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 June 30, 2023

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	**20-8149544**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
699 8th Street Suite 600 San Francisco, California	**94103**
(Address of Principal Executive Offices)	**(Zip Code)**

(415) 632-5700
(Registrant's Telephone Number, Including Area Code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 July 24, 2023, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 30,577,519.

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

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 macroeconomic conditions, including inflation, interest rate volatility, the federal debt ceiling and budget, instability in the global banking system and volatile market conditions, and global events, including public health crises, such as the persisting impacts of the COVID-19 pandemic, and the ongoing military conflict between Russia and Ukraine, on our business, operations and financial results;
- the impact of supply chain disruptions on our operations and financial results;
- the impact of inflationary costs on our operations and financial results;
- plans to conduct further clinical studies, including any clinical trials initiated by third parties;
- our plans to modify our current systems and services, or identify and develop, or acquire, new products or services, to address additional indications;
- the expected growth of our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement or other regulatory actions or decisions;
- our 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 and general and administrative expenses;
- our ability to retain and recruit key personnel, including the continued development of a sales and marketing infrastructure;
- our ability to obtain and maintain intellectual property protection for our systems and services;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this 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)

	June 30, 2023	December 31, 2022
(unaudited)		
Assets		
Current assets:		
Cash and cash equivalents	$ 61,578	$ 78,832
Marketable securities	103,161	134,312
Accounts receivable, net	51,108	49,918
Inventory	14,478	15,155
Prepaid expenses and other current assets	11,816	10,555
Total current assets	242,141	288,772
Property and equipment, net	89,845	75,670
Operating lease right-of-use assets	57,917	60,666
Goodwill	862	862
Other assets	38,723	22,252
Total assets	$ 429,488	$ 448,222
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,150	$ 7,517
Accrued liabilities	64,469	65,497
Deferred revenue	3,695	3,051
Operating lease liabilities, current portion	14,099	13,031
Total current liabilities	89,413	89,096
Debt, noncurrent portion	34,942	34,935
Other noncurrent liabilities	1,012	1,307
Operating lease liabilities, noncurrent portion	80,242	83,072
Total liabilities	205,609	208,410
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value - 5,000 shares authorized; none issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value - 100,000 shares authorized; 30,550 shares at June 30, 2023 and 30,193 at December 31, 2022 issued and outstanding	30	28
Additional paid-in capital	803,792	762,380
Accumulated other comprehensive loss	(152)	(396)
Accumulated deficit	(579,791)	(522,200)
Total stockholders' equity	223,879	239,812
Total liabilities and stockholders' equity	$ 429,488	$ 448,222

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
(unaudited)				
Revenue, net	$ 124,130	$ 102,051	$ 235,566	$ 194,429
Cost of revenue	37,905	31,806	73,660	62,425
Gross profit	86,225	70,245	161,906	132,004
Operating expenses:				
Research and development	13,677	11,945	28,519	22,487
Selling, general and administrative	91,420	81,751	191,763	154,909
Impairment and restructuring charges	—	—	—	26,608
Total operating expenses	105,097	93,696	220,282	204,004
Loss from operations	(18,872)	(23,451)	(58,376)	(72,000)
Interest expense	(832)	(482)	(1,782)	(2,511)
Interest and other income, net	1,435	69	2,867	85
Loss before income taxes	(18,269)	(23,864)	(57,291)	(74,426)
Income tax provision	213	33	300	80
Net loss	$ (18,482)	$ (23,897)	$ (57,591)	$ (74,506)
Net loss per common share, basic and diluted	$ (0.61)	$ (0.80)	$ (1.89)	$ (2.51)
Weighted-average shares, basic and diluted	30,502	29,843	30,400	29,720

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
(unaudited)				
Net loss	$ (18,482)	$ (23,897)	$ (57,591)	$ (74,506)
Other comprehensive income (loss):				
Net change in unrealized gains (losses) from marketable securities	(39)	(230)	288	(522)
Cumulative translation adjustment	(44)	—	(44)	—
Comprehensive loss	$ (18,565)	$ (24,127)	$ (57,347)	$ (75,028)

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)

	Six Months Ended June 30,	
	2023	**2022**
(unaudited)		
Cash flows from operating activities		
Net loss	$ (57,591)	$ (74,506)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	7,367	6,494
Stock-based compensation	32,350	29,001
Amortization of premium and accretion of discounts, net	(2,211)	363
Provision for doubtful accounts and contractual allowances	37,486	29,249
Amortization of operating lease right-of-use assets	2,749	7,863
Impairment charges	—	23,164
Other	141	227
Changes in operating assets and liabilities:		
Accounts receivable	(38,676)	(40,199)
Inventory	545	(4,346)
Prepaid expenses and other current assets	(1,260)	1,167
Other assets	(13,471)	(4,090)
Accounts payable	(367)	(4,522)
Accrued liabilities	(1,270)	(1,276)
Deferred revenue	644	(73)
Operating lease liabilities	(1,761)	(7,773)
Net cash used in operating activities	(35,325)	(39,257)
Cash flows from investing activities		
Purchases of property and equipment	(17,820)	(16,404)
Purchases of marketable securities	(72,851)	(91,519)
Sales of marketable securities	—	34,965
Maturities of marketable securities	106,500	64,000
Purchase of strategic investment	(3,000)	—
Net cash provided by (used in) investing activities	12,829	(8,958)
Cash flows from financing activities		
Payment of loans	—	(21,389)
Proceeds from term loan	—	35,000
Proceeds from issuance of common stock in connection with employee equity incentive plans	5,286	8,372
Payments of issuance costs for long-term debt	—	(77)
Net cash provided by financing activities	5,286	21,906
Effect of exchange rate changes	(44)	—
Net decrease in cash and cash equivalents	(17,254)	(26,309)
Cash and cash equivalents, beginning of period	78,832	127,562
Cash and cash equivalents, end of period	$ 61,578	$ 101,253
Supplemental disclosures of cash flow information:		
Interest paid	$ 1,417	$ 2,214
Cash taxes paid	$ 288	$ —
Cash received from tenant improvement allowances	$ 1,603	$ —
Non-cash investing and financing activities:		
Property and equipment included in accounts payable and accrued liabilities	$ 107	$ —
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 7,666
Capitalized stock-based compensation in property and equipment	$ 3,776	$ 2,782

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

IRHYTHM TECHNOLOGIES, INC.
Condensed Consolidated Statement of Stockholders' Equity
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
(unaudited)						
Balance at December 31, 2021	**29,494**	**$ 27**	**$ 685,594**	**$ (406,045)**	**$ (61)**	**$ 279,515**
Issuance of common stock in connection with employee equity incentive plans, net	275	—	1,076	—	—	1,076
Stock-based compensation	—	—	15,152	—	—	15,152
Net loss	—	—	—	(50,609)	—	(50,609)
Net change in unrealized loss on marketable securities	—	—	—	—	(292)	(292)
Balance at March 31, 2022	**29,769**	**$ 27**	**$ 701,822**	**$ (456,654)**	**$ (353)**	**$ 244,842**
Issuance of common stock in connection with employee equity incentive plans, net	195	1	7,295	—	—	7,296
Stock-based compensation	—	—	16,631	—	—	16,631
Net loss	—	—	—	(23,897)	—	(23,897)
Net change in unrealized loss on marketable securities	—	—	—	—	(230)	(230)
Balance at June 30, 2022	**29,964**	**$ 28**	**$ 725,748**	**$ (480,551)**	**$ (583)**	**$ 244,642**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
(unaudited)						
Balance at December 31, 2022	**30,193**	**$ 28**	**$ 762,380**	**$ (522,200)**	**$ (396)**	**$ 239,812**
Issuance of common stock in connection with employee equity incentive plans, net	270	2	903	—	—	905
Stock-based compensation	—	—	19,899	—	—	19,899
Net loss	—	—	—	(39,109)	—	(39,109)
Net change in unrealized gain on marketable securities	—	—	—	—	327	327
Balance at March 31. 2023	**30,463**	**$ 30**	**$ 783,182**	**$ (561,309)**	**$ (69)**	**$ 221,834**
Issuance of common stock in connection with employee equity incentive plans, net	87	—	4,383	—	—	4,383
Stock-based compensation	—	—	16,227	—	—	16,227
Net loss	—	—	—	(18,482)	—	(18,482)
Net change in unrealized loss on marketable securities	—	—	—	—	(39)	(39)
Cumulative translation adjustment	—	—	—	—	(44)	(44)
Balance at June 30, 2023	**30,550**	**$ 30**	**$ 803,792**	**$ (579,791)**	**$ (152)**	**$ 223,879**

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 remote cardiac monitoring services from its Medicare-enrolled independent diagnostic testing facilities ("IDTFs") and its qualified technicians. The Company has provided the Zio remote cardiac monitoring services, including extended Holter, traditional Holter, and mobile cardiac telemetry ("MCT") monitoring services ("Zio Services"), using the Zio Systems.

The Company is headquartered in San Francisco, California, which also serves as a clinical center. The Company has additional clinical centers in Deerfield, Illinois and Houston, Texas and a manufacturing facility in Cypress, California. The Company formed wholly owned subsidiaries in the United Kingdom in March 2016, in Singapore in June 2021, in Japan in June 2022 and in the Philippines in February 2023.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying financial statements 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, certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted, and accordingly the balance sheet as of June 30, 2023, and related disclosures, have been derived from the audited consolidated financial statements at that date 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 and six months ended June 30, 2023, are not necessarily indicative of the results to be expected for the year ending December 31, 2023, 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, 2022, included in the Company's Annual Report on Form 10-K, filed with the SEC on February 23, 2023.

Risks and Uncertainties

Macroeconomic Factors and Supply Chain Constraints

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

The Company's remote work arrangements resulting from the COVID-19 pandemic and subsequent decision to pursue a sublease for its San Francisco headquarters resulted in an impairment of its right-of-use ("ROU") asset and related leasehold improvements and furniture and fixtures during the six months ended June 30, 2022. As the Company continues to evaluate its 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 will have adequate liquidity over the next 12 months to operate its business and to meet its cash requirements. As of June 30, 2023, the Company is in compliance with its debt covenants.

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.

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

Use of Estimates

The preparation of the 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, allowance for doubtful accounts, the useful lives of property and equipment, the recoverability of long-lived assets including the estimated usage of the printed circuit board assemblies ("PCBAs"), the incremental borrowing rate for operating leases, accounting for income taxes, impairment of ROU assets, and various inputs used in estimating stock-based compensation. Actual results may differ from those estimates.

