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, 2022

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 August 1, 2022, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 30,026,565.

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

IRHYTHM TECHNOLOGIES, INC.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the impact of the COVID-19 pandemic on our 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;
- our plans to modify our current products, or develop new products, to address additional indications;
- the expected growth of our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our expectations regarding the size of our sales organization and expansion of our sales and marketing efforts 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 products;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;
- our ability to identify and develop new and planned products and acquire new products;
- our ability to remediate our material weaknesses over financial reporting;
- 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, even if new information becomes available in the future.

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

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 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
(Unaudited)
(In thousands, except share and per share data)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 101,253	$ 127,562
Short-term investments	103,238	111,569
Accounts receivable, net	57,380	46,430
Inventory	14,422	10,268
Prepaid expenses and other current assets	8,526	9,693
Total current assets	284,819	305,522
Property and equipment, net	65,923	55,944
Operating lease right-of-use assets	63,940	84,587
Goodwill	862	862
Other assets	20,142	16,052
Total assets	$ 435,686	$ 462,967
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,987	$ 10,509
Accrued liabilities	49,954	51,486
Deferred revenue	2,977	3,049
Debt, current portion	—	11,667
Operating lease liabilities, current portion	11,498	11,142
Total current liabilities	70,416	87,853
Debt, noncurrent portion	34,927	9,690
Other noncurrent liabilities	952	697
Operating lease liabilities, noncurrent portion	84,749	85,212
Total liabilities	191,044	183,452
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; none issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 29,963,627 shares at June 30, 2022 and 29,493,726 at December 31, 2021 issued and outstanding	28	27
Additional paid-in capital	725,748	685,594
Accumulated other comprehensive loss	(583)	(61)
Accumulated deficit	(480,551)	(406,045)
Total stockholders' equity	244,642	279,515
Total liabilities and stockholders' equity	$ 435,686	$ 462,967

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue, net	$ 102,051	$ 81,278	$ 194,429	$ 155,589
Cost of revenue	31,806	25,995	62,425	49,453
Gross profit	70,245	55,283	132,004	106,136
Operating expenses:				
Research and development	11,945	9,606	22,487	18,116
Selling, general and administrative	81,751	62,669	154,909	132,482
Impairment and restructuring charges	—	—	26,608	—
Total operating expenses	93,696	72,275	204,004	150,598
Loss from operations	(23,451)	(16,992)	(72,000)	(44,462)
Interest expense	(482)	(307)	(2,511)	(642)
Other income, net	69	55	85	179
Loss before income taxes	(23,864)	(17,244)	(74,426)	(44,925)
Income tax provision	33	116	80	214
Net loss	$ (23,897)	$ (17,360)	$ (74,506)	$ (45,139)
Net loss per common share, basic and diluted	$ (0.80)	$ (0.59)	$ (2.51)	$ (1.54)
Weighted-average shares, basic and diluted	29,843,141	29,318,894	29,720,415	29,242,089

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss	$ (23,897)	$ (17,360)	$ (74,506)	$ (45,139)
Other comprehensive loss:				
Net change in unrealized loss on available-for-sale securities	(230)	(5)	(522)	(4)
Comprehensive loss	$ (24,127)	$ (17,365)	$ (75,028)	$ (45,143)

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

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

	Six Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (74,506)	$ (45,139)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6,494	4,189
Stock-based compensation	29,001	30,490
Accretion of discounts on investments, net	363	923
Provision for doubtful accounts and contractual allowances	29,249	14,180
Amortization of operating lease right-of-use assets	7,863	3,227
Impairment charges	23,164	—
Other	227	87
Changes in operating assets and liabilities:		
Accounts receivable	(40,199)	(47,671)
Inventory	(4,346)	(4,027)
Prepaid expenses and other current assets	1,167	145
Other assets	(4,090)	(29)
Accounts payable	(4,522)	1,873
Accrued liabilities	(1,276)	(1,985)
Deferred revenue	(73)	1,577
Operating lease liabilities	(7,773)	(2,576)
Reimbursement of tenant improvement allowance	—	2,351
Net cash used in operating activities	(39,257)	(42,385)
Cash flows from investing activities		
Purchases of property and equipment	(16,404)	(10,134)
Purchases of available-for-sale investments	(91,519)	(46,429)
Sales of available-for-sale investments	34,965	—
Maturities of available-for-sale investments	64,000	175,300
Net cash provided by (used in) investing activities	(8,958)	118,737
Cash flows from financing activities		
Payment of long-term debt	(21,389)	(5,833)
Proceeds from term loan	35,000	—
Proceeds from issuance of common stock in connection with employee equity incentive plans	8,372	5,577
Tax withholding upon vesting of restricted stock awards	—	(25,852)
Payments of issuance costs for long term debt	(77)	—
Net cash provided by (used in) financing activities	21,906	(26,108)
Net (decrease) increase in cash and cash equivalents	(26,309)	50,244
Cash and cash equivalents beginning of period	127,562	88,628
Cash and cash equivalents end of period	$ 101,253	$ 138,872
Supplemental disclosures of cash flow information		
Interest paid	$ 2,214	$ 658
Non-cash investing and financing activities		
Property and equipment costs included in accounts payable and accrued liabilities	$ —	$ 5,319
Right-of-use assets obtained in exchange for operating lease liabilities	$ 7,666	$ 6,047
Capitalized stock-based compensation	$ 2,782	$ 1,632

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balances at March 31, 2022	**29,768,708**	**$ 27**	**$ 701,822**	**$ (456,654)**	**$ (353)**	**$ 244,842**
Issuance of common stock in connection with employee equity incentive plans, net	194,919	1	7,295	—	—	7,296
Stock-based compensation	—	—	16,631	—	—	16,631
Net loss	—	—	—	(23,897)	—	(23,897)
Net change in unrealized loss on investments	—	—	—	—	(230)	(230)
Balances at June 30, 2022	**29,963,627**	**$ 28**	**$ 725,748**	**$ (480,551)**	**$ (583)**	**$ 244,642**

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2021	**29,493,726**	**$ 27**	**$ 685,594**	**$ (406,045)**	**$ (61)**	**$ 279,515**
Issuance of common stock in connection with employee equity incentive plans, net	469,901	1	8,371	—	—	8,372
Stock-based compensation	—	—	31,783	—	—	31,783
Net loss	—	—	—	(74,506)	—	(74,506)
Net change in unrealized loss on investments	—	—	—	—	(522)	(522)
Balances at June 30, 2022	**29,963,627**	**$ 28**	**$ 725,748**	**$ (480,551)**	**$ (583)**	**$ 244,642**

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balances at March 31, 2021	**29,287,749**	**$ 27**	**$ 641,996**	**$ (332,463)**	**$ 12**	**$ 309,572**
Issuance of common stock in connection with employee equity incentive plans, net	98,397	—	4,001	—	—	4,001
Tax withholding upon vesting of restricted stock awards	—	—	(747)	—	—	(747)
Stock-based compensation	—	—	10,981	—	—	10,981
Net loss	—	—	—	(17,360)	—	(17,360)
Net change in unrealized gain on investments	—	—	—	—	(5)	(5)
Balances at June 30, 2021	**29,386,146**	**$ 27**	**$ 656,231**	**$ (349,823)**	**$ 7**	**$ 306,442**

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2020	**29,019,350**	**$ 27**	**$ 646,258**	**$ (304,684)**	**$ 11**	**$ 341,612**
Issuance of common stock in connection with employee equity incentive plans, net	366,796	—	5,577	—	—	5,577
Tax withholding upon vesting of restricted stock awards	—	—	(25,852)	—	—	(25,852)
Stock-based compensation	—	—	30,248	—	—	30,248
Net loss	—	—	—	(45,139)	—	(45,139)
Net change in unrealized gain on investments	—	—	—	—	(4)	(4)
Balances at June 30, 2021	**29,386,146**	**$ 27**	**$ 656,231**	**$ (349,823)**	**$ 7**	**$ 306,442**

The accompanying notes are an integral part of these 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 digital healthcare company redefining the way physicians diagnose cardiac arrhythmias by combining wearable biosensing technology with cloud-based data analytics and deep-learning capabilities. The Company began commercial operations in the United States in 2008 following initial 510(k) clearance of its technology by the U.S. Food and Drug Administration.

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 has wholly-owned subsidiaries in the United Kingdom, Singapore and Japan. The Company manages its operations as a single operating segment. The Company derives substantially all of its revenue and maintains substantially all of its assets in the United States. The Company provides ambulatory cardiac rhythm monitoring services that are regulated by the Centers for Medicare and Medicaid Services ("CMS") utilizing our medical device technology at our clinical centers, supporting the physicians who diagnose and treat cardiac arrhythmias.

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 ("U.S. 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 December 31, 2021, 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 condensed consolidated financial information. The results of operations for the three and six months ended June 30, 2022, are not necessarily indicative of the results to be expected for the year ending December 31, 2022, or for any other interim period or for any other future year.

The accompanying interim 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, 2021, included in the Company's annual report on Form 10-K, filed with the SEC on February 28, 2022.

Risks and Uncertainties

COVID-19

As a result of the COVID-19 pandemic, the Company has experienced significant business disruptions affecting the availability and cost of materials, which could disrupt our supply chain and reduce margins. While the Company has continued to deliver its Zio service by operating with remote employees and essential employees on site, any government mandates could further impact the Company's ability to provide its Zio service effectively, and could impede the progress of all ongoing initiatives. Appropriate social distancing techniques and other measures at the Company's facilities have been implemented for employees who are required by job scope or who have chosen to return to the Company's facilities.

Government mandates related to the COVID-19 pandemic have impacted our claims and appeals and are expected to continue to impact payors' processing times. This increase in response times may be due, in part, to staffing shortages at the payors.

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

The Company is continuously reviewing its liquidity and anticipated capital requirements in light of the significant uncertainty created by the COVID-19 pandemic. 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, 2022, the Company is in compliance with its debt covenants.

