upon achievement of various development and regulatory milestones. We have achieved milestones tied to payments totaling \$11.0 million through March 31, 2025, and may make additional milestone payments of \$1.75 million, subject to the achievement of specified milestones.

On August 30, 2024, we entered into a Technology License Agreement (the "License Agreement") with BioS, pursuant to which (i) we will receive a perpetual fully paid up license to certain of BioS' intellectual property, technology and products for research, development and commercialization of potential next generation products and services in certain fields of use, including an exclusive license to develop and commercialize pulse oximetry, accelerometry, and trending non-invasive blood pressure technologies for use within our ambulatory cardiac monitoring products and services, and (ii) iRhythm and BioS agreed to negotiate in good faith a supply agreement for pulse oximetry hardware.

Under the terms of the License Agreement, during the third quarter of 2024 we paid BioS an upfront fee of \$15.0 million in cash consideration. In connection with the License Agreement, we also purchased an aggregate of \$40.0 million of convertible promissory notes from BioS of which \$20.0 million of the convertible promissory notes ("Milestone Notes") were designated for satisfaction of the Company's regulatory milestone payment obligations. The Milestone Notes, plus accrued and unpaid interest, if any, shall be cancelled, if outstanding, upon the achievement of the regulatory milestones up through December 31, 2026.

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

	Three Months Ended March 31,	
	2025	2024
Net cash used in operating activities	\$ (7,891)	\$ (52,029)
Net cash (used in) provided by investing activities	(38,139)	39,998
Net cash provided by financing activities	1,729	504,641

Operating Activities

During the three months ended March 31, 2025, cash used in operating activities was \$7.9 million, a decrease of \$44.1 million, as compared to cash used in operating activities of \$52.0 million during the three months ended March 31, 2024. The reduction in cash used in operating activities was primarily attributable to reductions in our net loss driven by our revenue growth, timing of collections associated with our accounts receivable, as well as the timing of payments associated with our accounts payable and accrued liabilities. These reductions in cash used in operating activities were offset by an increase to prepaid expenses and other current assets.

Investing Activities

During the three months ended March 31, 2025, cash used in investing activities was \$38.1 million, an increase of \$78.1 million, as compared to cash provided by investing activities of \$40.0 million during the three months ended March 31, 2024. The increase in cash used in investing activities was primarily attributable to a net increase in the change in marketable securities of \$78.5 million, offset by decrease in purchases of property and equipment of \$0.4 million.

Financing Activities

During the three months ended March 31, 2025, cash provided by financing activities was \$1.7 million, a decrease of \$502.9 million as compared to \$504.6 million during the three months ended March 31, 2024. The decrease was primarily attributed to \$661.3 million in proceeds from the issuance of our 2029 Notes during the three months ended March 31, 2024. The decrease was offset by \$37.8 million associated with the payment of the SVB Loan Agreement and related termination costs, payment of \$5.5 million associated with the Braidwell Term Loan Facility debt issuance and termination costs, payment of \$16.6 million associated with debt issuance costs for our 2029 Notes, payment of \$72.4 million for the purchase of the 2029 Capped Calls, and payment of \$25.0 million for the repurchase of shares of our common stock.

1.50% Senior Convertible Notes due 2029

On March 7, 2024, we completed an offering of \$661.3 million aggregate principal amount of unsecured senior convertible notes with a stated interest rate of 1.50% and a maturity date of September 1, 2029 (the "2029 Notes"). The proceeds include the full exercise of the option granted by us to the initial purchasers of the 2029 Notes to purchase up to an additional \$86.3 million aggregate principal amount of notes. Interest on the 2029 Notes is payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2024. The net proceeds from the offering, after deducting initial purchasers' discounts and estimated costs directly related to the offering, were \$643.8 million. The initial conversion rate of the 2029 Notes is 6.7927 shares per \$1,000 principal amount of notes, which is equivalent to a conversion price of approximately \$147.22 per share, subject to adjustments. The 2029 Notes may be settled in cash, stock, or a combination thereof, solely at our discretion.

We used approximately \$72.4 million of the net proceeds from the offering to pay the cost of the 2029 Capped Calls, as described below. In addition, we used approximately \$80.2 million of the net proceeds from the offering for the repayment in full of the indebtedness outstanding from the Initial Tranche of the Braidwell Term Loan Facility (as each such term is defined below). We also used approximately \$25.0 million of the net proceeds from the offering to repurchase 229,252 shares of our common stock at a purchase price of \$109.05 per share in privately negotiated transactions effected through one of the initial purchasers or its affiliate. These repurchases could increase (or reduce the size of any decrease in) the market price of our common stock, and could result in a higher effective conversion price for the 2029 Notes. We intend to use the remainder of the net proceeds from the offering for general corporate purposes.

No principal payments are due on the 2029 Notes prior to maturity. Other than restrictions relating to certain fundamental changes and consolidations, mergers or asset sales and customary anti-dilution adjustments, the indenture relating to the 2029 Notes includes customary terms and covenants, including certain events of default after which the 2029 Notes may be due and payable immediately.

In connection with the offering of the 2029 Notes, we entered into the privately negotiated capped call transactions (the "2029 Capped Calls") with certain financial institutions. The 2029 Capped Calls will cover, subject to anti-dilution adjustments substantially similar to those applicable to the 2029 Notes, the number of shares of our common stock that will initially underlie the 2029 Notes. The 2029 Capped Calls are expected generally to reduce potential dilution to our common stock upon conversion of the 2029 Notes and/or offset any cash payments that we could be required to make in excess of the principal amount of converted 2029 Notes, as the case may be, with such reduction and/or offset subject to a cap. The 2029 Capped Calls have an initial cap price of \$218.10 per share, subject to adjustments, which represents a premium of 100% over the closing price of our common stock of \$109.05 per share on the Nasdaq Global Select Market on March 4, 2024.

Braidwell Debt

On January 3, 2024 (the "Closing Date"), we entered into the Credit, Security and Guaranty Agreement (the "Braidwell Credit Agreement") with Braidwell Transactions Holdings LLC – Series 5 ("Braidwell"), which provided for a senior secured term loan in an aggregate principal amount of up to \$150.0 million (the "Braidwell Term Loan Facility"). An initial tranche of \$75.0 million ("Initial Loan") was funded on the Closing Date. An additional tranche of \$75.0 million was accessible through the one year anniversary of the Closing Date, so long as we satisfied certain customary conditions.

Our net proceeds from the Initial Loan were approximately \$35 million, after deducting costs, fees and expenses, and repayment of our existing term loan from Silicon Valley Bank, as discussed below.

On March 7, 2024, in conjunction with the issuance of the 2029 Notes, we used approximately \$80.2 million of the net proceeds for the repayment in full of the \$75.0 million outstanding Initial Loan and \$5.2 million for interest, fees and expenses associated with terminating the Braidwell Credit Agreement.

SVB Term Loan

In October 2018, we entered into the Third Amended and Restated Loan and Security Agreement ("SVB Loan Agreement") with Silicon Valley Bank ("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. None of the remaining \$40.0 million of the 2022 Term Loans was borrowed up through December 31, 2023.

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.

On January 3, 2024, in connection with the entry into the Braidwell Credit Agreement, we used approximately \$37.8 million of the net proceeds for the repayment in full of the \$35.0 million outstanding principal balance as well as interest, fees and expenses associated with terminating the agreement. Upon termination of the SVB Loan Agreement, SVB's security interest in our assets and property was released. We continue to hold \$8.4 million in letters of credit with SVB, securing them with cash on deposit.

Contractual Obligations

Our contractual obligations as of December 31, 2024, are presented in our Annual Report on Form 10-K filed with the SEC on February 20, 2025. There were no significant changes to our lease obligations during the three months ended March 31, 2025. As of March 31, 2025, we had approximately \$67.7 million of open purchase orders and contractual obligations in the ordinary course of business, the majority of which are due within one year. See Note 8, Debt, in the notes to our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for changes in our debt obligations during the three months ended March 31, 2025.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which we have prepared in accordance with GAAP. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements as well as the reported revenue and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in Note 2, Summary of Significant Accounting Policies, to the consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024. Updates to our significant accounting policies are described in Note 2, Summary of Significant Accounting Policies, in the notes to our unaudited condensed consolidated financial statements in Part 1, Item 1 of this Quarterly Report on Form 10-Q. The critical accounting estimates that are most critical to a full understanding and evaluation of our reported financial results are described in Management's Discussion and Analysis of Financial Condition and Results of Operations in Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024. There were no material changes to our critical accounting estimates during the three months ended March 31, 2025.

ITEM 3. 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 marketable securities of \$520.6 million and \$535.6 million as of March 31, 2025, and December 31, 2024, 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 \$0.3 million impact to interest income for the three months ended March 31, 2025, and 2024, respectively.