Accounts Receivable, Allowance for Doubtful Accounts and Contractual Allowances

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

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

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

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

	Six Months Ended June 30, 2023	Year Ended December 31, 2022	Six Months Ended June 30, 2022
Balance, beginning of period	$ 18,475	$ 14,012	$ 14,012
Add: provision for doubtful accounts	9,424	17,191	7,623
Less: write-offs, net of recoveries and other adjustments	(8,489)	(12,728)	(7)
Balance, end of period	$ 19,410	$ 18,475	$ 21,628

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

	Six Months Ended June 30, 2023	Year Ended December 31, 2022	Six Months Ended June 30, 2022
Balance, beginning of period	$ 41,389	$ 31,274	$ 31,274
Add: provision for contractual adjustments	28,062	41,158	21,626
Less: contractual adjustments	(21,537)	(31,043)	(38)
Balance, end of period	$ 47,914	$ 41,389	$ 52,862

Concentrations of Risk

Credit Risk

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

Concentrations of credit risk with respect to accounts receivable are limited due to the large number of customers comprising the Company's customer base and their dispersion across many geographies. The Company does not require collateral. The Company records an allowance for doubtful accounts based on the assessment of the collectability of customer accounts, considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. CMS accounted for approximately 25% and 24% of the Company's revenue for the three and six months ended June 30, 2023, respectively, and 24% and 23% of the Company's revenue for the three and six months ended June 30, 2022, respectively. CMS accounted for 22% and 22% of accounts receivable at June 30, 2023 and December 31, 2022, respectively.

Inflationary Risk

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

Supply Risk

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

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

Revenue Recognition

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

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

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

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

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

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

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

- Contracted third-party payors – The Company has contracts with negotiated prices for services provided to patients with commercial healthcare insurance coverage.
- CMS – The Company has received IDTF approval from regional Medicare Administrative Contractors and will receive reimbursement per the relevant CPT code rates for the services rendered to the patient covered by CMS.
- Healthcare institutions – Healthcare institutions are typically hospitals or physician practices in which the Company has negotiated amounts for its monitoring services, including certain governmental agencies such as the Veterans Administration and Department of Defense.
- Non-contracted third-party payors – Non-contracted commercial and government payors often reimburse out-of-network rates provided under the relevant CPT codes on a case-by-case basis. The transaction price used for determining revenue recognition is based on factors including an average of the Company's historical collection experience for its non-contracted services. This rate is reviewed at least quarterly.

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

For contracted and CMS portfolios, the Company recognizes revenue, net of contractual allowances, and recognizes an allowance for doubtful accounts for uncollectible patient accounts receivable. The transaction price is determined based on negotiated rates, and the Company has historical experience of collecting substantially all of these contracted rates. These contracts also impose a number of obligations regarding billing and other matters, and the Company's noncompliance with a material term of such contracts may result in a denial of the claim. The Company accounts for denied claims as a form of variable consideration that is included as a reduction to the transaction price recognized as revenue.

The Company makes estimates around the amount of denied claims within a reporting period, a process that requires management judgment. The estimated denied claims are based on historical information, and judgement includes the historical period utilized. The Company monitors the estimated denied claims against the latest available information, and subsequent changes to the estimated denied claims are recorded as an adjustment to revenue in the periods during which such changes occur. Delays in claims submissions could lead to an increase in denials if the Company misses the payors' filing deadlines, which could result in a reduction in the Company's receipt of payments. Historical cash collection indicates that it is probable that substantially all of the transaction price, less the estimate of denied claims, will be received. Contracted payors may require that the Company bills patient co-payments and deductibles and from time to time the Company may not be able to collect such amounts due to credit risk. The Company provides for estimates of uncollectible patient accounts receivable, based upon historical experience where judgment includes the historical period utilized, at the time revenue is recognized, with such provisions presented as bad debt expense within the selling, general and administrative line item of the consolidated statements of operations. Adjustments to these estimates for actual experience are also recorded as an adjustment to bad debt expense.

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

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

Stock-Based Compensation

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

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

The Company recognizes compensation expense related to the Employee Stock Purchase Plan ("ESPP") based on the fair value at each enrollment date of the offering period using the Black-Scholes-Merton option-pricing model value. The stock-based compensation is reduced by the estimated forfeiture and is expensed on a straight-line basis over the offering period.

3. REVENUE

Disaggregation of Revenue

The Company disaggregates revenue from contracts with customers by payor type. The Company believes these categories aggregate the payor types by nature, amount, timing and uncertainty of its revenue streams. Disaggregated revenue by payor type and major service line for the three and six months ended June 30, 2023 and 2022 were as follows (in thousands, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2023		2022		2023		2022	
	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue
Contracted third-party payors	$ 67,324	54%	$ 55,451	54%	$ 129,231	55%	$ 107,202	55%
Centers for Medicare and Medicaid	30,871	25%	24,759	24%	57,362	24%	44,821	23%
Healthcare institutions	18,214	15%	15,671	16%	33,995	15%	30,749	16%
Non-contracted third-party payors	7,721	6%	6,170	6%	14,978	6%	11,657	6%
Total	$ 124,130		$ 102,051		$ 235,566		$ 194,429	

Revenue generated from the United States comprised substantially all of the Company's revenue. No other country comprised 10% or greater of the Company's revenue during each of the three and six months ended June 30, 2023 and 2022.

Contract Liabilities

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

Certain of the Company’s customers pay the Company directly for the Zio XT service upon shipment of devices. Such advance payments are contract liabilities and are recorded as revenue when Zio reports are delivered to the healthcare provider. During the six months ended June 30, 2023, $3.0 million relating to the contract liability balance at the beginning of 2023 was recognized as revenue. During the six months ended June 30, 2022, $3.0 million relating to the contract liability balance at the beginning of 2022 was recognized as revenue.

Contract Costs

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

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

4. CASH EQUIVALENTS AND MARKETABLE SECURITIES

The fair value of cash equivalents and marketable securities as of June 30, 2023 and December 31, 2022, were as follows (in thousands):

	June 30, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 23,562	$ —	$ —	$ 23,562
U.S. government securities	108,217	4	(113)	108,108
Total cash equivalents and marketable securities	$ 131,779	$ 4	$ (113)	$ 131,670
Classified as:				
Cash equivalents				$ 28,509
Marketable securities				103,161
Total cash equivalents and marketable securities				$ 131,670

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

5. FAIR VALUE MEASUREMENTS

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

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

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

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

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The 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's interest-bearing obligation is classified as Level 2. As of June 30, 2023 the fair value of the Company's outstanding interest-bearing obligation approximated the carrying value of $34.9 million. As of December 31, 2022, the fair value of the Company's outstanding interest-bearing obligation approximated the carrying value of $34.9 million.

The Company holds a strategic investment that it does not measure at fair value on a recurring basis. The carrying value of this investment is $3.0 million as of June 30, 2023. The Company includes this investment in other assets in its unaudited condensed consolidated balance sheets.

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):

	June 30, 2023			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 23,562	$ —	$ —	$ 23,562
U.S. government securities	—	108,108	—	108,108
Total	$ 23,562	$ 108,108	$ —	$ 131,670

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

6. BALANCE SHEET DETAILS

Inventory

Inventory consisted of the following (in thousands):

	June 30, 2023	December 31, 2022
Raw materials and work-in-process	$ 7,208	$ 9,338
Finished goods	7,270	5,817
Total	$ 14,478	$ 15,155

Other Assets

Other assets consisted of the following (in thousands):

	June 30, 2023	December 31, 2022
PCBAs	$ 30,153	$ 18,599
Cloud computing arrangements	4,443	2,523
Strategic investment	3,000	—
Other	1,127	1,130
Total	$ 38,723	$ 22,252

The Company uses PCBAs in each wearable Zio XT patch, Zio AT patch, and Zio Monitor patch, as well as the wireless gateway used in conjunction with the Zio AT patch. Each time a PCBA is used in a wearable Zio XT patch, Zio AT patch, or Zio Monitor patch, a portion of the cost of the PCBA is recorded as a cost of revenue. The PCBAs are charged over a period beyond one year. Charges to cost of revenue were $1.6 million and $3.0 million for the three and six months ended June 30, 2023, respectively, and $1.4 million and $2.5 million for the three and six months ended June 30, 2022, respectively.

During the six months ended June 30, 2023, PCBAs increased by $11.6 million primarily related to the expanded launch of the Zio Monitor System and an increase in purchases of the Zio XT patch PCBAs.

Property and Equipment, Net

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

	June 30, 2023	December 31, 2022
Laboratory and manufacturing equipment	$ 5,655	$ 4,911
Computer equipment and software	2,448	2,315
Furniture and fixtures	4,198	4,119
Leasehold improvements	23,533	23,144
Internal-use software	49,351	44,877
Internal-use software in development	40,345	28,069
Construction in progress	6,626	3,451
Total property and equipment, gross	132,156	110,886
Less: accumulated depreciation and amortization	(42,311)	(35,216)
Total property and equipment, net	$ 89,845	$ 75,670

Depreciation and amortization expense was $3.8 million and $7.4 million for the three and six months ended June 30, 2023, respectively, and $3.4 million and $6.5 million for the three and six months ended June 30, 2022, respectively, of which amortization related to internal-use software, was $2.8 million and $5.5 million, for the three and six months ended June 30, 2023, respectively, and $2.5 million and $4.7 million for the three and six months ended June 30, 2022, respectively.

During the three and six months ended June 30, 2023, internal-use software, both in service and in development, increased by $8.9 million and $16.8 million, respectively. This increase related to enhancements in the Company’s core technology, products and services and artificial intelligence, as well as investment in future technology, such as the Zio Monitor System, the Company's new biosensor technology platform, and the clinically-integrated ZEUS System for the Zio Watch.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2023	December 31, 2022
Accrued payroll and related expenses	$ 27,159	$ 34,752
Accrued vacation	10,041	8,608
Accrued expenses	10,255	7,006
Claims payable	7,257	4,464
Accrued employee share purchase plan contributions	1,090	1,045
Accrued income and sales taxes	2,604	2,388
Accrued professional services fees	6,063	7,234
Total accrued liabilities	$ 64,469	$ 65,497

During the year ended December 31, 2022 and the six months ended June 30, 2023, the Company has incurred expenses in connection with efforts to further globalize its operational footprint and expects to continue to incur such expenses through mid-2024. Included in accrued liabilities as of June 30, 2023, above, were $3.1 million in accrued payroll and related expenses and $0.8 million in accrued professional services fees.

7. IMPAIRMENT AND RESTRUCTURING CHARGES

During the three and six months ended June 30, 2023, there were no impairment and restructuring charges.