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. This impact is having a material, adverse impact on liquidity, capital resources, supply chain, operations and business and those of the third parties on which the Company relies, and could worsen over time. The extent to which the COVID-19 pandemic impacts the Company's results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the COVID-19 pandemic and the actions to contain the COVID-19 pandemic or treat its impact, among others. The full extent of potential delays or impacts on the business, financial condition, cash flows and results of operations remains unknown.

Reimbursement

Government payors may change their coverage and reimbursement policies, as well as payment amounts, in a way that would prevent or limit reimbursement for the Company's Zio service, which would significantly harm the Company's business. Government and other third-party payors require the Company to report the service for which it is seeking reimbursement by using a Current Procedural Terminology ("CPT") code-set maintained by the American Medical Association ("AMA"). For Zio XT, the Company had historically utilized temporary CPT codes (or Category III CPT codes), used for newly introduced technologies specific to its category of diagnostic monitoring. The process to convert temporary Category III CPT codes to permanent Category I CPT codes is governed by the AMA and CMS.

Determinations of which products or services will be eligible for reimbursement by Medicare can be developed at the national level through a national coverage determination ("NCD") issued by CMS or at the local level through a local coverage determination ("LCD"), issued by one or more of the regional Medicare Administrative Contractors ("MACs"), who are private contractors that process and pay claims on behalf of CMS for different geographic regions. In the absence of a specific NCD, as has historically been the case with the Zio XT service, the MAC with jurisdiction over a specific geographic region will have the discretion to issue an LCD. The Company's Zio service may be eligible for reimbursement at the rates set by the regional MACs until CMS establishes national payment rates for the CPT codes that the Company uses to seek reimbursement for the Zio XT service.

On October 25, 2019, the AMA's CPT Editorial Panel established eight new Category I CPT codes that are applicable to the Zio XT service and took effect on January 1, 2021. Category I CPT codes 93241 through 93248 are split between two sets of four codes with rates tied to those codes for (i) wear-time of greater than 48 hours and up to 7 days, and (ii) greater than 7 days and up to 15 days. The Company primarily relies on 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) to seek reimbursement for its Zio XT service. In November 2021, CMS published the Calendar Year 2022 Medicare Physician Fee Schedule Final Rule (the "2022 Final Rule"). In the 2022 Final Rule, CMS did not establish national pricing for Calendar Year 2022 for Category I CPT codes 93241, 93243, 93245 and 93247, which include the two CPT codes upon which the Company primarily relies for its Zio XT service. Instead, CMS designated these for contractor pricing in Calendar Year 2022, which meant that prices would be set regionally by each MAC.

In January 2022, Novitas Solutions, the MAC which covers the region where the Company's independent diagnostic testing facility ("IDTF") in Houston, Texas is located, updated reimbursement rates for CPT codes 93243 and 93247 for its jurisdiction to $223 and $233, respectively. These updated rates were retroactive to January 1, 2022. These rates were higher than the rates posted by Novitas in 2021, but continue to be significantly below historical Medicare rates for the Company's Zio XT service. In April 2022, NGS, the MAC which covers the region where the Company's IDTF in Deerfield, Illinois is located, updated reimbursement rates for CPT codes 93243 and 93247 for its jurisdiction to $335 and $347, respectively. These updated rates were retroactive to January 1, 2022. These rates are higher than the historical Medicare rates for the Company's Zio XT service.

In July 2022, CMS published its Calendar Year 2023 Medicare Physician Fee Schedule Proposed Rule (the "2023 Proposed Rule"). In the 2023 Proposed Rule, CMS proposed national payment rates for the Category I CPT codes that the Company primarily uses to seek reimbursement for its Zio XT service. In the 2023 Proposed Rule, CMS proposed relative value units for CPT codes 93247 and 93243 and a Calendar Year 2023 "Conversion Factor" which the Company interprets, collectively with the Medicare payment reduction (sequestration) and the sequestration under the Statutory Pay-As-You-Go Act of 2010, to imply national payment rates of $215 and $204 for CPT codes 93247 and 93243 codes, respectively. Based on the proposed Calendar Year 2023 Geographic Practice Cost Index ("GPCI") modifiers applicable to the locations of the Company's Medicare-enrolled IDTFs in Deerfield, Illinois, Houston, Texas, and San Francisco, California, the Company estimates the applicable payment rates could range from $218 to $295 for CPT code 93247 and $207 to $280 for CPT code 93243.

The 2023 Final Rule is expected to be announced by November 2022 for implementation on January 1, 2023. It is possible that CMS will adopt a lower national rate, a higher national rate, or continue applying contractor pricing.

The Company remains engaged with CMS and all of the MACs, and is working with other industry participants to submit additional cost data on long-term ECG monitoring for consideration to establish appropriate national or local rates. The Company cannot provide certainty at this time on the potential outcome of the discussions with the CMS or MACs or on the timing of any action to be taken.

Given the evolving nature of the healthcare industry and ongoing healthcare cost reforms, the Company is, and will continue to be, subject to changes to the level of Medicare coverage and reimbursement for its Zio service, and unfavorable coverage determinations at the national or local level could adversely affect its business and results of operations.

Further, a reduction in coverage by Medicare could cause some commercial third-party payors to implement similar reductions in their coverage or level of reimbursement of the Zio service. Although a large majority of commercial customers have re-contracted the Zio XT service at pre-existing rates since the establishment of the Category I codes on January 1, 2021, if the Company is unsuccessful in improving the Medicare rates, the Company believes that commercial rates may begin to be more negatively impacted.

As a result of the CPT code changes that took effect January 1, 2021, the number of claims from the first half of 2021, which contained differences between the submitted price and reimbursement rate and overall denials, increased significantly compared to the Company's historical experience as a result of CPT code transition issues with the payors. The Company continues to work with the payors to collect on these claims, however, the collection cycle for these claims is significantly longer than usual and may lead to higher write-offs of doubtful accounts for those periods and negatively impact the Company's results of operations.

If the Company is unable to achieve a level of revenues adequate to support its cost structure, or is unable to reduce its overall cost structure, this would raise substantial doubts about its ability to continue as a going concern.

Supply Chain Constraints

Economies worldwide have also seen indirect COVID-19 pandemic related disruptions, including supply chain impacts, material inflation, and labor constraints in certain markets and geographies. Such economic disruption has had an adverse effect on the Company's business environment as increased lead times and component shortages have resulted in higher inventory costs. While the Company has increased inventory safety stock levels to help mitigate the delays and disruptions in supply, the Company cannot be certain that any prolonged, intensified, or worsened effect from the COVID-19 pandemic would not further impact its supply chain.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, contractual allowances, allowance for doubtful accounts, the useful lives of property and equipment, the recoverability of long-lived assets including the estimated usage of the printed circuit board assemblies ("PCBAs"), the incremental borrowing rate for operating leases, accounting for income taxes, impairment of right-of-use assets ("ROU assets"), and various inputs used in estimating stock-based compensation. Certain of these estimates are impacted by uncertainties surrounding COVID-19, such as revenue recognition, contractual allowances for revenue, allowance for doubtful accounts, and stock-based compensation. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that management believes are reasonable under the circumstances, including assumptions as to future events. Actual results may differ from those estimates.

For further details on estimates used to calculate the impairment on ROU assets, see *Note 6. Impairment and Restructuring Charges.*

Impairment of Long-Lived Assets

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

Any impairments to right of use assets, leasehold improvements, or other assets as a result of a sublease or other similar action are initially recognized when a decision to take such action is made and recorded as an operating expense. Similar to other long-lived assets, management tests ROU assets for impairment whenever events or changes in circumstances occur that could impact the recoverability of these assets. For ROU assets, such circumstances may include subleases that do not fully recover the costs of the associated leases or commitments to sublease a property. For the three and six months ended June 30, 2022, the Company recorded $0 and $23.2 million, respectively, of long-lived asset impairment charges in the consolidated statement of operations. See Note 6. Impairment and Restructuring Charge*s*.

Accounts Receivable, Allowance for Doubtful Accounts and Contractual Allowances

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

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

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

The Company submitted the majority of Zio XT claims from the first and second quarter of 2021 on a delayed basis due to the transition from Category III CPT codes to Category I CPT codes and uncertainty over reimbursement rates. Claims were being held due to a combination of negotiations with payors and administrative delays in processing payments. Most of the held claims were released and submitted by the end of the second quarter of 2021. As of June 30, 2022, uncollected claims as a result of the CPT code transition were $10.7 million, net of contractual allowances. For the contracted portfolio, once submitted, the number of claims from the first half of 2021 which contained differences between the submitted price and reimbursement rate and overall denials increased significantly compared to our historical experience as a result of CPT code transition issues with the payors. The Company continues to work with the payors to collect on these claims, and the collection cycle for these claims is significantly longer than usual. This makes the timing of the Company's collections more difficult to predict. While the Company believes it has properly estimated the impact to our contractual allowances and allowance for doubtful accounts, inherent uncertainty caused by the longer-collection cycle and claims adjudication process could result in additional provisions for contractual allowances and doubtful accounts which would negatively impact the Company's results of operations in future periods.

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

	Six Months Ended June 30, 2022	Year Ended December 31, 2021	Six Months Ended June 30, 2021
Balance, beginning of period	$ 14,012	$ 12,711	$ 12,711
Add: provision for doubtful accounts	7,623	9,615	3,703
Less: write-offs, net of recoveries and other adjustments	(7)	(8,314)	(4,491)
Balance, end of period	$ 21,628	$ 14,012	$ 11,923

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

	Six Months Ended June 30, 2022	Year Ended December 31, 2021	Six Months Ended June 30, 2021
Balance, beginning of period	$ 31,274	$ 21,281	$ 21,281
Add: provision for contractual allowances	21,626	27,459	10,477
Less: realized contractual adjustments	(38)	(17,466)	(6,450)
Balance, end of period	$ 52,862	$ 31,274	$ 25,308

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 and 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 24% and 23% of the Company's revenue for the three and six months ended June 30, 2022, respectively, and 14% of the Company's revenue for each of the three and six months ended June 30, 2021. CMS accounted for 16% and 8% of accounts receivable at June 30, 2022 and December 31, 2021, respectively.