As of March 31, 2025, we had \$661.3 million in outstanding aggregate principal amount of fixed rate debt relating to our 2029 Notes. Accordingly, we do not have economic interest rate exposure on the 2029 Notes. However, changes in interest rates could impact the fair market value of the 2029 Notes. Generally, the fair market value of the fixed interest rate of the 2029 Notes will increase as interest rates fall and decrease as interest rates rise. The estimated fair value of our 2029 Notes as of March 31, 2025, was \$689.2 million.

Market Price Sensitive Instruments

The 2029 Capped Calls are expected generally to reduce potential dilution to our common stock upon conversion of the 2029 Notes and/or offset any cash payments that we could be required to make in excess of the principal amount of converted 2029 Notes, with such reduction and/or offset subject to a cap. See Note 8, Debt, in the notes to our unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for further information on our debt.

Foreign Currency Exchange Rate Sensitivity

As of March 31, 2025, there had not been a material change in any of the foreign currency risk information disclosed in Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

ITEM 4. 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 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.

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-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. 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 March 31, 2025.

Changes in Internal Control Over Financial Reporting

There have been no changes in internal control over financial reporting during the three months ended March 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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.

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.

PART II. OTHER INFORMATION

ITEM 1. 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 6, 2024, a putative class action lawsuit was filed in the United States District Court for the Northern District of California alleging that we and our current Chief Executive Officer, Quentin Blackford, our former Chief Financial Officer, Brice Bobzien, and our former Chief Financial Officer and former Chief Operating Officer, Mr. Devine violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder, and seeks unspecified damages purportedly sustained by the class. On July 19, 2024, an amended complaint was filed, naming us, Mr. Blackford, Mr. Bobzien, Mr. Devine, our Chief Commercial Officer Chad Patterson, our former Chief Technology Officer Mark Day, and our Chief Medical Officer, Chief Scientific Officer, and Executive Vice President of Product Innovation Mintu Turakhia as defendants. On October 7, 2024, a second amended complaint was filed to include events from the recent FDA inspections, but otherwise included the same claims under the Exchange Act. On December 10, 2024, the defendants filed a motion to dismiss. Oral arguments on the motion to dismiss were held in late April.

Our board members and certain of our current and former executives were named as defendants in two complaints filed as stockholder derivative actions in the United States District Court for the District of Delaware and the United States District Court for the Northern District of California, respectively. We are named as a nominal defendant in both complaints. The cases make similar allegations to those in the securities class action complaint described above and both cases have both been stayed pending the resolution of motion to dismiss briefing in the securities class action.

We believe the above securities class action and derivative lawsuits to be without merit and plan to continue 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 and services. On September 13, 2021, we received a second subpoena requesting additional information. On April 4, 2023, we received a Subpoena Duces Tecum from the Consumer Protection Branch, Civil Division of the U.S. Department of Justice (the "DOJ"), requesting production of various documents regarding our products and services. We are cooperating fully on these matters.

On July 1, 2024, the DOJ filed with the United States District Court for the Northern District of California a Petition for Order to Show Cause and Application for Enforcement with respect to the production of certain documentary materials which we assert are protected by legal privileges. We continue to defend our privilege assertions over such materials in our response to the DOJ's petition. The matter has been briefed, and oral argument is scheduled for May 1, 2025. Regardless of the outcome, it is not clear what, if any, action the DOJ may take following resolution of the dispute over legal privileges.

On February 20, 2024, Welch Allyn, Inc. ("Welch Allyn"), a subsidiary of Hill-Rom Holdings, Inc. now part of Baxter International, Inc., filed a lawsuit against us in the United States District Court for the District of Delaware, alleging that our Zio devices infringe certain of its patents and that the Company's infringement was willful. We filed a motion to dismiss Welch Allyn's willful infringement claims on April 11, 2024. Welch Allyn filed an amended complaint on April 24, 2024 that continued to allege that our Zio devices infringe certain of its patents and that our infringement was willful. We filed a motion to dismiss Welch Allyn's willful infringement allegations found in the amended complaint on May 22, 2024 and a hearing on the motion to dismiss was held on January 28, 2025. After hearing arguments, the Court granted our motion and the willful infringement claims in the amended complaint were dismissed without prejudice. Welch Allyn filed a second amended complaint adding additional patent claims on February 14, 2025. The Company filed a response to the allegations found in the second amended complaint on March 21, 2025 denying all allegations of patent infringement and asserting defenses including patent invalidity. Welch Allyn seeks money damages and attorneys' fees. We believe this lawsuit is without merit and plan to defend ourselves vigorously.

On December 10, 2024, Bardy Diagnostics, Inc. ("BardyDx"), a subsidiary of Hill-Rom Holdings, Inc. now part of Baxter International, Inc., filed a lawsuit against us in the United States District Court for the District of Delaware, alleging that our Zio Monitor patch infringes one of its patents. On December 26, 2024, BardyDx filed an amended complaint alleging that the Company's Zio Monitor patch infringes two of its patents. We filed a response to the allegations found in the amended complaint on March 3, 2025 denying all allegations of patent infringement, asserting defenses including patent invalidity, and asserting patent infringement counterclaims, and we filed an amended counterclaims and answer asserting infringement of two additional patents by BardyDx on March 24, 2025. On March 27, 2025, BardyDx filed an answer and counterclaims to our most recent filing asserting their own counterclaims for declaratory judgment for non-infringement and invalidity of the patents asserted by us. BardyDx seeks money damages and attorneys' fees. We believe this lawsuit is without merit and plan to defend ourselves vigorously.

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

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 Quarterly Report on Form 10-Q, 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 Part I, Item 2 of this Quarterly Report.

Summary of Risk Factors

- Reimbursement by Medicare is highly regulated and subject to change, and our failure to comply with applicable regulations, including regulations not designed for remote 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 or in our international markets, including through cost containment measures or changes to policies with respect to coding, coverage, and 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 remote 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 highly regulated, and we must dedicate substantial time and resources to the billing process. Failure to comply with legal, regulatory, or contractual requirements applicable to our billing and collection activities could subject us to penalties, and adversely affect our reputation, business and results of operations.
- Audits or denials of our claims by government agencies or payors could expose us to recoupment, regulatory scrutiny, and penalties.
- Although our current Zio Systems are comprised of medical devices that have received FDA marketing authorization (510(k) clearance) as well as, with respect to certain devices, regulatory certifications or approvals in the European Union ("EU"), Japan, Switzerland and the United Kingdom ("UK"), we may regularly engage in exploring and implementing product enhancements and in iterative changes to existing products, as well as seek 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, design, safety, performance, and post-market surveillance of the medical devices 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, risk, regulatory, or safety matters could trigger enforcement action by regulatory authorities, the need for a recall, a hold on the distribution of the marketed product, or other corrective actions to marketed product, and such matters have the potential to escalate to judicial actions that involve the DOJ.
- 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 services may have caused or contributed to an adverse event.
- 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.
- 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 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 company resources 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 regulators, enforcement authorities, or competitors.
- 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 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 customer 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.

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 remote 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.

During the three months ended March 31, 2025, we received approximately 24% 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 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.

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 ours 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. For example, CMS has not addressed billing for remote diagnostic tests that are performed from one or more IDTF or other remote locations. 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 or in our international markets, including through cost containment measures or changes to policies with respect to coding, coverage, and 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, 2025, CMS updated the national payment rates for the CPT codes we use to report our cardiac monitoring services: CPT code 93247 (ECG recording conducted over a period of greater than 7 days and up to 15 days), CPT code 93243 (ECG recording conducted over a period of greater than 48 hours and up to 7 days), and CPT code 93229 (mobile cardiovascular telemetry). While the payment rates for CPT codes 93247 and 93243 saw a slight increase for calendar year 2025, the rate for CPT code 93229 experienced a decrease as compared to calendar year 2024.

Because remote cardiac monitoring technology, including the Zio System, is 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. Further, CMS may reduce the rates for the CPT codes assigned to our services in the future, which would adversely affect our financial results, particularly to the extent commercial payors with which we contract follow suit.

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.

Finally, government and commercial payors have and may, in the future, consider healthcare policies and proposals intended to limit or reduce perceived increases in healthcare costs, including those that could significantly affect reimbursement for healthcare products such as our systems and services. These policies have included, and may in the future include: basing reimbursement policies and rates on clinical outcomes, the comparative effectiveness, and costs, of different treatment technologies and services, as well as other measures. Future significant changes in the healthcare systems in the United States or elsewhere could also have a negative impact on the demand for our current and future products and services. These include changes that may reduce reimbursement rates for our products and changes that may be proposed or implemented by the current or future laws or regulations.

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 as well as penalties for noncompliance. One such law, the federal No Surprises Act, requires covered providers to provide "good faith estimates" to uninsured and self-pay patients of their out-of-pocket responsibility and establishes a detailed and potentially costly independent dispute resolution process governing fee disputes between our IDTFs and payors. These laws and regulations may change and we anticipate these evolving, highly technical requirements may apply to our business in the future and could necessitate the dedication of additional resources to ensure compliance.