In February 2022, the Company's board of directors (the “Board”) approved a restructuring plan ("Restructuring Plan") to allow it to effectively and efficiently scale its business, which resulted in severance and other employment related costs of $3.4 million during the six months ended June 30, 2022. Also in February 2022, the Board approved reducing the Company's leased space for its headquarters in San Francisco, California, by a total amount of leased square footage of approximately 50%. As a result, the Company recognized an impairment of its ROU asset and related leasehold improvements and furniture and fixtures in the amount of $23.2 million during the six months ended June 30, 2022. The Company's restructuring and impairment charges are described below (in thousands):

	Six Months Ended June 30, 2022
Restructuring charges	$ 3,444
Impairment charges	23,164
Total	$ 26,608

The Company did not record any impairment charges during the three months ended June 30, 2022.

For further details, please refer to Note 7, *Impairment and Restructuring,* included in the financial statements accompanying the Company’s Annual Report on Form 10-K for the year ended December 31, 2022.

Restructuring

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

	December 31, 2022	Charges	Cash Payments	June 30, 2023
Employee severance	$ 394	$ —	$ (394)	$ —
Total	$ 394	$ —	$ (394)	$ —

8. COMMITMENTS AND CONTINGENCIES

Purchase Commitments

The Company is party to various purchase arrangements related to its manufacturing and research and development activities. During the six months ended June 30, 2023, there were no material changes to purchase commitments from those disclosed in Note 8, *Commitments and Contingencies,* included in the financial statements accompanying the Company’s Annual Report on Form 10-K for the year ended December 31, 2022.

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.

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

Year Ending December 31:		
2023 (remainder of the year)	$	10,417
2024		20,592
2025		20,385
2026		20,136
2027		19,736
Thereafter		36,124
Total lease payments		127,390
Less: imputed interest		(33,049)
Total lease liabilities	$	94,341

Legal Proceedings

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

On February 1, 2021, a putative class action lawsuit was filed in the United States District Court for the Northern District of California (the "Court") alleging that the Company and its former Chief Executive Officer, Kevin M. King, violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder ("Securities Class Action Lawsuit"). On August 2, 2021, the lead plaintiff filed an amended complaint, and filed a further amended complaint on September 24, 2021. The amended complaint names as defendants, in addition to the Company and Mr. King, its former Chief Executive Officer, Michael J. Coyle, and former Chief Financial Officer and former Chief Operating Officer, Douglas J. Devine. The purported class in the amended complaint includes all persons who purchased or acquired the Company's common stock between August 4, 2020 and July 13, 2021, and seeks unspecified damages purportedly sustained by the class. On October 27, 2021, the Company filed a motion to dismiss the amended complaint. The motion to dismiss was fully briefed and the Court held a hearing on the motion on February 4, 2022, after which the Court took the matter under submission. On March 31, 2022, the Court issued an order granting the Company's motion to dismiss the Securities Class Action Lawsuit, without allowing plaintiff further leave to amend, and entered judgment in favor of the Company and the other defendants. On April 29, 2022, the plaintiff that filed the initial complaint in the action filed a notice of appeal to the Ninth Circuit Court of Appeals. On September 7, 2022, the plaintiff-appellant filed its opening brief, and the Company filed a motion to dismiss for lack of standing to appeal and Article III standing on September 27, 2022. On October 17, 2022, the plaintiff filed its response to the Company's motion to dismiss, and the Company filed its reply in support of the motion to dismiss on November 3, 2022. The Company's motion to dismiss the appeal was denied without prejudice on December 8, 2022. The Company filed its responding brief on the appeal on February 16, 2023. Briefing on the appeal has been completed and the Ninth Circuit Court of Appeals heard argument on July 13, 2023. The Company believes the Securities Class Action Lawsuit to be without merit and plans 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 FDA and the Company's products and services. On September 14, 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, requesting production of various documents regarding the Company's products and services. The Company is cooperating fully on these matters.

Development Agreement

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

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

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

Indemnifications

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

9. DEBT

In October 2018, the Company entered into the Third Amended and Restated Loan and Security Agreement ("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. The remaining $40.0 million of 2022 Term Loans may be borrowed from time to time at the Company's option, in increments of at least $10.0 million, through December 31, 2023. The Company will pay interest only on the 2022 Term Loans until April 1, 2025, when it will commence repaying the 2022 Term Loans in 24 equal consecutive monthly installments, with all obligations under the 2022 Term Loans maturing on March 1, 2027. Interest charged on the 2022 Term Loans will accrue at a floating per annum rate equal to the greater of: (A) the Prime Rate plus 0.25%; and (B) 3.5%. The Company is also required to pay fees on any prepayment of the 2022 Term Loans, ranging from 1.0% to 3.0% depending on the date of prepayment, and a final payment equal to 5.0% of the principal amount of the 2022 Term Loans drawn. Once repaid or prepaid, the 2022 Term Loans may not be reborrowed. The Company accounted for the refinancing as an extinguishment of the original loans and paid a fee of $1.8 million, which was included in interest expense on the unaudited condensed consolidated statement of operations and recorded the 2022 Term Loans, net of issuance costs. The issuance costs on the new loans are amortized over the term of the loan.

The 2022 Amendment also amended the terms of the revolving credit line under the SVB Loan Agreement, which provided for an aggregate principal amount of $25.0 million, to: (i) extend the maturity date from August 1, 2023 to March 1, 2027, (ii) increase the letters of credit sublimit to $15.0 million and (iii) increase the cash management services sublimit to $15.0 million. Interest charged on the principal amount outstanding under the revolving credit line accrues at a floating per annum rate equal to the greater of (A) the Prime Rate plus 0.25% and (B) 3.5%. The Company is required to pay an annual fee equal to 0.15% of the revolving credit line. As of June 30, 2023, no loans were outstanding under the revolving credit line and the Company had used $8.4 million in letters of credit.

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

On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation and the Federal Deposit Insurance Corporation ("FDIC") was appointed as receiver. On March 12, 2023, the U.S. Department of the Treasury, Federal Reserve Board, and FDIC released a joint statement announcing that the FDIC would complete its resolution of SVB in a manner that fully protected all depositors at SVB and that depositors would have access to all of their money starting March 13, 2023. On March 26, 2023, it was announced that First-Citizens Bank & Trust Company would assume all of SVB's deposits and loans as of March 27, 2023. The Company continues to have access to the revolving credit line and letters of credit available pursuant to the SVB Loan Agreement and was in compliance with its loan covenants as of June 30, 2023.

Future minimum payments

Contractual obligations for the 2022 Term Loans comprise principal and interest payments as follows (in thousands):

Year Ending December 31,		
2023 (remainder of the year)	$	1,512
2024		3,025
2025		15,763
2026		18,693
2027		4,438
Total		43,431
Less: Amount representing interest		(8,431)
Less: Debt issuance costs		(58)
Principal payments	$	34,942

10. INCOME TAXES

The Company recorded a tax provision related to its U.S. state taxes and the U.K. subsidiary during the three and six months ended June 30, 2023 and 2022. 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.

11. STOCKHOLDERS' EQUITY

Common Stock

The Company's amended and restated certificate of incorporation dated October 25, 2016, as amended, authorizes the Company to issue 100,000,000 shares of common stock with a par value of $0.001 per share and 5,000,000 shares of preferred stock with a par value of $0.001 per share. The holders of common stock are entitled to receive dividends whenever funds and assets are legally available and when declared by the Board, subject to the prior rights of holders of all series of convertible preferred stock outstanding. No dividends were declared through June 30, 2023.

The Company had reserved shares of common stock for issuance as follows (in thousands):

	June 30, 2023	December 31, 2022
Options issued and outstanding	309	328
Unvested RSUs and PRSUs [1]	2,517	2,026
Shares available for grant under future stock plans	7,039	7,823
Shares available for future issuance	9,865	10,177

[1] PRSUs are based on the maximum number of PRSUs in the key executive grant agreements. The actual number of PRSUs granted will be based on the annual unit volume compound annual growth rate ("CAGR") discussed in Note 12, *Equity Incentive Plan and Stock-Based Compensation.*

12. EQUITY INCENTIVE PLAN AND STOCK-BASED COMPENSATION

A summary of awards available for grant under the Company's 2016 Equity Incentive Plan is as follows (in thousands):

	Shares Available for Grant
Balance as of December 31, 2022	7,823
Awards granted [1]	(938)
Awards forfeited [1]	154
Balance as of June 30, 2023	7,039

[1] Awards granted and forfeited include PRSUs, which are based on the maximum number of PRSUs in the key executive grant agreements. The actual number of PRSUs granted will be based on the annual unit volume CAGR discussed in Note 12, *Equity Incentive Plan and Stock-Based Compensation.*

Restricted Stock Units and Performance-Based Restricted Stock Units

The fair value of RSUs and PRSUs are based on the Company's closing stock price on the date of grant. The fair value of market based PRSUs were estimated at the date of grant using the Monte-Carlo option pricing model. A summary is as follows (in thousands, except weighted average grant date fair value):

	Restricted Stock Units		Performance Based Restricted Stock Units and Market-Based Units	
	Shares Underlying RSUs	Weighted Average Grant Date Fair Value	Shares Underlying PRSUs [1]	Weighted Average Grant Date Fair Value
Balance as of December 31, 2022	1,465	$ 111.16	561	$ 120.22
Granted	670	118.32	268	135.95
Vested	(268)	124.69	(24)	107.05
Forfeited	(91)	114.97	(64)	119.29
Balance as of June 30, 2023	1,776	$ 111.63	741	$ 126.42

[1] Based on the maximum number of PRSUs in the key executive grant agreements. The actual number of PRSUs granted will be based on the annual unit volume CAGR discussed in Note 12, *Equity Incentive Plan and Stock-Based Compensation.*

As of June 30, 2023, there was total unamortized compensation costs of $142.6 million, net of estimated forfeitures, related to unrecognized RSU expense, which the Company expects to recognize over a weighted average remaining period of 1.9 years. Aggregate intrinsic value of the RSUs was $185.3 million as of June 30, 2023.

As of June 30, 2023, there was total unamortized compensation costs of $27.4 million, net of estimated forfeitures, related to unrecognized PRSU expense, which the Company expects to recognize over a weighted average remaining period of 2.2 years. Aggregate intrinsic value of the PRSUs was $77.3 million as of June 30, 2023.

PRSUs and Market-based RSUs

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

For further details on PRSUs granted in 2022 and prior years, please refer to Note 13, *Equity Incentive Plans*, in the financial statements accompanying the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

In February 2023, the Company granted PRSUs ("February 2023 awards") to be earned based on the CAGR calculated between fiscal year 2025's and fiscal year 2022's annual unit volume and measuring a minimum performance threshold of 15% to earn 50.0% of target, and a maximum threshold of 25% achieved to earn 200.0% of target. These February 2023 awards are subject to the recipient's continued employment through the vesting date of March 15, 2026.