Revenue Recognition

The Company’s revenue is generated primarily from the provision of its ambulatory cardiac rhythm monitoring service, the Zio XT service. The Zio XT service is an ambulatory cardiac rhythm monitoring service that has a patient wear period of up to 14 days and is billable when the monitoring reports are delivered to the healthcare provider, which is also when the service is complete, and the Company recognizes revenue. The time from when the patient has the Zio XT device applied to the time the report is posted is generally around 25 days. The Company has concluded that the Zio XT service is a single performance obligation on the basis that the customer cannot benefit from each component of the service on its own or together with other resources that are readily available to the customer.

The Zio AT service is an ambulatory cardiac rhythm monitoring service that is provided during the patient wear period. During the patient wear period, the Zio AT monitoring system is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous ECG information. While continuously recording patient ECG data, both patient-triggered and automatically detected arrhythmia events are transmitted to a monitoring center for review and reporting according to physician-selected notification criteria. After wear, a final report is generated based on beat-to-beat information from the entire ECG recording. The Zio AT service revenue is recognized over the patient wear period and delivery of electronic Zio reports with two performance obligations.

The Company recognizes as revenue the amount of consideration to which it expects to be entitled in exchange for performing the Zio service. The consideration to which the Company is entitled varies by portfolio, as further defined below, and includes estimates that require significant judgment by management. A unique aspect of the healthcare industry is multiple parties' involvement in the service transaction. In addition to any payment made by the patient, often a third-party, such as 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: (i) payment history from both payors and patient out-of-pocket costs; (ii) payor coverage; (iii) whether there is a contract between the payor or healthcare institution and the Company; (iv) historical amount received for the service; and (v) 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 enrolled as an independent diagnostic testing facility with regional Medicare Administrative Contractors and will receive reimbursement per the relevant national or contractor-priced CPT code rates for the CMS-covered services rendered to the patient.
- 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.
- 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.

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

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

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

For non-contracted portfolios, the Company is providing an implicit price concession due to the lack of a contracted rate with the underlying payor, the result of which requires the Company to estimate the transaction price based on historical

cash collections utilizing the expected value method. All subsequent adjustments to the transaction price are recorded as an adjustment to revenue.

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 collection indicates 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.

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 three and six months ended June 30, 2022 and June 30, 2021 were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Contracted third-party payors	$ 55,451	$ 49,633	$ 107,202	$ 96,225
Non-contracted third-party payors	6,170	6,547	11,657	11,825
Centers for Medicare & Medicaid	24,759	10,989	44,821	21,166
Healthcare Institutions	15,671	14,109	30,749	26,373
Total	$ 102,051	$ 81,278	$ 194,429	$ 155,589

Contract Liabilities

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

Certain of the Company's customers pay the Company directly for the Zio XT service upon shipment of devices. Such advance payments are contract liabilities and are recorded as deferred revenue on the Condensed Balance Sheets and revenue is recognized when reports are delivered to the healthcare provider. 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. During the six months ended June 30, 2021, $0.9 million included in the contract liability balance at the beginning of 2021 was recognized as revenue.

Contract Costs

Under 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, as the asset that would have resulted from capitalizing these costs will be amortized in one year or less.

Stock-based Compensation

The Company measures its stock-based awards made to employees based on the estimated fair values of the awards as of the grant date. The fair value of market condition awards is determined using the Monte-Carlo option pricing model and the fair value of stock options is determined using the Black-Scholes option pricing model. Stock-based compensation expense is recognized over the requisite service period using the straight-line method and is based on the value of the portion of stock-based payment awards that is ultimately expected to vest. As such, the Company's stock-based compensation is reduced for the estimated forfeitures at the date of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. For restricted stock, the compensation cost for these awards is based on the closing price of the Company's common stock on the date of grant, and recognized as compensation expense on a straight-line basis over the requisite service period.

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

3. Cash Equivalents and Investments

The fair value of cash equivalents and available-for-sale investments at June 30, 2022 and December 31, 2021, were as follows (in thousands):

	June 30, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 53,471	$ —	$ —	$ 53,471
U.S. government securities	103,821	—	(583)	103,238
Total cash equivalents and available-for-sale investments	$ 157,292	$ —	$ (583)	$ 156,709
Classified as:				
Cash equivalents				$ 53,471
Short-term investments				103,238
Total cash equivalents and available-for-sale investments				$ 156,709

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

The following table summarizes the fair value of the Company's cash equivalents, short-term and long-term marketable securities classified by maturity (in thousands):

	June 30, 2022	December 31, 2021
Due within one year	$ 156,709	$ 221,706
Due after one year through three years	—	—
Total cash equivalents and available-for-sale investments	$ 156,709	$ 221,706

There were no available-for-sale securities that were in an unrealized loss position for more than twelve months as of June 30, 2022. Unrealized losses recognized in other comprehensive loss and amounts reclassified to net loss from available-for-sale securities were not material for the three and six month periods ended June 30, 2022 and June 30, 2021. Available-for-sale securities held as of June 30, 2022, had a weighted average maturity of 108 days. As of June 30, 2022, the available-for-sale securities in an unrealized loss position are primarily U.S. Treasury Bills of varying maturities, which are sensitive to changes in the yield curve and other market conditions. As of June 30, 2022, we do not intend to sell, and it is not more likely than not that we will be required to sell, the securities in a loss position before the market values recover or the underlying cash flows have been received, and there is no indication of default on interest or principal payments for any of our debt securities.

4. Fair Value Measurements

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

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

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

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

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

The fair value of the Company's outstanding interest-bearing obligations is estimated using the net present value of the future payments, discounted at an interest rate that is consistent with market interest rates, which is a Level 2 input. The carrying amount and the estimated fair value of the Company's outstanding interest-bearing obligations at June 30, 2022, were $34.9 million and $37.8 million, respectively. The carrying amount and the estimated fair value of the Company's outstanding interest-bearing obligations at December 31, 2021, were $21.4 million and $21.7 million, respectively.

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, 2022			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 53,471	$ —	$ —	$ 53,471
U.S. government securities	—	103,238	—	103,238
Total	$ 53,471	$ 103,238	$ —	$ 156,709

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

5. Balance Sheet Components

Inventory and Other Assets

Inventory consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Raw materials	$ 8,247	$ 5,101
Finished goods	6,175	5,167
Total	$ 14,422	$ 10,268

The Company uses PCBAs in each wearable Zio XT and Zio AT monitor as well as in the wireless gateway used in conjunction with the Zio AT monitor. The PCBAs are used numerous times and have useful lives beyond one year. Each time a PCBA is used in a wearable Zio XT monitor or a PCBA and wireless gateway are used with Zio AT monitor, a portion of the cost of the PCBA and gateway are recorded as a cost of revenue. PCBAs, which are recorded as other assets, were $17.1 million and $13.9 million as of June 30, 2022, and December 31, 2021, respectively.

Property and Equipment, Net

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

	June 30, 2022	December 31, 2021
Laboratory and manufacturing equipment	$ 6,236	$ 5,029
Computer equipment and software	2,534	2,353
Furniture and fixtures	3,897	4,174
Leasehold improvements	23,251	20,431
Internal-use software	59,203	46,661
Total property and equipment, gross	95,121	78,648
Less: accumulated depreciation and amortization	(29,198)	(22,704)
Total property and equipment, net	$ 65,923	$ 55,944

Depreciation and amortization expense was $3.4 million and $6.5 million for the three and six months ended June 30, 2022, and $2.2 million and $4.2 million for the three and six months ended June 30, 2021, respectively. During the six months ended June 30, 2022, the Company recorded $2.2 million and $0.5 million in impairment charges to leasehold improvements and furniture and fixtures disclosed above, respectively, in connection with its decision to sublease its San Francisco headquarters. See Note *6. Impairment and Restructuring*.

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

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Accrued payroll and related expenses	$ 26,267	$ 34,484
Accrued vacation	8,253	7,431
Accrued professional services fees	4,609	1,724
Claims payable	3,303	2,988
Accrued ESPP contributions	637	1,002
Restructuring liability	394	—
Accrued interest	279	78
Other	6,212	3,779
Total accrued liabilities	$ 49,954	$ 51,486

6. Impairment and Restructuring Charges

Restructuring

On February 15, 2022, the Company's Board of Directors (the "Board") approved a restructuring plan ("Q1 2022 Restructuring Plan") to allow the Company to effectively and efficiently scale its business. The Q1 2022 Restructuring Plan resulted in severance and other employment related costs. The Company completed required notifications under the Q1 2022 Restructuring Plan in March 2022 and recorded $3.4 million of restructuring charges for the three months ended March 31, 2022.

Restructuring liabilities are reported within accrued liabilities in the Condensed Consolidated Balance Sheets. The following table provides a summary of changes in the restructuring liabilities associated with the Q1 2022 Restructuring Plan (in thousands):

	December 31, 2021	Charges	Cash Payments	June 30, 2022
Employee severance	$ —	$ 3,444	$ (3,050)	$ 394
Total	$ —	$ 3,444	$ (3,050)	$ 394

The Company did not incur restructuring charges during the three months ended June 30, 2022.

Impairment

On October 4, 2018, the Company entered into a lease arrangement ("San Francisco Lease") in connection with its headquarters in San Francisco, California. The San Francisco Lease commenced on May 13, 2019, and the Company began using the premises as its corporate headquarters. The San Francisco lease expires in August 2031.

In an effort to reduce the Company's footprint and as a result of remote work arrangements, the Board of Directors (the "Board") agreed to pursue a sublease for a portion of the Company's Headquarters in San Francisco, CA in February 2022 in order to reduce the total amount of leased square footage by approximately 50%.

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

Significant judgment and estimates are required in assessing impairment of ROU assets, including identifying whether events or changes in circumstances require an impairment assessment, estimating future cash flows, and determining appropriate discount rates. The Company's fair value estimates are based on assumptions management believes to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates.