We report to third party payors the technical components of the remote cardiac monitoring services that are performed with our Zio Monitor, Zio XT, and Zio AT Systems using CPT codes established by the American Medical Association. These CPT codes are manufacturer- and technology-agnostic but describe general technical features required to support the diagnostic medical procedures represented by these billing codes. Given the nature of CPT codes, there is always some degree of risk for an entity that bills for its services that regulators or other third parties could assert that the CPT codes utilized were not appropriate, and recent events have the potential to increase the risk of questions or inquiry regarding our use of a specific CPT code.

The CPT codes used to report remote cardiac monitoring services, including those used to report our Zio Services, were drafted by the American Medical Association ("AMA") in a manufacturer- and specific technology-agnostic manner. Regulators or other third parties could assert that our technology does not support certain diagnostic procedures described by the CPT codes that we currently use to report our Zio Services. For example, a regulator or other third party could assert that the Zio AT System cannot support MCT services, which could jeopardize our ability to submit claims for reimbursement for services utilizing our Zio AT System and may require us to evaluate whether we have received any overpayments that must be reported and returned to third-party payors. Certain language in a warning letter we received from FDA on May 25, 2023 could increase the risk of inquiries regarding our historical or current use of CPT code 93229. Consistent with the AMA's definition of MCT and the technology categorization in FDA's outpatient cardiac telemetry product code, the Zio AT device is intended to capture and transmit symptomatic and asymptomatic cardiac events and record continuous ECG data for long-term monitoring on adult patients who may be asymptomatic or who may suffer from transient symptoms (e.g., palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety), with escalation to the patient's treating healthcare professional, consistent with the healthcare professional's prescribed notification criteria, during the monitoring period.

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 and/or 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 remote 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, and enhancing their product offerings with differentiating features. Our ability to compete effectively depends on our ability to distinguish our company and our Zio Services from our competitors and their products and services, 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. now part of Baxter International, 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., Fitbit and Samsung, among others, have added capabilities on their platforms to measure non-continuous ECG and to alert customers 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 highly regulated, and we must dedicate substantial time and resources to the billing process. Failure to comply with legal, regulatory, or contractual requirements applicable to our billing and collection activities could subject us to penalties, and adversely affect our reputation, business and results of operations.

Billing for diagnostic services is complex, highly regulated, time-consuming, and expensive, and failure to comply with legal or contractual requirements applicable to our billing and collection activities could subject us to penalties, and adversely affect our reputation, business and results of operations. 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.

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 and collecting co-payments, co-insurance, and deductible amounts from patients and other guarantors; 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. 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. We may also be adversely affected by the growth in patient responsibility accounts, as a result of increases in the adoption of plan structures, due to evolving health care policy and insurance landscapes, that shift greater responsibility for care to individuals through greater exclusions, prior authorizations, and co-payment and deductible amounts.

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 to undertake certain components of our billing and collections operations. While common in the healthcare industry, the outsourcing of billing and collections activities to third-party vendors requires diligent monitoring and oversight to ensure the completeness, accuracy, and propriety of the claims submitted to federal healthcare programs and other third-party commercial payors for our Zio Services. We may be held responsible by our regulators or payors for any acts, errors, or omissions by the third-party vendors engaged to perform billing and collections activities on our behalf.

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 for tests ordered by unaffiliated healthcare providers. These programs and payors, including contractors on their behalf, may conduct pre- and post-payment audits and reviews of claims submitted for reimbursement, including audits and reviews focused on the appropriateness of unaffiliated healthcare providers' decisions to order a particular test furnished by our IDTF, which impact our claims. 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 with applicable Medicare requirements and quality standards be excluded from participation in the Medicare program. CMS also engages Medicare Administrative Contractors, Comprehensive Error Rate Testing Contractors, Recovery Audit Contractors, and Unified Program Integrity Contractors to conduct a variety of pre- and post-payment reviews of healthcare providers' claims, and any aberrant practices or findings from such reviews may result in referrals to the Office of Inspector General, Department of Justice ("DOJ"), or other law enforcement agencies for further investigation and follow-up. 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 transforming 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 in the midst of a transformation of our revenue cycle management function, which transformation includes the utilization of third-party service providers to support certain activities. The success of this plan depends on our ability to complete the integration of these service providers in a timely manner to scale our operations to facilitate 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 provider, integrating technologies (including IT systems and processes, procedures, policies and operations), and retaining key personnel. These activities are 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 accounts 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) as well as, with respect to certain devices, regulatory certifications or approvals in the EU, Japan, Switzerland and the UK, we may regularly engage in exploring and implementing product enhancements and in iterative changes to existing products, as well as seek 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 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 Systems, 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 submission. FDA requirements dictate that we must evaluate potential changes and document our decision-making regarding the need for additional submissions and clearances or approvals. Unless effectively planned for in advance, our desired commercial timeline may be impacted.

Significant changes or modifications in design, components, method of manufacture, or the intended use or technological characteristics of our Zio Systems may require new or modified FDA marketing authorization, CE Mark certification in the EU, UKCA Mark certification, Swiss Medical Devices Ordinance ("MedDO") marketing authorization or Japanese Pharmaceutical and Medical Device Agency ("PMDA") marketing authorization. In some instances, we have identified a need for, and sought and obtained new, 510(k) clearances from FDA for these changes or modifications.

As permitted by applicable law, FDA allows device manufacturers to internally analyze and document a decision that a new clearance or approval is viewed by the manufacturer as unnecessary. Accordingly, we have made certain changes and modifications to our Zio Systems in the past that we believe did not require additional clearances or approvals by FDA.

Such internal decisions are, however, subject to review by FDA, and may require additional action in the event FDA questions earlier internal decision-making. For example, FDA raised questions in the warning letter issued on May 25, 2023 regarding certain changes and modifications to the Zio AT System for which we did not make 510(k) submissions, and rather documented our analysis in letters to file. We have recently (following, and in alignment with, discussion with FDA) submitted an updated 510(k) to address Zio AT device modifications that were, prior to our receipt of the warning letter, previously documented in letters to file. In October 2024, following, and in alignment with, discussion with FDA, we received FDA 510(k) clearance for these design updates, as well as additional 510(k) clearance relating to further enhancements to our Zio AT device.

In instances where FDA, an EU/UK Notified/Approved Body, the PMDA or the Swiss regulatory body disagrees with our internal analysis and decision that a new or additional approval or marketing authorization or certification is not needed for any such modifications, we may be required to recall and/or stop the distribution of the impacted Zio System and/or correct the labeling for such Zio System. We may be required to submit a new marketing application or certification, which could require additional testing or other supporting data, a redesign of a product, or otherwise impact the provision of services. In these circumstances, the process may require engagement with regulators to resolve concerns and reach a resolution for a product, and 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 and to meet market expectations for the provision of the services, which in turn could harm our future growth.

We are subject to extensive compliance requirements for the quality, design, safety, performance, and post-market surveillance of the medical devices 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, risk, regulatory, or safety matters could trigger enforcement action by regulatory authorities, the need for a recall, a hold on the distribution of the marketed product, or other corrective actions to marketed product, and such matters have the potential to escalate to judicial actions that involve the DOJ.

As a manufacturer of medical devices, we are subject to extensive regulation and related compliance requirements. Noncompliance and even allegations of noncompliance with these wide-ranging requirements may subject us to high compliance costs to remediate or defend against allegations of noncompliance, as well as enforcement action from U.S. federal or state regulators and enforcement authorities. Regulators may interpret or apply reportability or field action requirements differently than a company, which can result in enforcement risk. Actions to which a company may be subject 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 the Quality System Regulation ("QSR"), also known as 21 CFR Part 820, EU Standards (presently the Medical Devices Regulations ("EU MDR")), UK Medical Device Regulations ("UK MDR"), Japanese medical device Quality Management System ("Japanese QMS") and the Swiss MedDO could result in similar disruptions in these markets. 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.

Our design and manufacturing facilities and processes and those of certain third-party suppliers are subject to FDA, state, EU/UK Notified/Approved Body, PMDA and Swiss regulatory inspections for compliance with various medical device regulations and standards, including EU MDR, UK MDR, Japanese QMS and Swiss MedDO 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. For example, FDA has issued final regulations on updates to the QSR which will largely align with the ISO 13485 standard, and these are set to take effect February 2, 2026.

We are required to file various reports with FDA, as well as EU, UK, Japanese and Swiss regulators, including reports required by each jurisdiction's adverse event, certain malfunctions, 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 reasonable, 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, or to address requests from regulators to increase or expand the scope of reporting. An increase in the reporting of events associated with the use of our products and services from us or others and any delays to the filing of reports may increase regulator and public scrutiny, especially given that these reports are typically publicly available information in most jurisdictions, including the United States, which could harm our business.

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 FDA and, in many cases, similar reports to other regulatory agencies.

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, 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.