In addition, in February 2023, the Company granted market-based PRSUs to senior executive officers. These PRSUs to be earned will be based on the CAGR calculated between fiscal year 2025's and fiscal year 2022's annual unit volume and measuring performance thresholds mentioned above, as well as a comparison of the S&P Healthcare Index to the Company's Total Shareholder Return ("TSR"). The grant date fair value of the TSR was based on the expected term of 2.9 years, interest risk free rate of 4.5%, implied volatility of 83.8% and no dividend yield. These February 2023 awards are subject to the senior executive officers continued employment through the vesting date of March 15, 2026.

Options

The following table summarizes stock option activity during the six months ended June 30, 2023 (in thousands, except weighted average exercise price per share and years):

		Options Outstanding		
	Options Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Balance as of December 31, 2022	328	$ 43.00	4.43	$ 16,635
Options exercised	(19)	54.14		
Balance as of June 30, 2023	309	42.31	3.91	19,161
Options exercisable – June 30, 2023	309	$ 42.31	3.91	$ 19,161

There have been no options granted since December 31, 2019. As of June 30, 2023, the options were fully vested.

Employee Stock Purchase Plan

In October 2016, the Board and stockholders approved the ESPP. The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their eligible compensation, subject to any plan limitations. The ESPP provides for 12 month offering periods that contain two six-month purchase periods. At the end of each purchase period, employees purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the last day of the purchase period. During the six months ended June 30, 2023, approximately 46 thousand shares of the Company's common stock were issued to employees participating in the ESPP and approximately 2.2 million shares of the Company's common stock remained available for issuance under the ESPP.

For the offering period which started on June 1, 2023, the assumptions included the expected term ranging from 0.5 year to 1.0 year, expected volatility ranging from 48.8% to 59.2%, risk-free interest rate ranging from 5.1% to 5.4% and dividend yield of 0.0%.

During the six months ended June 30, 2023 there were no material changes to the ESPP from those described in Note 13, *Equity Incentive Plans*, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

As of June 30, 2023, the Company had $4.7 million of unrecognized compensation expense related to ESPP subscriptions that will be recognized over a weighted average period of 0.6 years.

Stock-Based Compensation Expense

The following table summarizes the total stock-based compensation expense included in the unaudited condensed consolidated statements of operations for the three and six months ended June 30, 2023 and 2022 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Cost of revenue	$ 784	$ 536	$ 1,348	$ 922
Research and development	2,155	1,629	4,542	3,124
Selling, general and administrative	11,160	12,933	26,460	24,955
Total stock-based compensation expense	$ 14,099	$ 15,098	$ 32,350	$ 29,001

13. NET LOSS PER SHARE

As the Company had net losses for the three and six months ended June 30, 2023 and 2022, 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 and six months ended June 30, 2023 and 2022 (in thousands, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Numerator:				
Net loss	$ (18,482)	$ (23,897)	$ (57,591)	$ (74,506)
Denominator:				
Weighted-average shares used to compute net loss per common share, basic and diluted	30,502	29,843	30,400	29,720
Net loss per common share, basic and diluted	$ (0.61)	$ (0.80)	$ (1.89)	$ (2.51)

The following outstanding shares of potentially dilutive securities have been excluded from diluted net loss per common share for the six months ended June 30, 2023 and 2022 because their inclusion would be anti-dilutive (in thousands):

	Six Months Ended June 30,	
	2023	2022
Options to purchase common stock	309	381
RSUs and PRSUs[1] unvested	2,518	2,017
Total	2,827	2,398

[1] PRSUs are based on the maximum number of PRSUs in the key executive grant agreements. The actual number of PRSUs granted will be based on the annual unit volume CAGR discussed in Note 12, *Equity Incentive Plan and 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 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."

Overview

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

Each Zio System combines a wire-free, patch-based, 14-day wearable biosensor that continuously records ECG data with a proprietary cloud-based data analytic software to help physicians monitor patients and diagnose arrhythmias. Since receiving FDA clearance, we have provided the Zio Services to over six million patients and have collected over one 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 remote cardiac monitoring services from our Medicare-enrolled IDTFs and our qualified technicians. We have provided our Zio Services using our Zio Systems.

We receive revenue for the Zio Services primarily from third-party payors, which include contracted third-party payors and 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Contracted third-party payors	54%	54%	55%	55%
Centers for Medicare and Medicaid	25%	24%	24%	23%
Healthcare institutions	15%	16%	15%	16%
Non-contracted third-party payors	6%	6%	6%	6%

Key Business Metric

Non-GAAP Financial Measure

Adjusted EBITDA is a key measure we use to assess our financial performance and it is also used for internal planning and forecasting purposes. We believe Adjusted EBITDA is helpful to investors, analysts and other interested parties because it can assist in providing a more consistent and comparable overview of our 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 and interest income and as further adjusted for stock-based compensation expense, impairment and restructuring charges, and business transformation costs. Business transformation costs include one-time professional services and employee termination costs to augment and restructure the organization to use both outsourced and offshore resources.

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (18,482)	$ (23,897)	$ (57,591)	$ (74,506)
Interest expense	832	482	1,782	2,511
Interest income	(1,468)	(196)	(2,902)	(328)
Income tax provision	213	33	300	80
Depreciation and amortization	3,791	3,351	7,367	6,494
Stock-based compensation	14,099	15,098	32,350	29,001
Impairment and restructuring charges	—	—	—	26,608
Business transformation costs	5,409	175	11,095	433
Adjusted EBITDA	$ 4,394	$ (4,954)	$ (7,599)	$ (9,707)

Macroeconomic Factors and the Effects of COVID-19

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

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

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

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

Our remote work arrangements resulting from the COVID-19 pandemic and subsequent decision to pursue a sublease for our San Francisco headquarters resulted in an impairment of our right-of-use ("ROU") asset and related leasehold improvements and furniture and fixtures during the six months ended June 30, 2022. As we continue to evaluate our real estate footprint, we may incur additional impairment charges related to real property lease agreements.

Revenue

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

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

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

Cost of Revenue

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

Research and Development Expenses

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

Selling, General and Administrative Expenses

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

Our general and administrative expenses consist primarily of payroll-related costs for executive, finance, legal and administrative personnel, including stock-based compensation. Other significant expenses include professional fees for legal and accounting services, consulting fees, recruiting fees, bad debt expense, third-party patient claims processing fees, and travel expenses. In addition, we incurred business transformation costs to scale our organization during 2022 and expect to incur additional business transformation costs throughout 2023 with the restructuring activities to be substantially complete by mid-2024. Upon completion, we expect to achieve operational efficiencies in our administrative expenses.

Interest Expense

Interest expense is attributable to borrowings under our loan agreements. See Note 9, *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 loan agreements.

Interest and Other Income, Net

Interest and other income, net consists primarily of interest income which consists of interest received on our cash and cash equivalents and marketable securities as well as realized and unrealized foreign currency exchange gains or losses.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2023 and 2022.

	Three Months Ended June 30,				Six Months Ended June 30,			
	2023	2022	$ Change*	% Change	2023	2022	$ Change*	% Change
	(dollars in thousands, except percentages)							
Revenue	$ 124,130	$ 102,051	$ 22,079	22%	$ 235,566	$ 194,429	$ 41,137	21%
Cost of revenue	37,905	31,806	6,099	19%	73,660	62,425	11,235	18%
Gross profit	86,225	70,245	15,980	23%	161,906	132,004	29,902	23%
Operating expenses:								
Research and development	13,677	11,945	1,732	14%	28,519	22,487	6,032	27%
Selling, general and administrative	91,420	81,751	9,669	12%	191,763	154,909	36,854	24%
Impairment and restructuring charges	—	—	—	—%	—	26,608	(26,608)	(100)%
Total operating expenses	105,097	93,696	11,401	12%	220,282	204,004	16,278	8%
Loss from operations	(18,872)	(23,451)	4,579	(20)%	(58,376)	(72,000)	13,624	(19)%
Interest expense	(832)	(482)	(350)	73%	(1,782)	(2,511)	729	(29)%
Interest and other income, net	1,435	69	1,366	nm	2,867	85	2,782	nm
Loss before income taxes	(18,269)	(23,864)	5,595	(23)%	(57,291)	(74,426)	17,135	(23)%
Income tax provision	213	33	180	545%	300	80	220	275%
Net loss	$ (18,482)	$ (23,897)	$ 5,415	(23)%	$ (57,591)	$ (74,506)	$ 16,915	(23)%

nm- percentage change not meaningful.
* Certain numbers expressed in millions may not sum due to rounding.

Revenue

Revenue increased by $22.1 million, or 22%, to $124.1 million during the three months ended June 30, 2023, as compared to $102.1 million during the three months ended June 30, 2022. Revenue increased by $41.1 million, or 21%, to $235.6 million during the six months ended June 30, 2023, as compared to $194.4 million during the six months ended June 30, 2022. For the three and six months ended June 30, 2023, the increases in revenue were primarily attributable to increases in the volume of Zio Services resulting from increasing demand, partially offset by a slight decline in average selling price.

Cost of Revenue

Cost of revenue increased by $6.1 million, or 19%, to $37.9 million during the three months ended June 30, 2023, as compared to $31.8 million during the three months ended June 30, 2022. Cost of revenue increased by $11.2 million, or 18%, to $73.7 million during the six months ended June 30, 2023, as compared to $62.4 million during the six months ended June 30, 2022. For the three and six months ended June 30, 2023, the increases in cost of revenue were primarily due to increases in the volume of Zio Services provided due to higher demand.

Research and Development Expenses

Research and development expenses increased $1.7 million, or 14%, to $13.7 million during the three months ended June 30, 2023, as compared to $11.9 million during the three months ended June 30, 2022. Research and development expenses increased $6.0 million, or 27%, to $28.5 million during the six months ended June 30, 2023, as compared to $22.5 million during the six months ended June 30, 2022. The increases in research and development expenses for the three and six months ended June 30, 2023 were primarily due to higher headcount-related costs and further development, enhancement, and functionality of our current and future product offerings.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $9.7 million, or 12%, to $91.4 million during the three months ended June 30, 2023, as compared to $81.8 million during the three months ended June 30, 2022. Selling, general and administrative expenses increased $36.9 million, or 24%, to $191.8 million during the six months ended June 30, 2023, as compared to $154.9 million during the six months ended June 30, 2022. The increases were primarily attributable to an increase in headcount related costs (including stock-based compensation) for incremental headcount and executive hires supporting growth in our operations, an increase in business transformation costs to scale the organization, and an increase in software and hardware costs to support the growth in our infrastructure.