The following table presents impairment charges recorded during the three and six months ended June 30, 2022:

	Three Months Ended June 30, 2022	Six Months Ended June 30, 2022
ROU Asset	$ —	$ 20,451
Furniture and Fixtures	—	2,211
Leasehold Improvements	—	502
Total	$ —	$ 23,164

For further details on the Company's leases, refer to *Note. 7. Commitments and Contingencies.*

7. Commitments and Contingencies

Lease Arrangements

The Company leases office, manufacturing, and clinical centers under non-cancelable operating leases, which expire on various dates through 2031. These leases generally contain scheduled rent increases or escalation clauses and renewal options. Operating lease right-of-use assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. The operating lease right-of-use 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 right-of-use asset as they are based on actual usage. The Company recognizes operating lease expense on a straight-line basis over the lease period. The total operating lease cost recognized during the six months ended June 30, 2022 was $6.4 million, primarily consisting of lease payments and common area maintenance costs. Cash paid for operating leases during the six months ended June 30, 2022, was $6.5 million.

On October 4, 2018, the Company entered into the San Francisco Lease to rent approximately 117,560 rentable square feet in San Francisco, California, which became the Company's new headquarters in October 2019. The term of the San Francisco Lease began on May 13, 2019, and expires on August 31, 2031. The Company has the option to extend the San Francisco Lease for an additional five-year term.

On October 29, 2009, the Company entered into a lease for a clinic ("Lincolnshire Lease") to rent approximately 41,500 rentable square feet in Lincolnshire, Illinois, which became the Company's clinical operational facilities. The term of the Lincolnshire Lease began on November 1, 2009, and expires on July 31, 2022.

On March 18, 2021, the Company entered into an office/industrial lease ("Cypress Lease") to rent approximately 68,933 rentable square feet in Cypress, California, which became the Company's new office and warehouse facilities. The term of the Cypress Lease began on October 25, 2021, and expires on April 30, 2032. The Company has the option to extend the Cypress Lease for an additional five-year term, subject to certain requirements.

In December 2021, the Company entered into a lease for 44,616 rentable square feet in Deerfield, Illinois ("Deerfield Lease") to replace the Lincolnshire Lease as the Company's clinical operations facility in Illinois. The effective term of the Deerfield Lease began on January 2, 2022 and will expire on June 1, 2033. The Company has the option to extend the Deerfield Lease for an additional five-year term.

On February 14, 2022, the Company entered into a lease for 3,238 rentable square feet in Encinitas, California ("Encinitas Lease") for office space for the Company's San Diego based employees. The term of the Encinitas Lease began on March 1, 2022, and expires on February 28, 2024.

On February 15, 2022, the Board agreed to pursue a sublease of the majority of space on one floor (approximately 50%) of the San Francisco Lease. The Company recorded $0 million and $20.5 million in impairment charges on its ROU asset during the three and six months ended June 30, 2022, respectively. See *Note 6. Impairment and Restructuring* for further details.

As of June 30, 2022, maturities of operating lease liabilities were as follows (in thousands):

Period Ending June 30:		
2022	$	3,091
2023		13,995
2024		14,265
2025		14,681
2026		15,108
Thereafter		75,393
Total lease payments		136,533
Less: imputed interest		(40,286)
Total lease liabilities	$	96,247

The weighted average remaining lease term of the Company's operating leases as of June 30, 2022, was 9.34 years. The weighted average discount rate of the Company's operating leases was 7.29% as of June 30, 2022.

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 its 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 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, the Company's former Chief Executive Officer, Michael J. Coyle, and current Chief Financial Officer and 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 the 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 and briefs for the appeal are now due in September and October 2022. The Company believes the class action 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 the Food and Drug Administration and the Company's products. On October 14, 2021, the Company received a second subpoena requesting additional information. The Company is cooperating fully and is providing the requested information.

Development Agreement

On September 3, 2019, the Company entered into a Development Collaboration Agreement (the "Development Agreement") with Verily Life Sciences LLC ("Verily"). 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 ("AF") 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. We have achieved milestones tied to payments totaling $11.0 million to date and expect to make additional payments over the term of the Development Agreement of $1.75 million, subject to the achievement of certain development and regulatory milestones including provisioning of the Zio Watch and completion of market evaluation scheduled to begin in 2023.

No payment-triggering milestones were achieved during the six months ended June 30, 2022.

The Development Agreement provides each party with licenses to use certain intellectual property of the other party for development activities in the field of AF 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.

8. Debt

Bank Debt

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

On March 28, 2022, the Company entered into a Second Amendment ("2022 Amendment") to its SVB Loan Agreement which provided for a term loan 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 shall pay interest only on the 2022 Term Loans until April 1, 2025, when it shall 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 shall accrue at a floating per annum rate equal to the greater of: (A) the Prime Rate plus 0.25%; and (B) 3.50%. The Company is also required to pay fees on any prepayment of the 2022 Term Loans, ranging from 3.0% to 1.0% depending on the date of prepayment, and a final payment equal to 5.0% of the principal amount of the 2022 Term Loans drawn. Once repaid or prepaid, the 2022 Term Loans may not be reborrowed.

The 2022 Amendment also amended the terms of the revolving credit line under the SVB Loan Agreement, which provided for an aggregate principal amount of $25.0 million, to: (i) extend the maturity date from August 1, 2023 to March 1, 2027, (ii) increase the letters of credit sublimit to $15.0 million and (iii) increase the cash management services sublimit to $15.0 million. Interest charged on the principal amount outstanding under the revolving credit line shall accrue at a floating per annum rate equal to the greater of (A) the Prime Rate plus 0.25% and (B) 3.50%. The Company is required to pay an annual fee equal to 0.15% of the revolving credit line. As of June 30, 2022, no loans were outstanding under the revolving credit line.

The 2022 Amendment also amended the SVB Loan Agreement to require the Company to comply, as of the last day of each fiscal quarter, with a quick ratio of at least 1.15 to 1.0 or minimum adjusted EBITDA of at least $15.0 million. The Company was in compliance with its loan covenants as of June 30, 2022.

Future minimum payments

Future minimum payments under the Amendment to the SVB Loan Agreement at June 30, 2022, are as follows (in thousands):

Year Ending December 31,	
2022	$ 879
2023	1,774
2024	1,779
2025	14,677
2026	18,202
Thereafter	4,412
Total	41,723
Less: Amount representing interest	(6,723)
Less: Debt Issuance Costs	(73)
Total Carrying Value	$ 34,927
Reported as:	
Short-term debt	$ —
Long-term debt	34,927
Total	$ 34,927

9. Income Taxes

The Company recorded a tax provision related to its U.S. state taxes and the U.K. subsidiary during the six months ended June 30, 2022, and June 30, 2021. 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 U.S. net operating loss carryforwards and other deferred tax assets.

10. 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 when funds and assets are legally available and when declared by the board of directors, subject to the prior rights of holders of all series of convertible preferred stock outstanding. No dividends were declared through June 30, 2022.

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

	June 30, 2022	December 31, 2021
Options issued and outstanding	380,551	504,106
Unvested restricted stock units	2,016,957	1,649,561
Shares available for grant under future stock plans	10,213,450	9,011,213
Shares available for future issuance	12,610,958	11,164,880

11. Equity Incentive Plans

Equity Incentive Plan Activity

A summary of share-based awards available for grant under the 2016 Equity Incentive Plan is as follows:

	Awards Available for Grant
Balance at December 31, 2020	**6,505,390**
Additional awards authorized	1,450,967
Awards granted	(1,289,567)
Awards forfeited	356,999
Awards withheld for tax purposes	135,886
Balance at December 31, 2021	**7,159,675**
Additional awards authorized	1,474,686
Awards granted	(799,085)
Awards forfeited	138,838
Awards withheld for tax purposes	—
Balance at June 30, 2022	**7,974,114**

The Company also offers an Employee Stock Purchase Plan ("ESPP"). As of June 30, 2022, the number of shares available for issuance under the ESPP is 2,239,336.

During the six months ended June 30, 2022, 531,770 restricted stock units (“RSUs”) were granted, 246,231 RSUs vested, and 112,256 RSUs were forfeited.

The following table summarizes stock option activity under the 2006 and 2016 Equity Incentive Plans:

		Options Outstanding		
	Options Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2020	**609,881**	$ 40.18	6.24	$ 120,163
Options exercised	(90,939)	$ 31.15		
Options forfeited	(14,836)	$ 68.81		
Balance at December 31, 2021	**504,106**	$ 40.97	5.20	$ 38,675
Options exercised	(122,181)	$ 38.16		
Options forfeited	(1,374)	$ 83.15		
Balance at June 30, 2022	**380,551**	$ 41.72	4.59	$ 25,234
Options exercisable – June 30, 2022	377,850	$ 41.42	4.57	$ 25,170
Options vested and expected to vest – June 30, 2022	380,520	$ 41.72	4.59	$ 25,233

The aggregate intrinsic values of options outstanding, exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the closing price of the Company’s common stock.

The Company did not grant any options during the six months ended June 30, 2022, and 2021.

12. Stock-Based Compensation

Market-based RSU Valuation

The fair value of market based RSUs was estimated at the date of grant using the Monte-Carlo option pricing model with the assumptions below. Additional details on the Company's market based RSUs are included below.

	Six Months Ended June 30,
	2022
Expected term (in years)	2.88
Expected volatility	81.2 %
Risk-free interest rate	1.72 %
Dividend yield	— %

Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of revenue	$ 536	$ 493	$ 922	$ 916
Research and development	1,629	1,427	3,124	3,086
Selling, general and administrative	12,933	8,340	24,955	26,488
Total stock-based compensation expense	$ 15,098	$ 10,260	$ 29,001	$ 30,490

As of June 30, 2022, there was total unamortized compensation costs of $0.1 million, net of estimated forfeitures, related to unvested stock options which the Company expects to recognize over a period of approximately 0.5 years, $153.3 million, net of estimated forfeitures, related to unrecognized RSU expense, which the Company expects to recognize over a period of 2.6 years, and $3.7 million unrecognized ESPP expense, which the Company will recognize over 0.7 years.