Examples of regulatory actions and communications in recent years include:

- Our receipt of Form 483 observations in August 2022 alleging certain quality system deficiencies, including in relation to our corrective and preventive action procedures, test validation, complaint handling and medical device reporting requirements. We submitted a response to FDA with further commitments to improve and remediate our Quality System. These activities, including dialogue with FDA, are ongoing.

- The Customer Advisory Notice we initiated September 28, 2022 to Zio AT customers, and our reports to FDA under 21 C.F.R. Part 806, regarding a Zio AT labeling correction involving 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. FDA classified this field action as a Class II Recall following our initial 806 report and although we believe we have completed the distribution of the Advisory Notice to our identified impacted customers, and we requested the closure of this field action in March 2023, the status remains open in the public FDA recall database. and FDA has not yet confirmed the termination or completion of this recall to us.
- Our May 25, 2023 receipt of a warning letter from FDA alleging non-conformities to regulations for medical devices, including medical device reporting requirements, relating to our Zio AT System and medical device quality system requirements. We submitted a timely response to FDA in June 2023 and are continuing to work with the agency to address the issues outlined in the warning letter, including specific dialogue on key topics and our planned path forward. As part of this dialogue we agreed to make two 510(k) submissions relating to the Zio AT, and on October 21, 2024, we were granted FDA clearance for one 510(k) encompassing design updates that had previously been documented through letters to file and on October 30, 2024 we were granted FDA clearance on a second 510(k) submission related to design modifications and labeling updates for the Zio AT device.
- Our retrospective submission of certain Medical Device Reports in the fourth quarter of 2023, as part of our commitments following the FDA 483 observations and FDA warning letter issued on May 25, 2023.
- Our receipt of 483 observations following July 2024 FDA inspections of our Cypress and San Francisco FDA-registered facilities centered on complaint handling and medical device reporting, risk analysis regarding the involvement of the technicians to prepare the Zio ECG reports, the corrective and preventive action process, process controls and statistical techniques. We timely submitted our initial responses regarding the July 2024 483 observations to FDA on August 21, 2024, and provided supplemental information on September 6, 2024. In these responses we committed to a number of follow-up actions, and we intend to work with FDA to resolve the issues identified.

Executing on our follow-up actions, commitments to FDA, and remediation activities will require significant time, attention, and resources that might otherwise be applied to future product development activities and initiatives, and could result in delays or changes to these plans. Our commitments will also require a high degree of attention to design strategy and compliance going forward.

In addition, although we continue to fully cooperate and are in dialogue with FDA, there are ongoing enforcement risks, including escalation of further action by FDA, that remain given the inspection and enforcement activities of FDA over the past few years. FDA may determine that our remediation efforts to date or our responses to the 2024 483 observations are insufficient or unsatisfactory, or FDA may decide that it does not agree with the plans and commitments we have outlined in our previous communications. FDA could issue another warning letter, issue a consent decree in collaboration with the DOJ, and/or require recall or cessation of marketing and shipping our Zio device.

We cannot give any assurances that FDA will be satisfied with our response, the actions taken to resolve the concerns raised in the warning letter or the more recent 483 observations, or the expected date for the resolution of such matters. Until these issues are resolved to FDA's satisfaction, additional legal or regulatory action may be taken with or without further notice. The warning letter and the 483 observations are publicly available on FDA's website and have been the subject of a high degree of media and industry attention, which subjects us to additional scrutiny.

As we are already subject to an FDA warning letter associated with our Cypress facility, and in light of the 2024 inspection results, if we are unable to successfully execute follow-up actions consistent with our commitments to FDA, or if FDA determines that our follow-up commitments are insufficient or are not completed with sufficient promptness, we may face a greater risk of potential escalation, which could involve issuance of additional warning letters, or there is a possibility that FDA could initiate consent decree discussions. This may pose a considerable expense, 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 applicable 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.

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 services may have caused or contributed to an adverse event.

Our Zio Systems and Zio Services are not intended to be prescribed or ordered for use as an emergency system. They are not intended for critical care patients or patients suspected of life-threatening arrhythmias who require inpatient or emergency ECG monitoring. 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 a Zio System. In some cases, it may be medically and logistically challenging to obtain information sufficient to definitively determine all contributing factors to an event. In some instances, we may receive initial reports of complaints from the qualified cardiac technicians or through our customer service representatives. The initial reports of these non-physicians are likely to contain information that requires verification and further investigation.

In addition, even though our services and their associated devices are not intended to recognize, detect, or initiate response to terminal end-of-life events, a patient may nevertheless be wearing a Zio device when they experience such an event. Given the functionality of our technology and our services, we may become aware of data reflecting a non-survivable, end-of-life cardiac event. We or others (such as healthcare professionals, patients, or family members) may report such events even where it does not appear to us that our device caused or could have prevented an end-of-life event. Given the structure of such reporting to FDA the full medical context is not generally available to the public, which may cause additional scrutiny, questions, or concerns regarding our products and services. For example, in the fourth quarter of 2023, as part of our commitments following the FDA Form 483 observations and warning letter issued on May 25, 2023, we retrospectively submitted certain Medical Device Reports to FDA, and the publicly available information in these reports may receive additional scrutiny.

We are subject to FDA requirements to investigate complaints about our Zio Systems. 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;
- the extent to which we become dependent upon others for the manufacture of our Zio Systems which could adversely affect our future profit margins and our ability to market our Zio Services;
- 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 would 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 or recall of finished products;
- 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 components related to 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, 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.

We have incorporated and continue to work to further incorporate AI into our products, services, and internal operations. Implementation of artificial intelligence and machine learning technologies may result in legal and regulatory risks, reputational harm, or other adverse consequences to our business.

We have and are continuing to incorporate AI, including machine learning and independent algorithms, in certain of our products, services and internal operations, including in our MCT Services with our Zio AT System, which is intended to enhance their operation and effectiveness internally and for physicians and patients. Our research and development of such technology remains ongoing. AI innovation presents risks and challenges that could impact our business. Issues relating to the use of new and evolving technologies such as AI that we integrate into our products, services and internal operations may cause us to experience brand or reputational harm, competitive harm, legal liability, new or enhanced governmental or regulatory scrutiny, and to incur additional costs to resolve such issues. As with many innovations, AI presents risks and challenges that could undermine or slow its adoption, and therefore harm our business to the extent we increase our reliance on AI in the future. Moreover, our competitors may introduce AI technologies and features into their products and services that achieve greater market acceptance than ours. Additionally, AI algorithms may be flawed or datasets may be insufficient or contain biased information resulting in perceived or actual negative outcomes. If the output that AI algorithms assist in producing are or are alleged to be inaccurate, deficient, or biased, our business, financial condition, and results of operations may be adversely affected. Developing, testing and deploying AI systems may also increase the costs of our product offerings due to the nature of the computing costs involved in such systems, which could impact our revenue and adversely affect our business and operating results.

Many countries and regions, including the EU, have proposed or passed new and evolving regulations related to the use of AI and machine learning technologies. The regulations may impose onerous obligations and may require us to unexpectedly rework or reevaluate improvements to be compliant. In particular, the EU Artificial Intelligence Act, which was adopted on June 13, 2024, will have a material impact on the way AI is regulated in the EU, may affect our use of AI technologies, and may require additional compliance measures and changes to our operations and processes. Use of AI technologies may expose us to an increased risk of regulatory enforcement and litigation. Furthermore, the integration of third-party AI models with our platform relies on certain safeguards implemented by the third-party developers of the underlying AI models, including those related to the accuracy, bias, and other variables of the data, and these safeguards may be insufficient. Moreover, some of the AI features involve the processing of personal data and may be subject to laws, policies, legal obligations, and codes of conduct related to privacy and data protection. AI development and deployment practices could subject us to competitive harm, regulatory enforcement, increased cyber risks, reputational harm, and legal liability.

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, inability or delay to obtain FDA marketing authorization or regulatory clearances in the EU and the UK, 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 in the past, and may explore or enter into in the future, development or collaboration agreements with third parties. These development and collaboration agreements may not result in the development of commercially viable devices or the generation of significant future revenues.

We have entered into a development and collaboration agreement in the past to develop certain next-generation Afib screening, detection, or monitoring devices to enhance our Zio Services, which could involve combining our technology platforms and capabilities with those of a third party, and we intend to enter into similar development and collaboration agreements with third parties in the future. The success of our collaboration with third parties is highly dependent on the efforts provided to the collaboration by such third parties 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. Product testing, market research, and related activities may result in a delay to any 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.

Any collaboration with a third party 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 any development or collaboration agreement, we may be required to devote additional resources to device development and we may face increased competition, including from our third party partner. A third party partner may use the experience and insights it develops in the course of any 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 any third party will result in the successful development of commercially viable devices and services or result in significant additional future revenues for our company.