Impairment and Restructuring Charges

There were no impairment and restructuring charges during the six months ended in June 30, 2023. In February 2022, our board of directors (the "Board") approved reducing our leased space for our headquarters in San Francisco, California. As a result, we recognized an impairment of our ROU asset and related leasehold improvements and furniture and fixtures in the amount of $23.2 million during the six months ended June 30, 2022. Also in February 2022, the Board approved a restructuring plan to allow us to effectively and efficiently scale our business, which resulted in severance and other employment related costs of $3.4 million during the six months ended June 30, 2022.

Interest expense

Interest expense increased by $0.4 million to $0.8 million during the three months ended June 30, 2023, as compared to $0.5 million during the three months ended June 30, 2022. The increase in interest expense was attributable to increases in interest rates period over period.

Interest expense decreased by $0.7 million to $1.8 million during the six months ended June 30, 2023, as compared to $2.5 million during the six months ended June 30, 2022. During the six months ended June 30, 2022, we incurred financing fees of $1.75 million associated with the second amendment to the SVB Loan Agreement (as defined below). Offsetting this reduction was an increase in interest expense of $0.9 million due to higher interest rates period over period.

Interest and other income, net

Interest and other income, net increased by $1.3 million to $1.4 million during the three months ended June 30, 2023, as compared to $0.1 million during the three months ended June 30, 2022. Interest and other income, net increased by $2.8 million to $2.9 million during the six months ended June 30, 2023, as compared to $0.1 million during the six months ended June 30, 2022. The increase was primarily due to higher interest earned from our cash and cash equivalents and marketable securities during the three and six months ended June 30, 2023, as compared to the same periods in 2022.

Liquidity and Capital Expenditures

Overview

As of June 30, 2023, we had cash and cash equivalents of $61.6 million, marketable securities of $103.2 million, and accounts receivable of $51.1 million. In addition, we have $40.0 million available under a term loans facility and $16.6 million available under a revolving credit line. We are continuously reviewing our liquidity and anticipated capital requirements in light of the significant uncertainty created by the current macroeconomic environment, including inflation, interest rate volatility, the federal debt ceiling and budget, instability in the global banking system, and the persisting impacts of the COVID-19 pandemic. 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. We believe that our current cash, cash equivalents, marketable securities balances, and term loans facility, together with income to be derived from the sales of our Zio Services, will be sufficient to meet our liquidity requirements for at least the next 12 months.

Under the terms of the Development Agreement, we agreed to make cash payments to Verily up to an aggregate of $12.75 million in milestone payments upon achievement of various development and regulatory milestones. We have achieved milestones tied to payments totaling $11.0 million through June 30, 2023, and anticipate making additional milestone payments of $1.75 million over the remainder of 2023 and into 2024, subject to achievement of specified milestones.

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

	Six Months Ended June 30,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (35,325)	$ (39,257)
Investing activities	12,829	(8,958)
Financing activities	5,286	21,906
Net decrease in cash and cash equivalents	$ (17,210)	$ (26,309)

Operating Activities

During the six months ended June 30, 2023, cash used in operating activities was $35.3 million, a decrease of $3.9 million, as compared to $39.3 million during the six months ended June 30, 2022. The reduction was primarily attributable to favorable impacts of $16.5 million from the timing of collections and payments associated with our accounts receivable, inventory, operating leases, and accounts payable, partially offset by an increase in payments for other assets of $9.4 million, primarily for the purchase of PCBAs.

Investing Activities

During the six months ended June 30, 2023, cash provided by investing activities was $12.8 million, an increase of $21.8 million as compared to cash used by investing activities of $9.0 million during the six months ended June 30, 2022. The increase was primarily attributable to a net increase in proceeds from marketable securities of $26.2 million, partially offset by increases in purchases of property and equipment of $1.4 million and the purchase of a strategic investment of $3.0 million.

Financing Activities

During the six months ended June 30, 2023, cash provided by financing activities was $5.3 million, a decrease of $16.6 million as compared to $21.9 million during the six months ended June 30, 2022. The decrease was primarily attributed to net proceeds during the first half of 2022 of $13.6 million, associated with a $35.0 million term loan offset by a $21.4 million debt repayment. Additionally, there was a decrease of $3.1 million in proceeds from the issuance of common stock in connection with our employee equity incentive plan.

Bank Debt

In October 2018, we entered into the Third Amended and Restated Loan and Security Agreement (the "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. The remaining $40.0 million of 2022 Term Loans may be borrowed from time to time at our option, in increments of at least $10.0 million, through December 31, 2023. We will pay interest only on the 2022 Term Loans until April 1, 2025, when we will commence repaying the 2022 Term Loans in 24 equal consecutive monthly installments, with all obligations under the 2022 Term Loans maturing on March 1, 2027. Interest charged on the 2022 Term Loans will accrue at a floating per annum rate equal to the greater of: (A) the Prime Rate plus 0.25%; and (B) 3.5%. We are also required to pay fees on any prepayment of the 2022 Term Loans, ranging from 1.0% to 3.0% depending on the date of prepayment, and a final payment equal to 5.0% of the principal amount of the 2022 Term Loans drawn. Once repaid or prepaid, the 2022 Term Loans may not be reborrowed.

The 2022 Amendment also amended the terms of the revolving credit line under the SVB Loan Agreement, which provided for an aggregate principal amount of $25.0 million, to: (i) extend the maturity date from August 1, 2023 to March 1, 2027, (ii) increase the letters of credit sublimit to $15.0 million and (iii) increase the cash management services sublimit to $15.0 million. Interest charged on the principal amount outstanding under the revolving credit line will accrue at a floating per annum rate equal to the greater of (A) the Prime Rate plus 0.25% and (B) 3.5%. We are required to pay an annual fee equal to 0.15% of the revolving credit line. As of June 30, 2023, no loans were outstanding under the revolving credit line and we had used $8.4 million in letters of credit.

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

On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation and the Federal Deposit Insurance Corporation ("FDIC") was appointed as receiver. On March 12, 2023, the U.S. Department of the Treasury, Federal Reserve Board, and FDIC released a joint statement announcing that the FDIC would complete its resolution of SVB in a manner that fully protected all depositors at SVB and that depositors would have access to all of their money starting March 13, 2023. On March 26, 2023, it was announced that First-Citizens Bank & Trust Company would assume all of SVB's deposits and loans as of March 27, 2023. We continue to have access to the revolving credit line and letters of credit available pursuant to the SVB Loan Agreement and we were in compliance with our loan covenants as of June 30, 2023.

Contractual Obligations

Our contractual obligations as of December 31, 2022, are presented in our Annual Report on Form 10-K filed with the SEC on February 23, 2023. See Note 8, *Commitments and Contingencies* to the unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for our lease obligations. See Note 9, *Debt* to the unaudited condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for refinancing of our debt agreement.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which we have prepared in accordance with GAAP. The preparation of these 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, *Significant Accounting Policies*, to the consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022. 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, 2022. There were no material changes to our critical accounting estimates during the six months ended June 30, 2023.

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 $164.7 million and $213.1 million as of June 30, 2023, and December 31, 2022, 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. Based upon our overall interest rate exposure as of June 30, 2023, a change of 10 percent in interest rates, assuming the amount of our investment portfolio and overall economic environment remains constant, would not have a material effect on interest income.

As of June 30, 2023 and December 31, 2022, we had total outstanding debt of $34.9 million for each period, net of debt issuance costs. The SVB Loan Agreement carries a variable interest rate based on the "Prime Rate" published by The Wall Street Journal. A hypothetical 10% change in interest rates during each of the three and six months ended June 30, 2023 and 2022 would have resulted in an immaterial impact on our unaudited condensed consolidated financial statements.

Foreign Currency Exchange Rate Sensitivity

We face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars, particularly in British Pound Sterling and in Philippine Pesos. As of June 30, 2023 and December 31, 2022, we do not consider this risk to be material. We do not utilize any forward foreign exchange contracts, although we may choose to do so in the future. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made. The volatility of exchange rates depends on many factors that we cannot forecast with reliable accuracy. In the event our foreign currency denominated assets, liabilities, sales, or expenses increase, our operating results may be more greatly affected by fluctuations in the exchange rates of the currencies in which we do business.

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

As required by Rule 13a under the Exchange Act, our management, including our CEO and CFO, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-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 June 30, 2023.

Changes in Internal Control Over Financial Reporting

There have been no changes in internal control over financial reporting during the three months ended June 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

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

On March 26, 2021, we received a grand jury subpoena from the U.S. Attorney's Office for the Northern District of California requesting information related to communications with the Food and Drug Administration and our products and services. On September 14, 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, requesting production of various documents regarding our products and services. We are cooperating fully on these matters.

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

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

- Reimbursement by Medicare is highly regulated and subject to change, and our failure to comply with applicable regulations, including regulations not designed for diagnostic tests like our Zio Services, could prevent us from receiving reimbursement under the Medicare program and some commercial payors, subject us to penalties, and adversely affect our reputation, business and results of operations.
- If reimbursement or other payment for our Zio Services is reduced or modified in the United States, including through cost containment measures or changes to policies with respect to 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 we must dedicate substantial time and resources to the billing process.
- Audits or denials of our claims by government agencies or payors could expose us to recoupment, regulatory scrutiny, and penalties.
- We are currently undertaking a transformation of our revenue cycle management function and we may fail to realize the anticipated benefits of these efforts.
- Although our current Zio Systems are comprised of medical devices that have received FDA marketing authorization (510(k) clearance) as well as regulatory certifications in the EU and the UK, we may regularly engage in product enhancements and in iterative changes to existing products, as well as seeking to develop new technology or use of technology for new indications for use. These medical device developments may trigger further regulatory reviews and the results of those reviews are unpredictable.
- We are subject to extensive compliance requirements for the quality, design, safety, performance and post-market surveillance of the medical device we manufacture for use in our Zio Services, and for vigilance on complaint-handling, escalation, assessment, and reporting of adverse events and malfunctions. A wide range of quality, risk, regulatory, or safety matters could trigger the need for a recall, a hold on the distribution of the marketed product, or other corrective actions to marketed products.
- Because of the patient populations for which our services are provided and the complexity of the healthcare environment in which we operate, a high degree of medical and clinical input may be necessary to evaluate complaints and adverse events, and in some cases, there may be disagreement over whether our services or the medical devices used in our service may have caused or contributed to an event.
- If we are unable to keep up with demand for our Zio Services, our revenue could be impaired, market acceptance for our Zio Services could be harmed, and physicians may instead order our competitors' services.
- We depend on third-party vendors for the supply and manufacture of certain components of our Zio Systems, as well as for other aspects of our operations.
- Our ability to compete depends on our ability to innovate successfully.
- We have entered into a development agreement with a third-party that may not result in the development of commercially viable devices or the generation of significant future revenues.
- International expansion of our business exposes us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.
- Our success depends on our ability to attract and retain senior management and key personnel.
- Failure to receive the Zio System patches used for the provision of the Zio Services we provide may result in a loss of capital as well as revenue where the receipt of returned devices and processing of data retrieved from returned devices is required to provide our Zio Services.