Performance-based RSUs ("PRSU") and Market-based RSUs

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

February 2020 Awards

In February 2020, the Company granted PRSUs ("February 2020 awards") for fiscal year 2022's annual unit volume CAGR compared to fiscal year 2019's annual unit volume CAGR, measuring a minimum performance threshold of 19.7% to earn 50% of target, and a maximum threshold of 29% achieved to earn 200% of target. A total of 133,834 PRSU shares were granted with grant date fair value of $11.0 million. The 2020 awards also include a service-based component.

Compensation cost in connection with the probable number of shares that will vest will be recognized ratably through March 31, 2023. The Company determined that it was probable that the February 2020 Awards would vest and recognized $0.2 million and $0.3 million of compensation cost for the three and six months ended June 30, 2022, respectively, and $0.2 million and $1.7 million of compensation cost for the three and six months ended June 30, 2021, respectively.

January 2021 Awards

In January 2021, the Company granted PRSUs ("January 2021 awards") for fiscal year 2021's annual consolidated revenue compared to fiscal year 2020's annual consolidated revenue, measuring a performance threshold of 10.0% to earn 100% of target. A total of 53,862 PRSU shares were granted with a grant date fair value of $13.9 million. The January 2021 awards also include a service-based component.

Compensation cost in connection with the probable number of shares that will vest were recognized ratably through March 31, 2022. As of June 30, 2022, the January 2021 Awards vested and the Company recognized $0 million and $2.2 million of compensation cost for the three and six months ended June 30, 2022, respectively, and $2.3 million and $4.5 million of compensation cost for the three and six months ended June 30, 2021, respectively.

February 2021 Awards

In February 2021, the Company granted PRSU's ("February 2021 awards") for fiscal year 2023's annual unit volume CAGR compared to fiscal year 2020's annual unit volume CAGR, measuring a minimum performance threshold of 19.7% to earn 50% of target, and a maximum threshold of 29% achieved to earn 200% of target. A total of 112,872 PRSU shares were granted with grant date fair value of $17.3 million. The February 2021 awards also include a service-based component.

Compensation cost in connection with the probable number of shares that will vest will be recognized ratably through March 31, 2024. The Company determined that it was probable that the February 2021 Awards would vest and recognized $0.2 million and $1.2 million of compensation cost for the three and six months ended June 30, 2022, respectively, and $0.3 million and $0.7 million of compensation cost for the three and six months ended June 30, 2021, respectively.

2022 Awards

In February 2022, the Company granted PRSU's ("2022 awards") for fiscal year 2024's annual unit volume CAGR compared to fiscal year 2021's annual unit volume CAGR, measuring a minimum performance threshold of 13.0% to earn 50% of target, and a maximum threshold of 23.0% achieved to earn 200% of target. A total of 170,997 PRSU shares were granted with grant date fair value of $21.8 million. The 2022 awards also include a service-based component.

The Company's Chief Executive Officer's 2022 awards included a multiplier based on total shareholder return ("TSR"). The number of RSUs that vest, determined in accordance with the performance metrics above, will be adjusted for certain levels of achievement of TSR by the Company, as compared to the TSR achieved by the companies comprising the Index.

Compensation cost in connection with the probable number of shares that will vest will be recognized ratably through March 31, 2025. During the three months ended June 30, 2022, the Company determined that it was probable that the 2022 Awards would vest and recognized $1.7 million and $2.4 million of compensation cost for the three and six months ended June 30, 2022, respectively.

Non-employee Stock-Based Compensation

On January 12, 2021, the Company's former Chief Executive Officer ("CEO") resigned and entered into a Consulting Professional Services Agreement ("CPSA") with the Company. Pursuant to the original terms of the awards, the former CEO will continue to vest in outstanding awards as long as services are provided to the Company under the CPSA as a non-employee consultant or a member of the Company's Board of Directors. In accordance with ASC 718, the Company recognized expense related to all awards expected to vest over the duration of the CPSA in the three months ended March 31, 2021, as an equity-based severance cost as the consulting services are not substantive.

The former CEO total expense related to non-employee stock-based compensation recognized for the six months ended June 30, 2022 and 2021 were $0.0 million and $5.0 million, respectively.

In March 2022, the former CEO retired from the Board and as a non-employee consultant. Vesting for all outstanding awards was accelerated upon his retirement. The Company recognized expense of $0.0 million and $0.9 million related to the retirement of the former CEO during the three and six months ended June 30, 2022, respectively.

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

The former CCO total expense related to non-employee stock-based compensation recognized for the three and six months ended June 30, 2022 was $0.2 million.

13. Net Loss Per Common Share

As the Company has net losses for the three and six months ended June 30, 2022, and 2021, all potential common shares were deemed to be anti-dilutive. The following table sets forth the computation of the basic and diluted net loss per share (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Numerator:				
Net loss	$ (23,897)	$ (17,360)	$ (74,506)	$ (45,139)
Denominator:				
Weighted-average shares used to compute net loss per common share, basic and diluted	29,843,141	29,318,894	29,720,415	29,242,089
Net loss per common share, basic and diluted	$ (0.80)	$ (0.59)	$ (2.51)	$ (1.54)

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, 2022 and 2021, because their inclusion would be anti-dilutive:

	Six Months Ended June 30,	
	2022	2021
Options to purchase common stock	380,551	527,536
PRSUs and RSUs unvested	2,016,957	1,074,814
Total	2,397,508	1,602,350

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 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 digital healthcare company redefining the way cardiac arrhythmias are clinically diagnosed by combining our wearable biosensing technology with cloud-based data analytics and deep-learning capabilities. Our goal is to be the leading provider of ambulatory electrocardiogram ("ECG") monitoring for patients at risk for arrhythmias. We have created a full portfolio of ambulatory cardiac monitoring services on a unique platform, called the Zio service, which combines an easy-to-wear and unobtrusive biosensor that can be worn for up to 14 consecutive days with powerful proprietary algorithms that distill data from millions of heartbeats into clinically actionable information. The Zio service consists of:

- wearable patch-based biosensors, the Zio XT and Zio AT monitors, which continuously record and store ECG data from the patient's heartbeat for up to 14 consecutive days; while continuously recording patient ECG data, the Zio AT service offers the option of timely transmission of patient-triggered and automatically detected arrhythmia events data to a monitoring center for review and reporting according to physician-selected notification criteria;
- cloud-based analysis of the recorded cardiac rhythms using our proprietary, deep-learned algorithms;
- a final quality assessment review of the data by our certified cardiographic technicians; and
- an easy-to-read Zio report, a curated summary of findings that includes high quality and clinically-actionable information which is sent directly to a patient's physician through ZioSuite and can be integrated into a patient's electronic health record.

We receive revenue for the Zio service primarily from third-party payors, which include commercial payors and Centers for Medicare and Medicaid Services ("CMS"). The remainder of our revenue comes from healthcare institutions, which are typically hospitals or private physician practices, who purchase the Zio service from us directly. Our revenue in the third-party commercial payor category is primarily contracted, which means we have entered into pricing contracts with these payors. Third-party contracted payors accounted for approximately 55% and 62% of our revenue for the six months ended June 30, 2022 and 2021, respectively. Approximately 23% and 14% of our total revenue for the six months ended June 30, 2022 and 2021, respectively, is received from CMS, which is under established reimbursement codes. Healthcare institutions accounted for approximately 16% and 17% of our revenue for the six months ended June 30, 2022 and 2021, respectively. Non-contracted third party payors and self-pay accounted for 6% and 8% of our total revenue for the six months ended June 30, 2022 and June 30, 2021, respectively. We rely on a third-party billing partner, XIFIN, Inc., to submit patient claims and collect from commercial payors, certain government agencies, and patients.

Following the initial 510(k) clearance of our technology by the U.S. Food and Drug Administration ("FDA"), we have provided the Zio service to over four million patients and have collected over one billion hours of curated heartbeat data. We believe the Zio service is well-positioned to penetrate an already-established approximately $2.0 billion U.S. ambulatory cardiac monitoring market by offering a user-friendly device to patients, actionable information to physicians, and value to payors.

We market our ambulatory cardiac monitoring solution in the United States through a direct sales organization comprised of sales management, field billing specialists, quota-carrying sales representatives, and a customer service team. Our sales representatives focus on initial introduction into new customers, penetration across a sales region, driving adoption within existing accounts, and conveying our message of clinical and economic value to service line managers, hospital administrators and other clinical departments. In addition, we will continue exploring sales and marketing expansion opportunities in international geographies.

COVID-19 Impact

Beginning in mid-March 2020, we experienced decreasing levels in patient registrations for the Zio service, which impacted our revenues during the years ended December 31, 2021 and 2020. This decrease in revenue is due to a variety of challenges associated with the COVID-19 pandemic in the United States, including, among others:

- a reduction in physician prescriptions for our Zio service due to:
    - a reduction in diagnostic testing outside of those tests related to severe respiratory distress;
    - reduction in the hours of physicians' offices and staffing shortages affecting these offices;
    - physicians and hospitals prioritizing the treatment of critically ill patients; and
    - patient reluctance to visit physician offices or hospitals for fear of contracting COVID-19;
- cancellation and reduction of physician attendance at professional medical society meetings and trade shows and our decision not to attend them due to COVID-19 safety precautions;
- travel restrictions and changing hospital policies that have limited access of our sales professionals to hospitals where the Zio services are ordered and where patients historically have been enrolled;
- delays in receiving Zio XT monitors back from patients at the conclusion of the Zio service with some patients failing to return the device at all; and
- patients who are unable to afford the Zio service to due to having lost jobs, being furloughed, having reduced work hours, or are worried about the continuation of medical insurance.

In the first quarter of 2022, we re-opened our offices for use and certain groups of employees have begun returning to work in our offices across the United States. Appropriate social distancing techniques and other measures at our facilities have been implemented for the employees who have returned to work.

While hospital systems and healthcare facilities shifted their focus and resources to treating COVID-19 patients and combating the spread of the coronavirus, we have adapted our service 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 device 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 caused us to recognize an impairment on our right of use asset and related leasehold improvements and furniture and fixtures and we believe we may incur additional impairment charges related to our real property lease agreements.