We generally intend to continue assessing the potential pathways for expanding indications and use cases for our Zio Services, and developing potential new products and services, for patient populations with unmet needs in the remote cardiac monitoring market and adjacent markets. We intend to continue to invest in research and development efforts to further differentiate our biosensor, data analytics and reporting, information system, and digital platform and we may explore or enter into development or collaboration agreements with third parties to further these efforts. We cannot predict whether such efforts will be viable from a regulatory and commercial standpoint, and development or collaboration agreements may not result in the development of commercially viable products or services or the generation of significant future revenues. For example, enforcement action such as that conveyed through the FDA warning letter we received in 2023, as well as other digital health industry regulatory developments, may also impact the availability or viability of potential opportunities.

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, the EU, the UK, Switzerland and Japan, 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 or regions;
- requirements to maintain and secure data and the processing of that data on servers located within such countries or regions, which requirements may be subject to change;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems, as well as with participating in public tenders or procurement processes run by national healthcare systems;
- logistics and regulations associated with shipping and returning our Zio patches following patient 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 of 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;
- increased risk of litigation or administrative proceedings in connection with product liability claims, driven in part by a growing third-party litigation funding market in the EU as well as legal and regulatory reform across product safety and product liability such as the newly adopted EU Product Liability Directive of October 23, 2024, the proposed AI Liability Directive and further implementation of the collective redress regime which may lead to group claims in respect of medical devices;
- natural disasters, political and economic instability, including wars and other geopolitical conflicts, terrorism, political unrest, outbreak of disease, boycotts, curtailment of trade, and other market restrictions;
- risks associated with any shifts in economic relations between the UK and the EU, which could result in tariffs or quotas on imported goods or services moving between the UK and the EU;
- regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), UK Bribery Act of 2010, and comparable laws and regulations in other countries;
- compliance risks associated with the General Data Protection Regulation (the "GDPR") (including as it applies in the UK by virtue of the Data Protection Act 2018), enacted to protect the privacy of all individuals in the EU and the UK, and which places certain restrictions on the export of personally identifiable data outside of the EU or the UK, as applicable;
- compliance risks associated with the revised regulations in the EU MDR that outline the requirements for medical device CE marking;
- compliance risks associated with the UK MDR, which replaces the CE marking requirements for medical devices marketed and sold in the UK with a UKCA mark following the UK's withdrawal from the EU, and the UK government's announcement to amend the UK MDR, in particular to create a new access pathway to support innovation and create an innovative framework for regulating software and AI as medical devices;
- compliance risks associated with the Japanese PMDA;
- compliance risks associated with the Swiss MedDO;
- compliance risks associated with new or upcoming regulations associated with AI applicable to Software as a Medical Device, including compliance with the EU Artificial Intelligence Act; and
- compliance risks associated with new or upcoming requirements and expectations associated with medical device cybersecurity.

Any of these factors may require significant resources to address and could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

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, quality, 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, for example the March 2023 resignation of Douglas Devine as Chief Operating Officer and the August 2024 resignation of Brice Bobzien as Chief Financial Officer and appointment of Daniel Wilson as Chief Financial Officer, and we 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, could complicate our efforts to retain other valuable employees, 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. Further, a move toward automation to address, for example, staffing or scalability needs, could result in unintended consequences, such as increased scrap rate negatively impacting profitability.

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 qualified cardiac technicians, 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. We have also seen hybrid situations where accounts, in response to staffing shortages, provide in-clinic Zio device packages to patients for application at home. Although in all three scenarios there is the potential that a patient will not return the device(s) at the conclusion of the wear period, home hookups historically 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 Monitor patch to us at the end of the patient wear period, we provide the Zio Monitor services, which include the end of service report based on the data stored on the Zio Monitor 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 strategic plans include a high degree of focus on the marketing of our services for proactive monitoring of undiagnosed arrhythmias, such as Afib screening. There are risks that the clinical or payor community will not identify, adopt or accept selection criteria to identify patients suitable for proactive monitoring of undiagnosed arrhythmias.

In January 2022, the U.S. Preventive Services Task Force ("USPSTF") published a recommendation statement on the screening criteria for Afib screening, stating that current evidence is insufficient to assess the balance of benefits and harm of Afib 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 Afib 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 USPSTF recommendation statement may deter some clinicians or payors from 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 our 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. For example, the License Agreement that we entered into with BioS may not result in the development of commercially viable products or services or the generation of significant future revenues. The success of our efforts is highly dependent on the efforts and skill sets of our employees, and support of these efforts requires significant resources, including research and development, manufacturing, quality assurance, and clinical and regulatory personnel. 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.

In addition, 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, investment required to address risks associated with the acquisition, or charges relating to acquired intangible assets.

The success of our collaboration with BioS and the extent to which we realize a return on investment in the technology licensed from BioS is dependent on our achievement of certain regulatory milestones. If those milestones are not met, or if any resulting products do not gain acceptance in the marketplace, our business and operating results may be negatively impacted.

Our License Agreement with BioS grants us an exclusive license to develop and commercialize pulse oximetry, accelerometry, and trending non-invasive blood pressure technologies for use within our remote cardiac monitoring products and services. It is anticipated that BioS's multiparameter sensing technologies will position us to expand the capabilities of our product platform within the remote cardiac monitoring field of use and potentially into adjacent indications such as OSA over time. This will require that any new products developed undergo validation and achieve certain regulatory milestones. Should we fail to meet those milestones, or if there are material delays in doing so, this could impede our ability to commercialize any new products or solutions utilizing the technologies covered by the License Agreement and realize our return on investment.

We are currently in the early stages of exploring opportunities to expand into the market of sleep apnea screening and diagnostics, which carries unique regulatory requirements and represents an ongoing area of focus for government enforcement. Commercialization of new products and services in the sleep testing space will require a significant investment of time and resources. If we are unable to successfully execute on these opportunities, it could have an adverse affect on our reputation, business, and results of operations.

Our exploration of the sleep apnea screening and diagnostics market is in the early evaluation stages, and although we are devoting time and resources to this evaluation, we do not anticipate meaningful revenue from any such opportunities to expand into the sleep apnea screening and diagnostics market for the foreseeable future. If we fail to capitalize on these opportunities, we may face threats from our competitors should they be able to commercialize products and services in the home sleep testing ("HST") space on a more expeditious timeline. Additionally, any new HST offering will be subject to specific requirements to qualify for reimbursement under Medicare and by third-party commercial payors. Improper billing activities related to HST services have been an area of significant government scrutiny in recent years. Failure to comply with the myriad, complex legal and regulatory requirements surrounding the provision of sleep apnea diagnostics could subject us to substantial civil or criminal penalties, exclusion from participation in the Medicare program, reputational harm, and other adverse consequences to our business and results of operations.

Risks Related to Healthcare Regulatory Matters

Our use of third-party service providers or 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 company resources 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 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 have established company resources in the Philippines to provide services in support of our IDTFs. These services include benefits verification, billing, collections, and customer service, which 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 reasonable controls intended to prohibit unauthorized use of patient data by service providers and 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, state and international healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- state licensure laws applicable to the manufacture, marketing, distribution, and sale of medical devices;
- federal and state laws and regulations regarding billing, claims payment, and enrollment for participation in government healthcare programs, including regulations requiring the timely identification and refunding of overpayments to Medicare and other federally funded healthcare programs;
- 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 FCA, 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, anti-kickback, and transparency 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;
- Health Insurance Portability and Accountability Act ("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 EU and the UK, 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 MDR that outline requirements for medical device CE marking;
- the UK MDR, which, post the UK's withdrawal from the EU, replaces the CE marking requirement for medical devices sold in the UK with a UKCA mark;
- the Swiss MedDO, which governs the approval and importation requirements of medical devices into Switzerland;
- the PMDA, which outlines comprehensive standards for the design, evaluation, marketing approval, production, labeling, distribution, and ongoing monitoring of medical devices in Japan; 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 individually identifiable information in certain circumstances (e.g., the Telephone Consumer Protection Act, the CAN-SPAM Act, and state privacy, consumer protection, and breach notification laws), 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 if 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. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. For violations assessed after January 15, 2025, the minimum FCA penalty increased from \$13,946 to \$14,308 per claim and the maximum penalty increased from \$27,894 to \$28,619 per claim. In addition, FCA lawsuits may expose defendants to follow-on claims by private payers based on fraudulent marketing practices. Recent growth in FCA litigation has increased the risk that companies will have to defend a false claim action, and pay settlements, fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and/or be excluded from Medicare or other federal and state healthcare programs. For example, our industry has experienced recent FCA enforcement, including a December 2023 settlement by BioTelemetry, Inc. and its subsidiary LifeWatch Services Inc. involving allegations that these companies submitted claims to federal programs for a higher level of remote cardiac monitoring than physicians had intended to order or that was medically necessary, thus inflating the level of reimbursement paid, 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.

Further, in June 2024, the U.S. Supreme Court reversed its longstanding approach under the Chevron doctrine, which provided for judicial deference to regulatory agencies, including FDA. As a result of this decision, we cannot be sure whether there will be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the U.S. Supreme Court. For example, this decision may result in more companies bringing lawsuits against FDA to challenge longstanding decisions and policies of FDA, which could undermine FDA's authority, lead to uncertainties in the industry, and disrupt FDA's normal operations, which could impact the timely review of any regulatory filings or applications we submit to FDA.