- Our plans include a high degree of focus on the mSToPs criteria for Afib screening. There are risks that the clinical or payor community will not fully accept these criteria as a basis for selection of patients suitable for screening.
- We may face risks associated with acquisitions of companies, products, and technologies and our business could be harmed if we are unable to address these risks.
- Our use of third-party service providers or company resources located outside the United States to support certain customer care, clinical and other operations of our independent diagnostic testing facilities ("IDTFs") may present challenges, and if we are ineffective in limiting work performed by these service providers or 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 regulatory, enforcement authorities, or competitors.
- While most of our revenue results from claims submitted to payors for diagnostic medical procedures, we offer, and are looking to expand, alternative payment and service delivery models. Piloting, evaluating, and implementing these alternative payment and service delivery models requires interactions with commercial payors, physicians, and patients; these interactions are subject to laws and regulations aimed at preventing healthcare fraud and abuse. If these models are unsuccessful, or if we are unable to fully comply with such laws as we pursue these strategies, our commercial success could be compromised and we could face substantial penalties.
- In the future we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations.
- Our financial results may fluctuate significantly from quarter-to-quarter and may not fully reflect the underlying performance of our business.
- We are subject to legal proceedings and government investigations that could adversely affect our business, financial condition, and results of operations.
- We are subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from shipping affected devices, require us to obtain licenses from third parties or to develop non-infringing alternatives, and subject us to substantial monetary damages and injunctive relief.
- We are subject to complex and evolving U.S. and foreign laws and regulations and other requirements regarding privacy, data protection, security, and other matters. Many of these laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, monetary penalties, increased cost of operations, or declines in user growth or engagement, or otherwise harm our business.
- If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.
- Our stock price is highly volatile and investing in our stock involves a high degree of risk, which could result in substantial losses for investors.
- Increasing our financial leverage could affect our operations and profitability.
- We may be impacted by domestic and global economic and political conditions, as well as natural disasters, pandemics, and other catastrophic events, which could adversely affect our business, financial condition or results of operations.

Risks Related to Our Industry, Business and Operations

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

During the three and six months ended June 30, 2023, we received approximately 25% and 24%, respectively, of our total revenue from the Medicare program (inclusive of Medicare Advantage). The Medicare program is administered by CMS, which imposes extensive and detailed requirements on diagnostic services providers, including IDTFs. These requirements include, but are not limited to, rules that govern how we structure our relationships with physicians, how we operate our IDTFs and market our Zio Services, when we may perform diagnostic tests, and how and when we submit reimbursement claims. Our failure to comply with the applicable Medicare rules and requirements could result in discontinuation of our reimbursement under the Medicare payment program, a requirement to return funds already paid to us, civil monetary penalties, criminal penalties, and/or exclusion from the Medicare program, which would have a material adverse impact on our reputation, business and results of operations.

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

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

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

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

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

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

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

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

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

We report to third party payors the technical components of the remote cardiac monitoring services that are performed with our Zio XT, Zio AT, and Zio Monitor 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 the warning letter could increase the risk of inquiries regarding our historical or current use of CPT code 93229. Consistent with the AMA's definition of MCT, the Zio AT System's indications for use under our 510(k) clearance include uninterrupted ECG recording during normal day-to-day activities to capture, analyze and report diagnostic information regarding asymptomatic arrhythmias as well as other transient, non-critical symptoms (e.g., palpitations, pre-syncope, syncope, shortness of breath or dizziness) for review by our IDTFs and 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 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. Our ability to compete effectively depends on our ability to distinguish our company and our Zio Services from our competitors and their products, and includes such factors as safety and effectiveness; acute and long-term outcomes; ease of use; price; physician, hospital, and clinic acceptance; and third-party reimbursement.

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

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

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

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

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

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

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

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

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

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

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

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

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

Before a new medical device or a new intended use for a medical device can be marketed in the United States, a company must first submit an application and receive either 510(k) clearance, De Novo marketing rights or premarket approval from FDA, unless an exemption applies. All of these processes can be expensive, lengthy and unpredictable. We may not be able to obtain the clearances or approvals we seek or may be unduly delayed in doing so, which could harm our business. Even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained 510(k) clearances to market our Zio System, our clearances can be revoked if safety, efficacy, or significant regulatory compliance problems develop. Even planned changes and improvements to devices and their uses can trigger the need for a new 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 System may require new or modified FDA marketing authorization, CE Mark certification (European Union) or UKCA Mark certification (United Kingdom). 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. For example, FDA has 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 are in the process of discussing such matters with FDA.

In such instances where FDA or an EU/UK Notified/Approved 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 device we manufacture for use in our Zio Services, and for vigilance on complaint-handling, escalation, assessment, and reporting of adverse events and malfunctions. A wide range of quality, risk, regulatory, or safety matters could trigger the need for a recall, a hold on the distribution of the marketed product, or other corrective actions to marketed products.

Our design and manufacturing facilities and processes and those of certain third-party suppliers are subject to unannounced FDA, state, and Notified/Approved Body regulatory inspections for compliance with various medical device regulations and standards, including the Quality System Regulation ("QSR"), also known as 21 CFR Part 820, European Union Medical Device Directive ("EU MDD"), New European Union Medical Device Regulations ("EU MDR"), and UK Medical Device Regulations ("UK MDR") requirements. Developing and maintaining a compliant quality system is time consuming and investment intensive. Requirements and standards may change and evolve over time, and we will need to adapt. Failure to maintain compliance with, or not fully complying with the requirements of FDA and state regulators could result in enforcement actions, which could include the issuance of warning letters, adverse publicity, seizures, prohibitions on product sales, recalls, and civil and criminal penalties, any one of which could significantly impact our manufacturing supply and provision of services and impair our financial results. Failure to maintain full compliance with the requirements of EU MDD, EU MDR, and UK MDR could result in similar disruptions in these markets.

We are required to file various reports with FDA, and EU or UK 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. Regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. These reports are typically publicly available information in most jurisdictions, including the United States. If we initiate a field action (whether a "correction" made relative to a device that remains in the field, which could be through a labeling or software update, or "removal" or "recall" and return of that device to us, or field advisory notices) to reduce a risk to health posed by our Zio System, we would be required to report the Correction or Removal to FDA and, in many cases, similar reports to other regulatory agencies.

For example, on September 28, 2022, we initiated a Customer Advisory Notice to Zio AT customers regarding a Zio AT labeling correction; the labeling changes involve additions and modifications to the Zio AT labeling precautions relating to the device's maximum transmission limits during wear, and also to the need for healthcare providers to complete registration to initiate monitoring services. We reported this Customer Advisory Notice and related information to FDA under 21 C.F.R., Part 806 and FDA classified this field action as a Class II Recall following our initial 806 report. We have completed the distribution of the Advisory Notice to our identified impacted customers; and although the status remains open in FDA recall database, we requested the closure of this field action on March 31, 2023. This labeling correction followed our assessment of topics raised in the August 2022 FDA inspection focused on Zio AT. We were in dialogue with FDA in relation to the inspection process, and in connection with our Customer Advisory Notice and 806 report. Our communications to FDA continued through our monthly updates, following our 483 responses submitted in September of 2022. FDA observation responses, field action or corrections and the 806 process can be unpredictable and can present regulatory and commercial risks and uncertainties relating to matters including product labeling, the scope and approach of the correction, and/or customer and patient perception of our technologies and services.

Additionally, on May 25, 2023, we received a warning letter from FDA, which alleged 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 on June 16, 2023 and are continuing to work with the agency to address the issues outlined in the warning letter. Although our belief based on the dialogue with FDA to date following our warning letter response is that we will be able to work through FDA's matters of concern relating to our Zio AT System, 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 expected date for the resolution of such matters. Until the issues identified in the warning letter are resolved to FDA's satisfaction, additional legal or regulatory action may be taken with or without further notice. The warning letter is publicly available on FDA website and has been the subject of a high degree of media and industry attention, which subjects us to additional scrutiny, even as we are in ongoing dialogue with FDA.

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. Furthermore, even if we adhere to regulatory standards and expectations in our corrective actions, the public nature of such actions can result in broader negative publicity and perceptions, which could harm our reputation.

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

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

Our Zio System and Zio Services are not intended to be prescribed or ordered for use as an emergency system. 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 our 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 certified cardiographic technicians ("CCTs") or through our customer service representatives. The initial reports of these non-physicians are likely to contain information that requires verification and further investigation.

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 (for example, cardiac arrest), a patient may nevertheless be wearing a Zio device when they experience such an event (for example, as was the case with the patients involved in COMP-2021-6388 and COMP-2021-6385 which were referenced by FDA in the May 25, 2023 warning letter). 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 (going forward and in light of recent feedback from FDA regarding its reporting expectations) 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.

We are subject to FDA requirements to investigate complaints about our Zio System. If we do not effectively manage and monitor our complaint-handling procedures, we may be subject to regulatory enforcement action, litigation risks, and risk of negative publicity.

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

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

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

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

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

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

- inability to obtain adequate supply in a timely manner or on commercially reasonable terms, including due to our reliance on a single supplier for certain critical components and materials for which, in some cases, there are relatively few alternative sources of supply;
- modifications to, or discontinuation of, a vendor's operations due to natural disasters, labor disruptions, human error, infrastructure failure, pandemics, military conflicts, or political or economic disruption, which may adversely impact our operations or otherwise lead to interruption of or shortage or delays in supply, including shortages impacting our printed circuit board assembly;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications;
- inability of the manufacturer or supplier to comply with our quality criteria and specifications and, where applicable, the QSR, state regulatory authorities, and, in some cases, the Notified Body audits;
- miscommunication of design specifications due to errors/omissions by either the vendor or our company, resulting in delayed delivery of acceptable materials or components for incorporation into our devices 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, such as those that we have experienced during the COVID-19 pandemic, or our inability to obtain substitute components, sub-assemblies or materials from alternate sources at acceptable prices and in a timely manner could impair our ability to meet the demand for our Zio Services, significantly affect our future revenue and harm our relations and reputation with physicians, hospitals, clinics, and patients.