Components of Results of Operations

Revenue

The majority of our revenue is derived from provision of our Zio service to customers in the United States. We earn revenue from the provision of our Zio service 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 a delivered report, and Zio service provided, we consider factors such as: (i) claim payment history from both payors and patient out-of-pocket costs; (ii) payor coverage; (iii) whether there is a contract between the payor or healthcare institution and the Company; (iv) historical amount received for the service; and (v) any current developments or changes that could impact reimbursement and healthcare institution payments.

We are subject to seasonality similar to other companies in our field, as vacations by physicians and patients tend to affect enrollment in the Zio service more during the summer months and during the end of calendar year holidays compared to other times of the year. Revenue may be impacted by the outcome of adjudications with contracted and non-contracted payors,

as well as changes in the CMS reimbursement rates. Clinical capacity limitations may also restrict our ability to complete the performance obligations to achieve revenue recognition.

Cost of Revenue and Gross Margin

Cost of revenue includes direct labor, material costs, equipment and infrastructure expenses, device scrap and loss, amortization of internal-use software, allocated overhead, and shipping and handling. Direct labor includes payroll and personnel-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 monitors and amortization of the reusable printed circuit board assemblies ("PCBAs"). Each Zio XT monitor includes a PCBA, and each Zio AT monitor includes a PCBA and gateway board, the cost of which is amortized over the anticipated number of uses of the board. We expect the cost of revenue to increase in absolute dollars as our revenue increases due to increased direct labor, direct materials, and variable spending, partially offset by economies of scale in relation to fixed costs such as overhead, depreciation and amortization, and facilities costs.

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

Although a large majority of our commercial customers have renewed their contracts for the Zio XT service since the establishment of the Category I codes on January 1, 2021 matching to pre-existing rates, if we are unsuccessful in improving the Medicare rates, we believe that commercial rates may begin to be more negatively impacted, which would have a negative impact on our gross margins.

Research and Development Expenses

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

Selling, General and Administrative Expenses

Our sales and marketing expenses consist of payroll and personnel-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 and personnel-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.

Impairment and Restructuring Expenses

Our impairment and restructuring expenses consist of impairment charges on our San Francisco right-of-use asset and severance charges in connection with our 2022 restructuring plan.

Interest Expense

Interest expense is attributable to borrowings under our loan agreements. See *Note 8. Debt*, for further information on our loan agreements.

Other Income, Net

Other income, net consists primarily of interest income which consists of interest received on our cash equivalents and investments.

Results of Operations

Comparison of the Three Months Ended June 30, 2022 and 2021

	Three Months Ended June 30,			
	2022	2021	$ Change	% Change
	(dollars in thousands)			
Revenue	$ 102,051	$ 81,278	$ 20,773	26 %
Cost of revenue	31,806	25,995	5,811	22 %
Gross profit	70,245	55,283	14,962	27 %
Gross margin	69 %	68 %		
Operating expenses:				
Research and development	11,945	9,606	2,339	24 %
Selling, general and administrative	81,751	62,669	19,082	30 %
Total operating expenses	93,696	72,275	21,421	30 %
Loss from operations	(23,451)	(16,992)	(6,459)	38 %
Interest expense	(482)	(307)	(175)	57 %
Other income, net	69	55	14	25 %
Loss before income taxes	(23,864)	(17,244)	(6,620)	38 %
Income tax provision	33	116	(83)	(72)%
Net loss	$ (23,897)	$ (17,360)	$ (6,537)	38 %

Revenue

Revenue increased $20.8 million, or 26%, to $102.1 million during the three months ended June 30, 2022, from $81.3 million during the three months ended June 30, 2021. The increase in revenue was primarily attributable to an increase in volume of Zio services provided as a result of increased demand and improved CMS reimbursement rates, partially offset by a decrease in adjudication performance with contracted and non-contracted payors.

Cost of Revenue and Gross Profit

Cost of revenue increased $5.8 million, or 22%, to $31.8 million during the three months ended June 30, 2022, from $26.0 million during the three months ended June 30, 2021. The increase in cost of revenue was primarily due to increased Zio service volume and higher costs associated with our new operating facility in Cypress, California that commenced operation in September 2021.

Gross profit increased $15.0 million to $70.2 million during the three months ended June 30, 2022 from $55.3 million for the three months ended June 30, 2021. The increase in profit was primarily due to increased volume and average selling price, partially offset by increases in cost per unit.

Research and Development Expenses

Research and development expenses increased $2.3 million, or 24%, to $11.9 million during the three months ended June 30, 2022, from $9.6 million during the three months ended June 30, 2021. The increase was primarily attributable to a $1.0 million increase in compensation expense, a $1.1 million increase in professional service fees related to clinical trials, recruiting and consulting, and a $0.2 million increase in stock-based compensation.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $19.1 million, or 30%, to $81.8 million during the three months ended June 30, 2022, from $62.7 million during the three months ended June 30, 2021. The increase was due to a $8.4 million

increase in compensation costs as a result of increased headcount and corporate bonus, an increase of $4.3 million in stock based compensation expense, an increase in professional service fees of $3.6 million and an increase in bad debt expense of $2.6 million.

Interest Expense

Interest expense was $0.5 million for the three months ended June 30, 2022, compared to $0.3 million for the three months ended June 30, 2021. There were no significant changes in interest expense during the three months ended June 30, 2022, compared with the three months ended June 30, 2021.

Other Income, Net

Other income, net was immaterial for the three months ended June 30, 2022 and 2021. There were no significant changes in other income, net during the three months ended June 30, 2022, compared with the three months ended June 30, 2021.

Comparison of the Six Months Ended June 30, 2022 and 2021

	Six Months Ended June 30,			
	2022	2021	$ Change	% Change
	(dollars in thousands)			
Revenue	$ 194,429	$ 155,589	$ 38,840	25 %
Cost of revenue	62,425	49,453	12,972	26 %
Gross profit	132,004	106,136	25,868	24 %
Gross margin	68 %	68 %		
Operating expenses:				
Research and development	22,487	18,116	4,371	24 %
Selling, general and administrative	154,909	132,482	22,427	17 %
Impairment and restructuring charges	26,608	—	26,608	100 %
Total operating expenses	204,004	150,598	53,406	35 %
Loss from operations	(72,000)	(44,462)	(27,538)	62 %
Interest expense	(2,511)	(642)	(1,869)	291 %
Other income, net	85	179	(94)	(53)%
Loss before income taxes	(74,426)	(44,925)	(29,501)	66 %
Income tax provision	80	214	(134)	(63)%
Net loss	$ (74,506)	$ (45,139)	$ (29,367)	65 %

Revenue

Revenue increased $38.8 million, or 25%, to $194.4 million during the six months ended June 30, 2022 from $155.6 million during the six months ended June 30, 2021. The increase in revenue was primarily attributable to an increase in volume of Zio services provided as a result of increased demand and improved CMS reimbursement rates, partially offset by a decrease in adjudication performance with contracted and non-contracted payors.

Cost of Revenue and Gross Profit

Cost of revenue increased $13.0 million, or 26%, to $62.4 million during the six months ended June 30, 2022, from $49.5 million during the six months ended June 30, 2021. The increase in cost of revenue was primarily due to increased Zio service volume and higher costs associated with our new operating facility in Cypress, California that commenced operation in September 2021.

Gross profit increased $25.9 million to $132.0 million during the six months ended June 30, 2022 from $106.1 million during the six months ended June 30, 2021. The increase in gross profit was primarily due to increased volume and an increase in net average selling price partially offset by higher cost per unit.

Research and Development Expenses

Research and development expenses increased $4.4 million, or 24%, to $22.5 million during the six months ended June 30, 2022, from $18.1 million during the six months ended June 30, 2021. The increase was primarily attributable to a $3.2 million increase in compensation costs as a result of increased headcount and a $1.1 million increase in professional service fees related to clinical trials, recruiting and consulting.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $22.4 million, or 17%, to $154.9 million during the six months ended June 30, 2022 from $132.5 million during the six months ended June 30, 2021. The increase was due to a $15.7 million increase in compensation costs as a result of increased headcount, a $4.1 million increase in professional service fees, and a $3.9 million increase in bad debt expense partially offset by a $3.2 million decline in commissions and $1.5 million decrease in stock-based compensation.

Impairment and Restructuring Charges

In February 2022, our board of directors (the "Board") approved reducing our leased space for our headquarters in San Francisco, California. As a result, we recognized an impairment of our right of use asset and related leasehold improvements and furniture and fixtures in the amount of $23.2 million during the six months ended June 30, 2022.

In February 2022, the board approved a restructuring plan to allow the Company to effectively and efficiently scale its business. The 2022 Restructuring Plan resulted in severance and other employment related costs. We recorded $3.4 million in charges under the 2022 Restructuring plan during the six months ended June 30, 2022.

The Company did not incur impairment and restructuring charges during the six months ended June 30, 2021.

Interest Expense

Interest expense was $2.5 million for the six months ended June 30, 2022, compared to $0.6 million for the six months ended June 30, 2021. The increase was due to additional financing fees of $1.75 million related to our term loan paid in March 2022.

Other Income, Net

Other income, net was $0.1 million for the six months ended June 30, 2022, compared to $0.2 million for the six months ended June 30, 2021. There were no significant changes in other income, net during the six months ended June 30, 2022 compared with the six months ended June 30, 2021.

Liquidity and Capital Expenditures

Overview

We are continuously reviewing our liquidity and anticipated capital requirements in light of the significant uncertainty created by the COVID-19 global pandemic. We believe we will have adequate liquidity over the next twelve months to operate our business and to meet our cash requirements.

As of June 30, 2022, we had cash and cash equivalents of $101.3 million, short-term investments of $103.2 million, and an accumulated deficit of $480.6 million. In addition, we have term loan facilities of $40.0 million and a revolving credit line of $25.0 million available.