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. There remains general uncertainty regarding future government activities. The new presidential administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new diagnostic products or services. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we become negatively impacted by future governmental orders, regulations, policies or guidance as a result of the new federal administration, there could be a material adverse effect on us and 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 could be negatively impacted by changes in the United States political environment.

Any policy changes as a result of the new presidential administration and Congress could significantly affect our business as well as the markets in which we operate. Specific legislative and regulatory proposals discussed during election campaigns and since inauguration that might materially impact our business include, but are not limited to, promoting access to healthcare via market competition and pricing transparency, enhancing flexibility and choice in healthcare at the state and individual level, prioritizing domestic production and increasing tariffs on imports (which may complicate and increase costs associated with our supply chain and our international expansion), and rolling back regulatory initiatives adopted under the previous administration. We cannot predict whether industry initiatives to seek tariff carve-outs for devices or other life sciences goods and products will be successful.

Some of these legislative and regulatory proposals have manifested to date in the form of specific tariff proposals, and actions to reduce the size of the federal government, including large-scale reductions in force at FDA. The loss of key personnel at FDA, including those in leadership positions, is likely to impact the operations at FDA, which could result in, among other things, delays or limitations on our ability to obtain guidance from FDA on our products, longer review times, and delays in obtaining regulatory approvals. The new administration also has issued, and is expected to continue relying upon, executive orders to address a wide range of policy areas, some of which may impact our business. Examples of executive orders that have already been issued on public health and healthcare topics include orders seeking to withdraw the United States from the World Health Organization, rescind a 2022 order issued under the prior administration to lower the cost of prescription drugs, and address COVID-19 vaccination requirements. Such political developments may require us to allocate significant time, resources, and expense to modifying our policies and procedures, processes, systems, and practices to ensure compliance or adapt to the new regulatory climate, particularly to the extent such actions are subject to protracted and uncertain legal challenges. To the extent changes in the political environment have a negative impact on us or on our markets, our business, results of operation, and financial condition could be materially and adversely affected in the future.

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 structure and 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 FCA, 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 regulators, enforcement authorities, or competitors.

Our sales and marketing efforts and initiatives, as well as other communications with healthcare professionals ("HCPs"), may subject us to a high degree of scrutiny for compliance with applicable laws and regulations and our practices of effective communication of risk information, benefits, or claims will be subject to oversight by FDA, the Federal Trade Commission ("FTC") and others.

In addition, 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. There is potential for differing interpretations of whether certain communications are consistent with a product's FDA-required labeling, including with respect to communications that may reference or contemplate the use of the Zio devices with specified patient populations. FDA will evaluate communications, in context, on a fact-specific basis. This is a continued area of focus for regulators. In the fourth quarter of 2023, FDA issued final guidance focused on the presentation of quantitative risk and efficacy information to the consumer audience, with heightened focus on presenting such information in a manner that is accurate, understandable, and consumer-friendly. The FTC has also released updated guidance on health claims, with a high expectation for clinical data to support these claims.

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 and their practices and health systems 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 and product information under the Preapproval Information Exchange Act. Recent FDA final guidance on communication of scientific information on unapproved uses of cleared/approved medical products with HCPs further illustrates the agency's focus on ensuring that such communications to those in a position to order or prescribe products are consistent with available scientific data and subject to organizational controls maintaining separation and distinction from promotional marketing.

For example, certain of our physicians may order the Zio Services for patients who are under 18, which is outside the cleared indications for use. While we do not intend for any personnel to promote our devices for pediatric use and we have policies addressing appropriate responses to unsolicited requests for information about pediatric use, our approach may be subject to ongoing scrutiny from FDA.

If FDA or other federal, state, or foreign enforcement authorities determine that our labeling, advertising, promotional materials, or user training materials, or representations made by our personnel include the promotion of an off-label use for the device, or that we have made false or misleading or inadequately substantiated promotional claims, or claims that could potentially change the regulatory status of the product, FDA or other authorities could take the position that these materials have misbranded our devices and request that we modify our labeling, advertising, or user training or promotional materials and/or subject us to regulatory or legal enforcement actions, including the issuance of an Untitled Letter or a Warning Letter, injunction, seizure, recall, adverse publicity, civil penalties, criminal penalties, including substantial fines, or other adverse actions. In that event, we would be subject to extensive fines and penalties and our reputation could be damaged and adoption of the products would be impaired. Although we intend to refrain from statements that could be considered off-label promotion of our products, FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion.

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 which 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 federal Anti-Kickback Statute, 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 Monitor System or 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 have endeavored to properly design these billing and service models and structure our program development efforts, including related affiliations and relationships with physicians or other healthcare entities, to comply with applicable 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 and our internal control over financial reporting 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 our 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 had been successful and that the previously identified material weakness in internal control over financial reporting had 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 business, political, and economic conditions, including inflation, interest rate volatility, cybersecurity events, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, potential instability in the global banking system, political instability, and military hostilities, including ongoing geopolitical conflicts, such as the war in Ukraine and conflict in the Middle East.

Further, we recognize a portion of our revenue from non-contracted third-party commercial payors. For example, during the three months ended March 31, 2025, revenue from non-contracted third-party commercial payors accounted for approximately 6% 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 our third party billing vendors 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 \$30.7 million and \$45.7 million during the three months ended March 31, 2025, and 2024, respectively. As of March 31, 2025, we had an accumulated deficit of \$789.6 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 to, among other things, 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 (the "Code"), 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. Sections 382 and 383 of the Code 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 the applicable tax jurisdictions. If we have insufficient future taxable income in the applicable tax jurisdiction for any reason, including as a result of 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 9, Income Taxes to the consolidated financial statements included herein 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 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 (without regard for certain deductions). 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, patent litigation and other matters and may become involved in other legal proceedings that arise from time to time in the future. For example, as discussed further in Note 7, Commitments and Contingencies, to the Consolidated Financial Statements included herein, a putative securities class action lawsuit has been filed against us and certain of our current officers or former officers alleging violations of Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder, and two patent lawsuits have been filed against us by companies affiliated with Baxter International.

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 7, Commitments and Contingencies, to the Consolidated Financial Statements included herein, 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 FDA and our Zio Systems, and, in September 2021, received a subpoena requesting additional information. On April 4, 2023, we received a Subpoena Duces Tecum from the Consumer Protection Branch, Civil Division of the DOJ, requesting production of various documents regarding our products and services. In addition, on May 25, 2023, we received a warning letter from FDA, which resulted from the inspection of our facility located in Cypress, California that concluded in August 2022. The warning letter alleges non-conformities to regulations for medical devices, including medical device reporting requirements, relating to our Zio AT System and medical device quality system requirements. On July 15, 2024, FDA initiated inspections of our Cypress and San Francisco facilities. We received 483 observations at the close of the inspection. We are cooperating fully in connection with these matters. 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.

Further, three decisions from the U.S. Supreme Court in July 2024 may lead to an increase in litigation against regulatory agencies that could create uncertainty and thus negatively impact our business. The first decision overturned established precedent that required courts to defer to regulatory agencies' interpretations of ambiguous statutory language. The second decision overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. The third decision extended the statute of limitations within which entities may challenge agency actions. These cases may result in increased litigation by industry against regulatory agencies and impact how such agencies choose to pursue enforcement and compliance actions. However, the specific, lasting effects of these decisions, which may vary within different judicial districts and circuits, is unknown. We also cannot predict the extent to which FDA and SEC regulations, policies, and decisions may become subject to increasing legal challenges, delays, and changes.

Compliance with requirements of being a public company 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 the requirement to capitalize research and development expenditures and amortize such expenditures over five years for domestic expenditures and fifteen years for foreign expenditures for taxable years beginning on or after January 1, 2022. 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, 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 presence in the UK, as well as sales in the UK, such that any changes in tax laws in the UK will impact our business. The overall impact of these changes is uncertain, and our business and financial condition could be adversely affected.

In addition, our tax obligations and effective tax rates could be adversely affected by changes in the relevant tax, accounting and other laws, regulations, principles and interpretations, including those relating to income tax nexus, by recognizing tax losses or lower than anticipated earnings in jurisdictions where we have lower statutory rates and higher than anticipated earnings in jurisdictions where we have higher statutory rates, by changes in foreign currency exchange rates, or by changes in the valuation of our deferred tax assets and liabilities. The TCJA introduced a Base Erosion and Anti-Abuse Tax ("BEAT") which imposes a minimum tax on adjusted income of corporations with average applicable gross receipt of at least \$500 million for the prior three tax years and that make certain payments to related foreign persons. In addition, the Organization for Economic Cooperation and Development has proposed a global minimum tax of 15% of reported profits ("Pillar 2") that has been agreed upon in principle by over 140 countries. Many countries have taken steps to incorporate Pillar 2 into their domestic tax laws. While neither BEAT nor Pillar 2 impact our results of operations currently, if applicable in the future, they could have an impact on our financial results, the extent of which is uncertain.