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

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

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

In order to remain competitive, we must continue to develop new product offerings and enhancements to our Zio Services. We can provide no assurance that we will be successful in fully recognizing the strategic value of our ECG database, expanding the indications for our Zio Services, developing new services and related devices, or commercializing them in ways that achieve market acceptance. In addition, if we develop new services, sales of those services may reduce revenue generated from our existing services. Maintaining adequate research and development personnel and resources to meet the demands of the market is essential. If we are unable to develop new services and related devices, applications, or features, or improve our algorithms due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills, 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 a development agreement with a third-party that may not result in the development of commercially viable devices or the generation of significant future revenues. We may explore or enter into other development or collaboration agreements with other third parties, and these similarly may not result in development of commercially viable devices or services or the generation of significant future revenues.

We have entered into the Development Agreement with Verily to develop certain next-generation Afib screening, detection, or monitoring devices to enhance our Zio Services, which involves combining our technology platforms and capabilities with those of Verily. As part of the Development Agreement, we paid Verily an up-front fee of $5.0 million in cash, and through December 31, 2022 and June 30, 2023, we have achieved milestones and additional related payment obligations totaling $11.0 million. We have agreed to make additional payments over the term of the Development Agreement up to an aggregate of $1.75 million, subject to the achievement of certain development and regulatory milestones. The success of our collaboration with Verily is highly dependent on the efforts provided to the collaboration by Verily and us and the skill sets of our respective employees. Support of these efforts requires significant resources, including research and development, manufacturing, quality assurance, and clinical and regulatory personnel. Even with FDA's clearance of our clinically-integrated ZEUS System for the Zio Watch, continued product testing, market research, and related activities may result in a delay to device launch and additional expense associated with any commercialization efforts. Even if and when launched, the developed devices may also not be accepted in the marketplace, and there is no assurance that adequate coverage or reimbursement would be available, or that an alternative payment model can be developed.

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

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

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 May 25, 2023 warning letter we received, 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 and the United Kingdom, and we may increase our use of administrative and support functions from locations outside the United States, which could expose us to risks associated with international sales and operations. Additionally, our international expansion efforts may not be successful, we may experience difficulties in scaling these functions from locations outside the United States, and we may not experience the expected cost efficiencies.

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

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

- compliance risks associated with the revised regulations in the EU MDR that outline the requirements for medical device CE marking;
- compliance risks associated with the UK MDR, which replaces the CE marking requirements for medical devices marketed and sold in the United Kingdom with a UKCA mark following the United Kingdom's withdrawal from the European Union;
- compliance risks associated with changing our EU Notified Body from (National Standards Authority of Ireland (NSAI) to British Standards Institution (BSI) to better support our international expansion initiatives and emerging regulations in the United Kingdom; and
- compliance risks associated with new or upcoming regulations associated with artificial intelligence applicable to Software as a Medical Device.

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.

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

Our operations in the United Kingdom account for approximately 1% of our revenue for the three and six months ended June 30, 2023 and we intend to continue to pursue growth opportunities in the United Kingdom. There are still a number of areas of uncertainty in connection with the future of the United Kingdom and its relationship with the European Union following the United Kingdom's exit from the European Union in 2020 (commonly referred to as "Brexit"), including the application and interpretation of the UK-EU trade agreement (the "Trade and Cooperation Agreement"), which went into force in May 2021. For example, because a significant proportion of the regulatory framework in the United Kingdom is currently derived from EU directives and regulations, Brexit could result in material changes to the regulatory regime applicable to many of our current operations. The UK government and the MHRA began undertaking public consultations on the future regulation of medical devices in 2022 and plan to introduce the new regulatory system from July 2025 onwards. Although the Trade and Cooperation Agreement offers UK and EU companies preferential access to each other's markets, ensuring imported goods will be free of tariffs and quotas, economic relations between the United Kingdom and the European Union are on more restricted terms than existed previously. Therefore, at this time, we cannot predict the impact that the Trade and Cooperation Agreement and any future agreements contemplated under the terms of the Trade and Cooperation Agreement will have on our future business efforts to commercialize our Zio Services in the United Kingdom and the European Union. Accordingly, it is possible that the Trade and Cooperation Agreement may adversely affect our operations and financial results.

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

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

We have recently experienced significant changes in our executive leadership, including the appointment of Quentin S. Blackford as our President and Chief Executive Officer in October 2021 following the resignation of our prior President and Chief Executive Officer, Kevin King, in January 2021. Douglas Devine, our former Chief Operating Officer, and Michael Coyle served as Chief Executive Officer from June 2021 to October 2021 and January 2021 to June 2021, respectively, before Mr. Blackford's appointment. We have had additional executive officer positions changes recently (including the March 2023 resignation of Douglas Devine as Chief Operating Officer) and may experience further changes in executive leadership in the future.

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

Further, we may undertake reorganizations of our workforce from time to time, which may result in a temporary reduction in the number of employees in certain locations. We would undertake a reorganization to reduce operating expenses or achieve other business objectives, though we cannot guarantee any specific amount of long-term cost savings. Further, the turnover in our employee base could result in operational and administrative inefficiencies, which could adversely impact the results of our operations, stock price, and customer relationships, 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 CCTs, within the framework of our wide-ranging regulatory obligations. Such improvements could impact the content of our Zio reports. In addition, rapid and significant growth may strain our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial, and management controls, reporting systems, and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

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

Our Zio System patches and gateways are provided to patients either (1) during in-office visits with a healthcare provider or (2) remotely via at-home hookup. We have also seen hybrid situation 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 result in a higher likelihood that the patient will fail to return his or her device, which negatively impacts our financial condition when we are unable to provide the Zio Services. For example, when the patient returns the Zio XT patch to us at the end of the patient wear period, we provide the Zio XT Services, which include the end of service report based on the data stored on the Zio XT patch, after which we submit a claim to the relevant payor or to the patient for the services rendered. If a patient fails to return a device, we experience financial losses, which include the cost of the device as well as the loss of potential revenue for the service that is contingent on the returned device for the submission of the associated claim.

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

In January 2022, the U.S. Preventive Services Task Force ("USPSTF") published a recommendation statement on the screening criteria for Afib screening, stating that the current evidence (including the mSToPs study) 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 USPTSF recommendation statement may deter some clinicians or payors from accepting the mSToPs study inclusion and exclusion criteria as a standard for selecting patients for screening for Afib. We cannot predict whether or when the USPSTF's recommendation on Afib screening will change or be modified based on findings from additional randomized trials, other research or through the continued use of our products and services or other similarly situated products and services designed for remote cardiac monitoring.

We may face risks associated with acquisitions of companies, products, and technologies and 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. 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.

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 for items of services furnished outside the United States, other applicable laws and regulations, and any requirements imposed pursuant to our contracts with commercial payors. If these controls do not work as intended, or if regulators or commercial payors disagree with our interpretation of these requirements and their application to our operations, we may be subject to a requirement to return funds already paid to us, civil monetary penalties, other government enforcement, as highlighted by a recent enforcement action against our competitor, BioTelemetry, Inc., with respect to the support of certain clinical operations by vendors performing work outside the United States, and termination of contracts with commercial payors, as well as the loss of revenue associated with those contracts.

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

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

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

- federal and state laws and regulations regarding billing and claims payment;

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act (the "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 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 European Union and the United Kingdom, respectively;
- the FDA's Code of Federal Regulations, including but not limited to, 21 CFR Parts 820, 803, 806, and 801, that outlines requirements for medical device design, testing, marketing authorization, manufacturing, labeling, distribution, and post-market surveillance requirements;
- the EU MDD and EU MDR that outline requirements for medical device CE marking;
- the UK MDR, which, post the United Kingdom's withdrawal from the European Union, replaces the CE marking requirement for medical devices sold in the United Kingdom with a UKCA mark; and
- state law equivalents of each of the above U.S. federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of 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 successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal FCA including mandatory treble damages and significant per-claim penalties, which were increased from $13,508 to $27,018 per false claim for violations assessed after January 30, 2023. For example, our industry has experienced recent FCA enforcement, which highlights the importance of compliance with the rules and regulations governing claims submitted to federal healthcare programs.

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

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

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

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

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

Our sales and marketing efforts and initiatives may subject us to additional scrutiny of our practices of effective communication of risk information, benefits, or claims under the oversight of FDA and the Federal Trade Commission ("FTC"). For example, 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, and FDA will evaluate communications on a fact-specific basis. The FTC also recently 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 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.

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

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

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

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

Our operations may be directly or indirectly affected by various broad state and federal healthcare fraud and abuse laws, including the 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 XT System to screen at-risk patient populations as part of a value-added service offered by managed care organizations, including Medicare Advantage Organizations, to qualifying participants. Although we believe these billing and service models and our program development efforts are properly designed to comply with laws and regulations, these types of initiatives may draw a high degree of scrutiny and may subject us to assertions of non-compliance. If our past, present, or future operations are found to be in violation of fraud and abuse laws, we or our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from Medicare program participation. Furthermore, if we knowingly file, or "cause" the filing of, false claims for reimbursement with government programs such as Medicare, we may be subject to substantial civil penalties, including treble damages.

Risks Related to Financial and Accounting Matters

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

We previously identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. As previously disclosed, in preparing our consolidated financial statements as of and for the years ended December 31, 2021 and 2020, our management concluded that our disclosure controls and procedures were not effective at the reasonable assurance level due to a failure to maintain a sufficient number of professionals with an appropriate level of accounting and internal control knowledge, training, and experience to timely and accurately analyze, record, and disclose accounting matters. This material weakness contributed to additional material weaknesses, which have been previously disclosed and remediated. In aggregate, these material weaknesses (including the previously remediated material weaknesses) contributed to the misstatement of our revenues, revenue reserves, bad debt expense, property and equipment, research and development expense, and related financial disclosures, and in the revision of 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 have been successful and that the previously identified material weakness in internal control over financial reporting has been remediated. However, while the material weakness has been remediated, we continue to seek improvements to enhance our control environment and to strengthen our internal controls to provide reasonable assurance that our financial statements continue to be fairly stated in all material respects.

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

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

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

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

- our inability to manufacture an adequate supply of our Zio Systems to support demand for our Zio Services at appropriate quality levels and acceptable costs;

- possible delays in our research and development programs or in the completion of any third-party clinical trials relating to our Zio Services;
- a lack of acceptance of our Zio Services, including our Zio Systems, by physicians and potential patients;
- the inability of patients to receive reimbursements from third-party payors;
- the purchasing patterns of physicians and patients, including as a result of seasonality;
- failures to comply with regulatory requirements, which could lead to withdrawal of our Zio Services, including our Zio Systems, from the market;
- our failure to continue the commercialization of our Zio Services;
- competition;
- inadequate financial and other resources; and
- global political and economic conditions, including inflation, increasing interest rates and the persisting impacts of the COVID-19 pandemic, the federal debt ceiling and budget, instability in the global banking system, political instability, and military hostilities, including the ongoing military conflict between Russia and Ukraine.