Our expected future capital requirements may depend on many factors, including expanding our customer base, the expansion of our sales force, and the timing and extent of spending on the development of our technology to increase our product offerings. We expect the next Verily milestone of $1.75 million to be met in 2023. Additionally, we will complete the build out of our new Deerfield, Illinois facility in the second half of 2022.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

Cash Flows

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

	Six months ended June 30,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$ (39,257)	$ (42,385)
Investing activities	(8,958)	118,737
Financing activities	21,906	(26,108)
Net (decrease) increase in cash and cash equivalents	$ (26,309)	$ 50,244

Cash Used in Operating Activities

During the six months ended June 30, 2022, cash used in operating activities was $39.3 million, which consisted of a net loss of $74.5 million, adjusted by non-cash charges of $96.3 million and a net change of $61.1 million in our net operating assets and liabilities. The non-cash charges were primarily comprised of impairment charges of $23.2 million, stock-based compensation expense of $29.0 million, allowance for doubtful accounts and contractual allowances of $29.2 million, depreciation and amortization of $6.5 million and amortization of right of use assets of $7.9 million. The change in our net operating assets and liabilities was primarily due to an increase of $40.2 million in accounts receivable, an increase of $4.3 million in inventory, a decrease of $1.3 million in accrued liabilities, a decrease of $4.5 million in accounts payable and a decrease of $7.8 million in operating lease liability.

The number of claims from the first half of 2021 which contained differences between the submitted price and reimbursement and overall denials increased significantly compared to our historical experience as a result of CPT code transition issues with the payors. We continue to work with the payors to collect on these claims and the collection cycle for these claims is significantly longer than usual. While we believe we have properly estimated the impact to our contractual allowances and allowance for doubtful accounts, the inherent uncertainty caused by longer collection cycle and claims adjudication process could result in additional provisions for contractual allowances and doubtful accounts which would negatively impact our results of operations in future periods. As of June 30, 2022, uncollected claims as a result of the CPT code transition were $10.7 million, net of contractual allowances. We believe we have adequate balance sheet liquidity to manage through these delays

During the six months ended June 30, 2021, cash used in operating activities was $42.4 million, which consisted of a net loss of $45.1 million, adjusted by non-cash charges of $53.1 million and a net change of $50.3 million in our net operating assets and liabilities. The non-cash charges were primarily comprised of a change in stock-based compensation of $30.5 million, allowance for doubtful accounts and contractual allowances of $14.2 million, depreciation and amortization of $4.2 million and amortization of right of use assets of $3.2 million. The change in our net operating assets and liabilities was primarily due to an increase of $47.7 million in accounts receivable, an increase of $4.0 million in inventory, a decrease of $2.0 million in accrued liabilities, an increase of $1.9 million in accounts payable and a decrease of $2.6 million in operating lease liability.

Cash Provided by (Used in) Investing Activities

Cash used in investing activities during the six months ended June 30, 2022 was $9.0 million, which primarily consisted of $91.5 million in purchases of available for sale investments and $16.4 million of capital expenditures, partially offset by cash received from the maturities of available for sale investments of $64.0 million, and sales of available for sale investments of $35.0 million.

Cash provided by investing activities during the six months ended June 30, 2021 was $118.7 million, which primarily consisted of cash received from the maturities of available for sale investments of $175.3 million, partially offset by $46.4 million in purchases of available for sale investments and $10.1 million of capital expenditures.

Cash Provided by (Used in) Financing Activities

During the six months ended June 30, 2022, cash provided by financing activities was $21.9 million, primarily due to $35.0 million in proceeds received from the closing of our Second Amendment to our SVB Loan Agreement and $8.4 million of proceeds from the issuance of common stock in connection with employee equity incentive plans, partially offset by a $21.4 million repayment of the outstanding balance under the existing SVB term loan.

During the six months ended June 30, 2021, cash used in financing activities was $26.1 million, primarily due to $25.9 million in tax withholding upon the vesting of RSUs. This practice has been updated to require employees to sell shares to cover tax liabilities and has not been a use of company cash beginning in June 2021. In addition, cash used in financing activities was due to repayment of debt of $5.8 million, partially offset by $5.6 million in proceeds from the issuance of common stock in connection with employee options exercises and our Employee Stock Purchase Plan.

Bank Debt

In October 2018, we entered into a Third Amended and Restated Loan and Security Agreement with SVB ("SVB Loan Agreement"). 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 ("2022 Amendment") to the SVB Loan Agreement which provided for a term loan 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 of 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 shall 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 accrues at a floating per annum rate equal to the greater of (A) the Prime Rate plus 0.25% and (B) 3.50%. We are also required to pay fees on any prepayment of the 2022 Term Loans, ranging from 3.0% to 1.0% depending on the date of prepayment, and a final payment equal to 5.0% of the principal amount of the 2022 Term Loans made. 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 shall accrue at a floating per annum rate equal to the greater of (A) the Prime Rate plus 0.25% and (B) 3.50%. We are required to pay an annual fee equal to 0.15% of the revolving credit line. As of June 30, 2022, no loans were outstanding under the revolving credit line.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Contractual Obligations

Our contractual obligations as of December 31, 2021, are presented in our Form 10-K filed with the SEC on February 28, 2022. There have been no material changes.

Critical Accounting Policies and Estimates

For a complete description of what we believe to be the critical accounting policies and estimates used in the preparation of our Unaudited Condensed Consolidated Financial Statements, refer to our Annual Report on Form 10-K for the year ended December 31, 2021 ("Annual Report"). Refer to Note 2. *Summary of Significant Accounting Policies*, in the Notes to Unaudited Condensed Consolidated Financial Statements in Item 1 of Part I of this Quarterly Report on Form 10-Q, for all significant accounting policies. There have been no significant changes to our critical accounting policies as described in our Annual Report.

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 investments of $204.5 million as of June 30, 2022, which consisted of bank deposits, money market funds and U.S. government securities. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our condensed consolidated financial statements.

We had total outstanding debt of $34.9 million, which is net of debt issuance costs, as of June 30, 2022. The Third Amended and Restated SVB Loan Agreement Note carries a variable interest rate based on the "Prime Rate" published by The Wall Street Journal. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Foreign Currency Exchange Rate Sensitivity

We face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars, particularly in British Pound Sterling. As of June 30, 2022, we do not consider this risk to be material. We do not utilize any forward foreign exchange contracts. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made.

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-15(b) 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 report. Based on that evaluation, our CEO and our CFO have concluded that as of the end of the period covered by this quarterly report, our disclosure controls and procedures were not effective as of June 30, 2022, at the reasonable assurance level because of the material weakness in internal controls which was disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, and continues to exist as of June 30, 2022. Notwithstanding the material weakness, our management, including our CEO and CFO, has concluded that our consolidated financial statements, included in the Annual Report on Form 10-K for the year ended December 31, 2021, and in the Form 10-Q for the three-month period ended June 30, 2022, fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented in conformity with generally accepted accounting principles.

Material Weakness Related to the Control Environment

We did not design or maintain an effective control environment commensurate with our financial reporting requirements. Given the rapid growth in the size and complexity of the business, we failed to maintain a sufficient number of professionals with an appropriate level of accounting and internal control knowledge, training and experience to appropriately

analyze, record and disclose accounting matters timely and accurately. This material weakness contributed to additional material weaknesses, previously disclosed and remediated. In aggregate, these material weaknesses contributed to the misstatement of our revenues, revenue reserves, bad debt expense, property and equipment, research and development expense and related financial disclosures, and in the revision of the Company's consolidated financial statements for the years ended December 31, 2017, December 31, 2018, and each interim period therein as well as the quarters ended March 31, 2019, June 30, 2019, and September 30, 2019. Additionally, this material weakness could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

Remediation Plan Activities

As it relates to the material weakness that continues to exist as of June 30, 2022, we performed the following actions:

- Increased the depth and experience of our Finance organization by increasing the number of management and staff members, expanding our technical experience in accounting, auditing and reporting matters, and performing internal controls training for management and staff members.
- In January 2022, hired an Information Technology ("IT") Compliance Director with technical experience in IT and assist in driving remediation and performing internal controls training for management and staff members.
- In May 2022, hired a Chief Risk Officer to lead our ongoing corporate compliance, internal audit and enterprise risk management efforts.
- In May 2022, established a SOX Steering Committee with Internal Audit and key members of Finance and IT management to achieve our remediation goals.
- In June 2022, hired a Senior Director, Internal Audit with broad financial and information technology control experience who focuses on the development, maintenance and monitoring of our overall control environment and system of key internal controls over financial reporting.

We remain committed to the continued hiring and on-boarding of additional members of the organization supporting the internal control over financial reporting. As of June 30, 2022, we have filled key positions within the Finance and IT organization and will continue to add skilled talent as complexities grow and needs arise.

These investments in resources have significantly improved the stability of our accounting organization. While significant progress has been made in response to the material weakness in the control environment, remediation plan activities include ongoing training programs and hiring of additional resources in support of certain control activities.

We believe the measures described above will facilitate the remediation of the control deficiencies we have identified and strengthen our internal control over financial reporting. We are committed to continuing to improve our currently designed and implemented internal control processes. The material weakness will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control Over Financial Reporting

The remediation activities described above are changes in internal control over financial reporting during the quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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 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 current Chief Operating Officer and Chief Financial 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 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 and briefs for the appeal are now due in September and October 2022. We believe the class action to be without merit and plan to defend ourselves vigorously.