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 UK, 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 may be 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, confidentiality and invention assignment agreements with employees and third parties, unfair competition, and other related laws 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 granted to third parties. There may be existing patents or patent applications now pending by third parties 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.

In addition, licensing technologies from third parties exposes us to increased risk of being the subject of intellectual property infringement and vulnerabilities due to, among other things, our lower level of visibility into the development process with respect to such technology and the care taken to safeguard against risks. We currently rely on or incorporate, and will in the future rely on or incorporate, technology that we license from third parties, including software, into our solutions. We cannot be certain that our licensors do not or will not infringe on the intellectual property rights of third parties or that our licensors have or will have sufficient rights to the licensed intellectual property in all jurisdictions in which we may sell our platform. Some of our agreements with our licensors may be terminated by them for convenience, or otherwise provide for a limited term. If we are unable to continue to license technology because of intellectual property infringement claims brought by third parties against our licensors or against us, or if we are unable to continue our license agreements or enter into new licenses on commercially reasonable terms, our ability to develop and sell solutions and services containing or dependent on that technology would be limited, and our business, including our financial conditions, cash flows and results of operations could be harmed. Additionally, if we are unable to license technology from third parties, we may be forced to acquire or develop alternative technology, which we may be unable to do in a commercially feasible manner, or at all, and may require us to use alternative technology of lower quality or performance standards. This could limit or delay our ability to offer new or competitive solutions and increase our costs. Third-party software we rely on may be updated infrequently, unsupported or subject to vulnerabilities that may not be resolved in a timely manner, any of which may expose our solutions to vulnerabilities. Any impairment of the technologies or of our relationship with these third parties could harm our business, operating results, and financial condition.

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 be 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, nondisclosure agreements, unfair competition laws, and other related laws, and contractual provisions to protect our intellectual property with our customers, third-party partners, and consultants. 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 U.S. Patent and Trademark Office ("USPTO"), which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. We cannot be certain that we were the first to make the inventions claimed in our pending patent applications or that we were the first to file for patent protection. Additionally, the process of obtaining patent protection is expensive and time-consuming, and we may not be able to prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, recent changes to the patent laws in the U.S. may bring into question the validity of certain software patents and may make it more difficult and costly to prosecute patent applications. Such changes may lead to uncertainties or increased costs and risks surrounding the prosecution, validity, ownership, enforcement, and defense of our issued patents and patent applications and other intellectual property, the outcome of third-party claims of infringement, misappropriation, or other violation of intellectual property brought against us and the actual or enhanced damages (including treble damages) that may be awarded in connection with any such current or future claims, and could have a material adverse effect on our business, operating results, and financial condition.

Despite our efforts to protect our proprietary rights, unauthorized parties may attempt to copy aspects of our platform or obtain and use information that we regard as proprietary. In particular, we are unable to predict or assure that:

- our intellectual property rights will not lapse or be invalidated, circumvented, challenged, or, in the case of third-party intellectual property rights licensed to us, be licensed to others;
- our intellectual property rights will provide competitive advantages to us;
- rights previously granted by third parties to intellectual property licensed or assigned to us, including portfolio cross-licenses, will not hamper our ability to assert our intellectual property rights or hinder the settlement of currently pending or future disputes;
- any of our pending or future patent, copyright, or trademark applications will be issued or have the coverage originally sought;
- we will be able to enforce our intellectual property rights in certain jurisdictions where competition is intense or where legal protection may be weak; or
- we have sufficient intellectual property rights to protect our products or our business.

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. Lastly, the measures we employ to limit the access and distribution of our proprietary information may not prevent unauthorized use or disclosure of our proprietary technology or intellectual property. As such, we cannot guarantee that the steps taken by us will prevent misappropriation of our technology.

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 EU 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. However, despite that registration, we have successfully obtained a registration for the IRHYTHM mark in the EU in Classes 9 and 10 and we also 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, services interruptions and other incidents affecting the confidentiality, integrity or availability of our data and systems, could result in the compromise of confidential data or critical systems and give rise to potential harm to our patients, remediation costs 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 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, and contractors. 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 and other cyber incidents have become more prevalent and much harder to detect and defend against. These cyber-attacks and other incidents include unauthorized access to our network, information technology and data, and that of our contractors and service providers; compromise of employee credentials and accounts; transmission of computer viruses and other malware; phishing and spamming attacks; ransomware attacks and other acts of cyber extortion; and malicious actions by persons inside our organization and other insider threats. For example, during the first quarter of 2024, we experienced a temporary delay in the billing of our contracted and non-contracted payer customers, performed by our third-party claims processing vendor. The delay was due to a cybersecurity incident experienced by Change Healthcare, a division of UnitedHealth Group, which our third-party vendor engages for services relating to billing and collections. While we substantially cleared the billing backlog as of the end of the first quarter of 2024, the delay in billing resulted in a temporary delay in our cash collections. The increasing use of mobile devices for remote access to our systems and data also increases these vulnerabilities and risks.

Our internal technology systems and infrastructure, and those of our contractors, are vulnerable to damage from natural disasters, acts of terrorism, war and other acts of foreign governments and failures of telecommunication, electrical and other critical systems. 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 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. If our Zio devices are subject to cybersecurity vulnerabilities leading to potential harm to patients or compromises data security and confidentiality, we may be required to initiate field actions, including device recalls, or subject to government inspections, investigations or enforcement actions.

The secure maintenance, processing, and transmission of data is critical to our business operations and we are 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, or failures to adequately scale our data platforms and architectures to 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 still be vulnerable to attacks. Further, any resulting unauthorized 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, mitigation, 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 marketing authorizations and regulatory certifications or approvals in the EU, Japan and the UK, could create risks to patients.

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 and are subject to extensive oversight from FDA and foreign regulatory authorities with requirements designed to manage the risks of cyber-attacks with the potential to impact patient safety. 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 marketing authorizations and regulatory certifications or approvals in the EU, Japan and the UK, may create risks to patients and potential exposure to our company.

We are required to comply with various laws and regulations with respect to implementing appropriate cybersecurity measures to ensure our devices and services are not compromised or disrupted, which could lead to potential risk of harm or injury to patients. FDA has issued guidance on cybersecurity management of medical devices during post market, and more recently finalized guidance on cybersecurity considerations for quality systems in device premarket submissions. These guidance documents serve as an indicator of agency expectations. If we do not implement the necessary quality measures to manage cybersecurity and minimize or avoid risks of a potential cyber-attack that impacts our devices and services, we could be subject to a range of FDA enforcement action, and such a situation could trigger the need for a recall, a hold on the distribution of our products, or require other corrective actions to our products.

In the EU, a number of interlocking rules regulate cybersecurity for medical devices. For example, the new Cybersecurity Directive (EU) 2022/2555 (also known as the NIS 2 Directive (Network and Information Security)) entered into force in January 2023. The EU NIS 2 Directive affects Critical National Infrastructure (CNI) providers, which includes the health sector and the manufacturers of medical devices considered to be critical during a public health emergency, as well as other covered entities. The requirements in the NIS 2 Directive will sit alongside the cybersecurity requirements addressed in the EU MDR, which are supplemented by specific guidance issued by the EU's Medical Device Coordination Group. In addition, at this time, we cannot predict the impact on cybersecurity compliance that recent and forthcoming EU legislation such as the Artificial Intelligence Act and the European Health Data Space Regulation, may have. In addition, on January 15, 2024, the European Commission launched a European action plan to strengthen the cybersecurity of hospitals and healthcare providers. Several specific actions will be rolled out progressively in 2025 and 2026. At this time, it is not clear what these actions will entail. In the UK, the government announced as part of its consultations on the future regulation of medical devices, that it intends to develop legislation to impose cybersecurity requirements for software as a medical device, including for AI.

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 customer growth or engagement, or otherwise harm our business.

In the ordinary course of our business, we collect, use and store, and transmit confidential and 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, 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. U.S. and foreign 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. Further, if we fail to comply with applicable privacy laws, we could face civil and criminal penalties, or claims for breach of contract. In the United States, there are numerous federal and state patient and consumer, privacy and data security laws and regulations governing the collection, use, disclosure, protection and breach of personal information. HIPAA, for example, establishes privacy standards that limit the use and disclosure of individually identifiable health information (or “protected health information”); requires the implementation of reasonable administrative, physical and technological safeguards to protect the privacy and security of this information and ensure its confidentiality, integrity and availability; and sets forth notification standards in the event of a data breach. In addition, states have shown an increased interest in regulating personal information in general (for example, through state consumer privacy laws and data breach notification laws), and specifically with respect to consumer health data.

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. Other foreign laws, such as the GDPR, impose strict requirements for processing and cross-border transfers of personal data.