Further, we recognize a portion of our revenue from non-contracted third-party commercial payors. For example, during the year ended December 31, 2022 and six months ended June 30, 2023, revenue from non-contracted third-party commercial payors accounted for approximately six percent of our total revenue. We have limited visibility as to when we will receive payment for our Zio Services with non-contracted payors and we or XIFIN must appeal any negative payment decisions, which often delays collections further. Additionally, a portion of the revenue from non-contracted payors is received from patient co-pays, which we may not receive for several months following delivery of service or may not receive at all. For revenue related to non-contracted payors, we estimate an average collection rate based on factors including historical cash collections. Subsequent adjustments, if applicable, are recorded as an adjustment to revenue. Fluctuations in revenue may make it difficult for us, research analysts, and investors to accurately forecast our revenue and operating results or to assess our actual performance. If our revenue or operating results fall below expectations, the price of our common stock would likely decline.

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

We have incurred net losses since our inception in September 2006. We generated net losses of $18.5 million and $23.9 million during the three months ended June 30, 2023 and 2022, respectively, $57.6 million and $74.5 million during the six months ended June 30, 2023 and 2022, respectively, and $116.2 million and $101.4 million during fiscal 2022 and 2021, respectively. As of June 30, 2023, we had an accumulated deficit of $579.8 million. We have financed our operations to date primarily through private and public offerings of equity securities and revenue generated by prescriptions of our Zio Services. We have and expect to continue to incur significant research and development, sales and marketing, regulatory, and other expenses as we expand our marketing efforts to increase the prescription of our Zio Services, expand existing relationships with physicians, obtain regulatory clearances or approvals for our current or future services and related devices, conduct clinical trials on our existing and future services, and develop new services or add new features to our existing Zio Services. We also expect that our general and administrative expenses will continue to increase due, among other things, to the operational and regulatory burdens applicable to medical service providers that are public companies. As a result, we expect to continue to incur operating losses in the future. These losses, among other things, may have an adverse effect on our stockholders' equity and the value of our common stock.

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

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

- the revenue generated by our Zio Services;
- the costs, timing, and risks of delay of additional regulatory approvals;
- the expenses we incur in manufacturing, developing, selling, and marketing our Zio Services;
- our ability to scale our manufacturing operations to meet demand for the Zio Systems used in our current and any future Zio Services or other offerings;
- the costs of filing, prosecuting, defending, and enforcing any patent claims and other intellectual property rights;

- the rate of progress and cost of our clinical trials and other development activities;
- the success of our research and development efforts;
- the emergence of competing or complementary technologies;
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish;
- the cost of ongoing compliance with legal and regulatory requirements, and third-party payors' policies;
- the cost of obtaining and maintaining regulatory or payor clearance or approval for our current or future offerings including those integrated with other companies' products; and
- the acquisition of business, products, and technologies.

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

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

Our ability to use our net operating losses ("NOLs") to offset future taxable income may be subject to certain limitations which could subject our business to higher tax liability. We may be limited in the portion of NOL carryforwards that we can use in the future to offset taxable income for U.S. federal and state income tax purposes, and federal tax credits to offset federal tax liabilities. Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state law provisions, limit the use of NOLs and tax credits after a cumulative change in corporate ownership of more than 50% occurs within a three-year period. The statutes place a formula limit on how much NOLs and tax credits a corporation can use in a tax year after a change in ownership. Avoiding an ownership change is generally beyond our control. We could experience an ownership change that might limit our use of NOLs and tax credits in the future. In addition, realization of deferred tax assets, including NOL carryforwards, depends upon our future earnings in applicable tax jurisdictions. If we have insufficient future taxable income in the applicable tax jurisdiction for any reason, including any future corporate reorganization or restructuring activities, we may be limited in our ability to utilize some or all of our net operating losses to offset such income and reduce our tax liability in that jurisdiction. See Note 10, *Income Taxes* to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022 for additional information.

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

Risks Related to Other Legal and Regulatory Matters

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

We are involved in legal proceedings related to securities litigation and may become involved in other legal proceedings that arise from time to time in the future. For example, as discussed further in Note 8, *Commitments and Contingencies,* to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, a putative securities class action lawsuit has been filed against the company and certain current officers or former officers of the Company alleging violations of Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder.

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

In addition, healthcare companies are subject to numerous investigations and inquiries by various governmental agencies. For example, as discussed further in Note 8, *Commitments and Contingencies*, to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, 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 October 2021, received a subpoena requesting additional information. More recently, on April 4, 2023, we received a Subpoena Duces Tecum from the Consumer Protection Branch, Civil Division of the U.S. Department of Justice, requesting production of various documents regarding 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 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.

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

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

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

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

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

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

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

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

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

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

Risks Related to Privacy and Security

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

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

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

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

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

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

Cyber-attacks aimed at accessing our devices and services, or related devices and services, and modifying or using them in a way inconsistent with our FDA marketing authorizations and regulatory certifications in the EU and the UK, could create risks to users.

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

Risks Related to Our Common Stock

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

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

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

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

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

- securities analyst coverage or lack of coverage of our common stock or changes in their estimates of our financial performance;
- variations in quarterly operating results;
- future sales of our common stock by our stockholders;
- investor perception of us and our industry;
- announcements by us or our competitors of significant agreements, acquisitions, or capital commitments or service or product launches or discontinuations;
- changes in market valuation or earnings of our competitors;

- negative business or financial announcements regarding our partners;
- general economic conditions;
- regulatory actions;
- legislation and political conditions;
- global health pandemics, such as the COVID-19 pandemic;
- terrorist acts, acts of war, or periods of widespread civil unrest, including the ongoing military conflict between Russia and Ukraine and actions taken by third parties in response to such conflict; and
- general economic, industry, and market conditions, including inflation, interest rate volatility, the federal debt ceiling and budget, instability in the global banking system and foreign currency exchange rates.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Debt

Increasing our financial leverage could affect our operations and profitability.

We are party to a Third Amended and Restated Loan and Security Agreement, dated as of October 23, 2018, with Silicon Valley Bank (as amended by the Second Amendment to Third Amended and Restated Loan and Security Agreement, dated as of March 28, 2022, the "SVB Loan Agreement"), which provides for a (i) a revolving line of credit in the aggregate principal amount of up to $25.0 million and (ii) a term loans facility in the aggregate principal amount of up to $75.0 million. As of June 30, 2023, we had nothing outstanding under the revolving credit line and $35.0 million outstanding under the term loans.

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

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

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

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

The SVB Loan Agreement imposes numerous financial and other restrictive covenants on our operations, including financial covenants. As of June 30, 2023, we were in material compliance with the covenants imposed by the SVB Loan Agreement. If we violate these or any other covenants under the SVB Loan Agreement or fail to make payments in connection therewith, Silicon Valley Bank could declare an event of default, which would give it the right to terminate its commitment to provide additional loans and declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, Silicon Valley Bank would have the right to proceed against the assets we provided as collateral pursuant to the loan. Any of the foregoing may limit our ability to borrow additional funds and pursue other business opportunities or strategies that we would otherwise consider to be in our best interests.

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

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

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

General Risk Factors

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

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

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

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

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

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

We were incorporated in Delaware on September 14, 2006. Our principal executive offices are now located at 699 8th Street, Suite 600, San Francisco, CA 94103, and our telephone number is (415) 632-5700. Our website address is www.iRhythmTech.com. Investors and others should note that we announce material financial information to our investors using SEC filings, press releases, our investor relations website, public conference calls and webcasts. We use these channels as well as social media to communicate with investors, customers and the public about our company, our products and other issues. It is possible that information we post on social media channels could be deemed to be material information. We encourage investors, our customers and others interested in our company to review the information we post on our Facebook page (https://www.facebook.com/iRhythmTechnologies/) and Twitter feed (https://twitter.com/iRhythmTech). The information on, or that may be accessed through, our website and social media channels is not incorporated by reference into this Quarterly Report on Form 10-Q and should not be considered a part of this Quarterly Report on Form 10-Q.

Rule 10b5-1 Trading Plans

Adoption

On May 31, 2023, Dan Wilson, the Company's Executive Vice President of Corporate Development and Investor Relations, entered into a pre-arranged written stock sale plan in accordance with Rule 10b5-1 (the "Wilson Rule 10b5-1 Plan") under the Exchange Act for the sale of shares of the Company's common stock. The Wilson Rule 10b5-1 Plan was entered into during an open trading window in accordance with the Company's policies regarding transactions in the Company's securities and is intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act. The Wilson Rule 10b5-1 Plan provides for the potential sale of up to 20,706 shares of the Company's common stock, including upon the vesting and settlement of restricted stock units and performance restricted stock units for shares of the Company's common stock, so long as the market price of the Company's common stock is higher than certain minimum threshold prices specified in the Wilson Rule 10b5-1 Plan, between August 22, 2023 and August 15, 2024.

The Wilson Rule 10b5-1 Plan includes a representation from Mr. Wilson to the broker administering the plan that he was not in possession of any material nonpublic information regarding the Company or the securities subject to the Rule 10b5-1 Plan at the time it was entered into. A similar representation was made to the Company in connection with the adoption of the Wilson Rule 10b5-1 Plan under the Company's policies regarding transactions in the Company's securities. Those representations were made as of the date of adoption of the Wilson Rule 10b5-1 Plan, and speak only as of such date. In making those representations, there is no assurance with respect to any material nonpublic information of which the insider was unaware, or with respect to any material nonpublic information acquired by the insider or the Company after the date of the representation.

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

		Incorporated by Reference			
Exhibit Number	Description	Form	Date	Number	Filed Herewith
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: August 4, 2023

By: /s/ Quentin S. Blackford

Quentin S. Blackford
President and Chief Executive Officer

(Principal Executive Officer)

Date: August 4, 2023

By: /s/ Brice A. Bobzien

Brice A. Bobzien
Chief Financial Officer

(Principal Financial Officer)

Exhibit 31.1

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

I, Quentin S. Blackford, certify that:

1. I have reviewed this 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: August 4, 2023

By: /s/ Quentin S. Blackford

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

Exhibit 31.2

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

I, Brice A. Bobzien, 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: August 4, 2023

By: /s/ Brice A. Bobzien

Brice A. Bobzien
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of iRhythm Technologies, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2023, 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: August 4, 2023

By: /s/ Quentin S. Blackford

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

By: /s/ Brice A. Bobzien

Brice A. Bobzien
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.