Determining how protected health information may be used, shared, or processed in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. 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. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make other operational changes; and/or it could adversely affect our business, financial condition, results of operations and prospects.

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 have been highly volatile as a result of macroeconomic conditions, including inflation, interest rate volatility and ongoing geopolitical conflicts, such as the war in Ukraine and conflict in the Middle East.

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;
- regulatory actions;
- legislation and political conditions;
- cybersecurity events;
- global health pandemics, such as the COVID-19 pandemic;
- terrorist acts, acts of war, or periods of widespread civil unrest, including ongoing geopolitical conflicts, such as the war in Ukraine and conflict in the Middle East; and
- general economic, industry, and market conditions, including inflation, interest rate volatility, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, potential instability in the global banking system, and fluctuating 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 to us or our stockholders by any of our directors, officers, or other employees or agents; 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

Our indebtedness could adversely affect our financial health and our ability to respond to changes in our business.

As a result of our level of increased debt following the completion of the offering of our 1.50% Convertible Senior Notes due 2029 (the "2029 Notes"):

- our vulnerability to adverse general economic conditions and competitive pressures will be heightened;
- we will be required to dedicate a larger portion of our cash flow from operations to interest payments, limiting the availability of cash for other purposes;
- our flexibility in planning for, or reacting to, changes in our business and industry may be more limited; and
- our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions, general corporate purposes or other purposes may be impaired.

We cannot be sure that our leverage resulting from the level of increased debt will not materially and adversely affect our ability to finance our operations or capital needs or to engage in other business activities. In addition, we cannot be sure that additional financing will be available when required or, if available, will be on terms satisfactory to us. Further, even if we are able to obtain additional financing, we may be required to use such proceeds to repay a portion of our debt.

Furthermore, we will not be restricted under the terms of the indenture governing the 2029 Notes from incurring additional debt, securing future debt, recapitalizing our debt, repurchasing our stock, pledging our assets, making investments, paying dividends, guaranteeing debt or taking a number of other actions that could have the effect of diminishing our ability to make payments on the 2029 Notes when due.

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

Our ability to repay the principal of, to pay interest on or to refinance our indebtedness, including the 2029 Notes, or to make cash payments in connection with any conversions of 2029 Notes, depends on our future 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 service our existing indebtedness and any future indebtedness we may incur and 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, restructuring debt or obtaining additional debt financing or equity capital on terms that may be onerous or highly dilutive. Our ability to refinance any current or 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 or engage in these activities on desirable terms or at all, which could result in a default on our debt obligations. In addition, any of our future current or future debt agreements may contain restrictive covenants that may prohibit us from adopting any of these alternatives. Our failure to comply with these covenants could result in an event of default which, if not cured or waived, could result in the acceleration of our debt.

In addition, we may be unable to repurchase the 2029 Notes upon a fundamental change when required by the holders or repay prior to maturity any accelerated amounts due under the 2029 Notes upon an event of default or redeem the 2029 Notes or pay cash upon conversion of the 2029 Notes, and our future debt may contain limitations on our ability to pay cash upon conversion, repurchase or repayment of the 2029 Notes.

The capped call transactions may affect the value of our common stock.

In connection with the pricing of the 2029 Notes, we entered into capped call transactions with the option counterparties. The 2029 Capped Calls are expected generally to reduce the potential dilution to our common stock upon conversion of the 2029 Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted 2029 Notes, as the case may be, with such reduction and/or offset subject to a cap.

The option counterparties or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the 2029 Notes (and are likely to do so during any observation period related to a conversion of 2029 Notes or following any redemption or repurchase of 2029 Notes by us, in each case, if we elect to unwind a corresponding portion of the 2029 Capped Calls in connection with such conversion or such redemption or repurchase). This activity could also cause or avoid an increase or a decrease in the market price of our common stock.

We are subject to counterparty risk with respect to the capped call transactions.

The option counterparties are financial institutions or affiliates of financial institutions, and we are subject to the risk that one or more of such option counterparties may default under the 2029 Capped Calls. Our exposure to the credit risk of the option counterparties is not secured by any collateral. Past and current global economic conditions, including recent changes in prevailing interest rates, have resulted in the actual or perceived failure or financial difficulties of many financial institutions. If any option counterparty becomes subject to bankruptcy or other insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under the capped call transaction with such option counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be positively correlated to an increase in our common stock market price and in the volatility of the market price of our common stock. In addition, upon a default by an option counterparty, we may suffer adverse tax consequences and dilution with respect to our common stock. We can provide no assurance as to the financial stability or viability of any option counterparty.

Conversion of the 2029 Notes will, to the extent we deliver shares upon conversion of such 2029 Notes, dilute the ownership interest of existing stockholders, including holders who had previously converted their 2029 Notes, or may otherwise depress our stock price.

The conversion of some or all of the 2029 Notes will dilute the ownership interests of existing stockholders to the extent we deliver shares upon conversion of any of such 2029 Notes. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the 2029 Notes may encourage short selling by market participants because the conversion of the 2029 Notes could be used to satisfy short positions, or anticipated conversion of the 2029 Notes into shares of our common stock could depress our stock price.

The conditional conversion feature of the 2029 Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the 2029 Notes is triggered, holders of the 2029 Notes will be entitled to convert the 2029 Notes at any time during specified periods at their option. If one or more holders elect to convert their 2029 Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than cash in lieu of any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders of the 2029 Notes do not elect to convert their 2029 Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2029 Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible debt securities that may be settled in cash, such as the 2029 Notes, could have a material effect on our reported financial results.

Under current accounting principles, we do not expect to separately account for the liability and equity components of the 2029 Notes and will instead present the entire amount of the 2029 Notes as debt on the balance sheet. Additionally, under the “if-converted” method, diluted earnings per share is generally calculated assuming that all the debt securities were converted solely into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive, which could adversely affect our diluted earnings per share. However, if we were to make an irrevocable election to settle the principal amount of the 2029 Notes in cash, the if-converted method for calculating diluted earnings per share will only take into consideration the number of shares that would be issuable based on the extent to which the conversion value of such 2029 Notes exceeds their principal amount, provided the effect were dilutive. Furthermore, if any of the conditions to the convertibility of the 2029 Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the 2029 Notes as a current, rather than a long-term, liability. This reclassification could be required even if no holders convert their 2029 Notes and could materially reduce our reported working capital.

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 ongoing geopolitical conflicts such as the war in Ukraine and conflict in the Middle East, domestic and global inflationary trends, interest rate volatility, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto, potential instability in the global banking system, global supply shortages, and a tightening labor market. 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, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, including those affiliated with the manufacture of certain components of our Zio Monitor System, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers’ ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation.

Further, 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.

At the same time, an increasing number of stakeholders, regulators and lawmakers have expressed or pursued contrary views, including the proposal or enactment of “anti-ESG” policies, legislation, executive orders or initiatives or issued related legal opinions. Conflicting regulations and a lack of harmonization of ESG legal and regulatory environments across the jurisdictions in which we operate may create enhanced compliance risks and costs. We may also face increasing scrutiny from our investors, physicians, patients, employees and other stakeholders relating to the appropriate role of ESG practices and disclosures.

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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Sales of Unregistered Securities

None.

Use of Proceeds

None.

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Trading Plans

During the three months ended March 31, 2025, no Section 16 officers or directors adopted, modified, or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement” (each as defined in Item 408 of Regulation S-K of the Exchange Act).

ITEM 6. EXHIBITS

The exhibits listed in the accompanying exhibit index are filed as part of, and incorporated by reference into, this Quarterly Report on Form 10-Q.

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference				Provided Herewith
		Form	File No.	Exhibit No.	Filing Date	
31.1	Certification of Chief Executive Officer required by Securities Exchange Act Rules 13a-14(a) and 15d-14(a).					X
31.2	Certification of Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a).					X
32.1*	Certification of Chief Executive Officer and Chief Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350.					X
101.INS	Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its Inline XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					X

* The certifications filed as Exhibits 32.1 are not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall they be deemed and are not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended or the Exchange Act, whether made before or after the date hereof irrespective of any general incorporation by reference language contained in any such filing, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements 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: May 1, 2025

By: /s/ Quentin Blackford
Quentin Blackford
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 1, 2025

By: /s/ Daniel Wilson
Daniel Wilson
Chief Financial Officer
(Principal Financial Officer)

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 Quarterly Report on Form 10-Q 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: May 1, 2025

By: /s/ Quentin S. Blackford

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

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, Daniel Wilson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: May 1, 2025

By: _____ /s/ Daniel Wilson

Daniel Wilson
Chief Financial Officer
(Principal Financial Officer)

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 Quarterly Report of iRhythm Technologies, Inc. (the “Company”) on Form 10-Q for the period ended March 31, 2025, 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: May 1, 2025

By: /s/ Quentin S. Blackford
Quentin S. Blackford
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Daniel Wilson
Daniel Wilson
Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is 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 the Form 10-Q), irrespective of any general incorporation language contained in such filing.