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

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report on Form 10-Q, including our financial statements and the related notes thereto, before making a decision to invest in our common stock. The realization of any of the following risks could materially and adversely affect our business, financial condition, operating results and prospects. In that event, the price of our common stock could decline, and you could lose part or all of your 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 or 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 that you should consider before investing in our company, as more fully described below. The principal factors and uncertainties that make investing in our company risky include, among others:

- changes in federal health care program coverage and CMS reimbursement rates for the Zio service could affect the adoption and profitability of our Zio service;
- if third-party commercial payors do not provide any or adequate reimbursement, rescind or modify their reimbursement policies, or delay payments for our Zio service, including as a result of CMS or MAC reimbursement rates, including Novitas Solutions reimbursement rates for our Zio XT service, or if we are unable to successfully negotiate reimbursement contracts, our commercial success could be compromised;
- the COVID-19 pandemic and efforts to reduce its spread have adversely impacted, and is expected to continue to materially and adversely impact, our business and operations;

- we have a history of net losses, which we expect to continue, and we may not be able to achieve or sustain profitability in the future;
- our business is dependent upon physicians adopting our Zio service and if we fail to obtain broad adoption, our business would be adversely affected;
- we plan to introduce new products and services and our business will be harmed if we are not successful in selling these new products and services to our existing customers and new customers;
- the market for ambulatory cardiac monitoring solutions is highly competitive. If our competitors are able to develop or market monitoring products and services that are more effective, or gain greater acceptance in the marketplace, than any products and services we develop, our commercial opportunities will be reduced or eliminated;
- we have recently experienced management turnover, which creates uncertainties and could harm our business;
- we may become a party to intellectual property litigation, litigation resulting from employment disputes, or administrative proceedings that could be costly and could interfere with our ability to provide the Zio service;
- changes in the regulatory environment may constrain or require us to restructure our operations, which may harm our revenue and operating results; and
- we must obtain new product clearances, approvals, and/or certifications from various U.S. and international regulatory agencies, and changes in the regulatory environment or increased complexity in the products may create challenges and risks in obtaining such regulatory approvals.

Additional risks, beyond those summarized above or discussed elsewhere in this Quarterly Report on Form 10-Q, may apply to our activities or operations as currently conducted or as we may conduct them in the future or in the markets in which we operate or may in the future operate.

Risks Related to Our Business

The COVID-19 pandemic and efforts to reduce its spread have adversely impacted, and is expected to continue to materially and adversely impact, our business and operations.

The COVID-19 pandemic has had, and is expected to continue to have, an adverse impact on our operations, particularly as a result of preventive and precautionary measures that we, other businesses, and governments are taking. Although we saw recovery of patient registrations for the Zio service beginning in 2021, we expect these challenges of the COVID-19 pandemic to continue to impact the volume of Zio services provided for the duration of the pandemic, however, its extent cannot be quantified at this time. Our customers' patients are also experiencing the economic impact of the current pandemic. Even an important diagnostic procedure like the Zio service may be less of a priority than other items for those patients who have lost their jobs, are furloughed, have reduced work hours or are worried about the continuation of their medical insurance. Such economic effects on patients may delay or disrupt our ability to both provide our service and collect co-payments or out-of-pocket costs, which would have an adverse effect on our revenue and cash flow. Patients may also be reluctant to visit their physicians or hospitals due to fear of contracting COVID-19. Physicians are not performing as many diagnostic tests for their patients, and the facilities where these tests are performed may not be adequately staffed, open during regular business hours, or open at all. Even where physicians continue to treat symptomatic patients, in many cases treatment of asymptomatic patients is being deferred. The reduction in diagnostic testing and physician visits, the increase in deferred treatment, and changes in patient behaviors are translating into fewer Zio services being ordered.

Government mandates related to the COVID-19 pandemic have impacted, and are expected to continue to impact, our personnel and personnel at third-party manufacturing facilities in the United States and other countries, and the availability or cost of materials, which could disrupt our supply chain and reduce margins. While we have continued to deliver the Zio service in line with industry response to the COVID-19 pandemic by operating with remote employees where appropriate, and essential employees on-site where appropriate, any government mandates could further impact our ability to effectively provide the Zio service, and could impede progress of all ongoing initiatives. Appropriate social distancing techniques and other measures at our facilities have been implemented for employees who are required by job scope or who have chosen to return to our facilities.

Additionally, we have experienced increased delays in receiving Zio XT monitors back from patients at the conclusion of the Zio service, with some patients failing to return the device at all. As a result, the increased prevalence of COVID-19 could

result in negative changes to historical expectations around device return timelines and loss rates, both of which would negatively impact our finances. Finally, we anticipate that the COVID-19 pandemic may impact clinical and regulatory matters. COVID-19 is delaying enrollment in new clinical trials across the medical device industry and may affect any new trials we decide to pursue. Regulatory clearances may take extended duration of time as agencies focus on COVID-19-related priorities which, in turn, would delay our introduction of new products and services.

The COVID-19 pandemic has also created global supply chain shortages and delays, particularly for some electronic components, such as those contained in our PCBAs. We have experienced longer lead times, sometimes in excess of 52 weeks, and increased broker fees during the COVID-19 pandemic, which have increased our cost of revenue. We have also had to increase our inventory levels as a result of these potential shortages. If we are unable to secure our typical supply of components on a timely basis, it may affect our ability to provide the Zio service on a timely basis, which would affect our cash flows and ability to operate.

Any of these occurrences, individually or in concert, may significantly harm our business, financial condition, cash flows and prospects. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. This uncertain and rapidly evolving impact is having a material, adverse impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely, and could worsen over time. The extent to which the COVID-19 pandemic impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions necessary to contain COVID-19 or treat its impact, among others. We do not yet know the full extent of potential delays or impacts on our business, financial condition, cash flows and results of operations.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The COVID-19 pandemic has caused extreme volatility and disruptions in the global capital and credit markets. A severe or prolonged economic downturn, could result in a variety of risks to our business, including driving hospitals to tighten budgets and curtail spending, which would negatively impact our sales and business. In addition, higher unemployment rates or reductions in employer-provided benefits plans could result in fewer commercially insured patients, which could negatively impact our revenue and business as a result. A weak or declining economy could also strain our third-party manufacturers or suppliers, possibly resulting in supply disruptions, or cause our customers to delay making payments for our Zio service. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely affect our business.

We have a history of net losses, which we expect to continue, and we may not be able to achieve or sustain profitability in the future.

We have incurred net losses since our inception in September 2006. The losses and accumulated deficit were primarily due to the substantial investments we made to develop and improve our technology and products and improve our business and the Zio service through research and development efforts and infrastructure improvements. Over the next several years, we expect to continue to devote substantially all of our resources to increase the adoption of and reimbursement for our Zio service, which includes Zio XT and Zio AT, and to develop additional arrhythmia detection and management products and services. These efforts may prove more expensive than we currently anticipate and we may not succeed in increasing our revenue sufficiently to offset these higher expenses or at all. Accordingly, we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future could cause the market price of our common stock to decline.

Our business is dependent upon physicians adopting our Zio service and if we fail to obtain broad adoption, our business would be adversely affected.

Our success will depend on our ability to bring awareness to the Zio service and educate physicians regarding the benefits of our Zio service over existing products and services, such as traditional, short-term Holter monitors and event monitors, or competitive technologies or services, and to provide sufficient evidence to support the selection of the Zio service as the appropriate ambulatory cardiac monitoring service for their patients. We do not know if the Zio service will be successful over the long term and market acceptance may be hindered if physicians are not presented with compelling clinical data demonstrating the effectiveness of our service compared to existing or alternative technologies. Any studies that we or others may conduct comparing our Zio service with alternative technologies will be expensive, time consuming and may not yield positive or definitive results. Clinical data may be subject to different interpretations, especially if the data involved are not drawn from head-to-head studies. Communications about our clinical data in relation to our products and services are also subject to a range of regulatory standards which vary depending on the audience and purpose of the communication; such communications can be subject to a high degree of scrutiny.

Additionally, adoption will be directly influenced by a number of financial factors, including the ability of patients or providers to obtain sufficient coverage or reimbursement from payors for the Zio service. The effectiveness, safety, performance, and affordability of our Zio service, both on a stand-alone basis and relative to competing services, will impact the availability of and access to the Zio service. We do not have direct payor contracts with contracted rates with all major payors for the Zio service. Physicians may be reluctant to prescribe the Zio service to patients who have coverage with non-contracted payors due to the inherent uncertainty surrounding reimbursement rates from such non-contracted payors and the out-of-pocket cost to the patient, as well as any associated administrative burden of engaging with patients to answer their questions and support their efforts to reduce their cost for the Zio service in such situations. If physicians do not adopt and prescribe our Zio service, our revenue will not increase and our financial condition will suffer as a result.

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

As demand for the Zio service 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;
- key components of the Zio monitors are provided by a 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 monitors, 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;
- shelter-in-place orders and other restrictions in effect in California and elsewhere due to the COVID-19 public health emergency;
- we may experience a delay in completing validation and verification testing for new production processes and/or equipment at our manufacturing facilities;
- we are subject to state, federal and international regulations and standards, including, but not limited to, the FDA's Quality System Regulation ("QSR"), the EU's Medical Device Directive ("MDD") and the EU's Medical Device Regulation ("MDR"), and the developing regulations by Medicines & Healthcare Regulatory Agency (MHRA) post Brexit in the United Kingdom for both the manufacture of the Zio monitor and the provision of the Zio service, noncompliance with which could cause an interruption in our manufacturing and services;
- 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 the Zio service.

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

Our design and manufacturing facilities and processes and those of our third-party suppliers are subject to unannounced FDA, state and Notified Body regulatory inspections for compliance with various regulations and standards, including the QSR, MDD, MDR, UK MDR requirements. Developing and maintaining a compliant quality system is time consuming and investment intensive. Requirements and standards may change and evolve over time and we will need to adapt. For example, the FDA has proposed revisions to the Quality System Regulation aimed at aligning with the international standard ISO 13485. Failure to maintain compliance with, or not fully complying with the requirements of the FDA and state regulators could result in enforcement actions against us or our third-party suppliers, 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 compliance with, or not fully complying with the requirements of MDD, MDR, and UK MDR could result in similar disruptions in these markets.

We depend on third-party vendors to manufacture some of our components, which could make us vulnerable to supply shortages and price fluctuations that could harm our business.

We rely on third-party vendors for components and sub-assemblies used in our Zio monitors. 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;
- interruption of supply, including shortages and delays, resulting from modifications to, or discontinuation of, a supplier's operations, including those caused by pandemics such as COVID-19, or by military conflict or political or economic disruption, including shortages impacting our PCBAs;
- 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 products;
- delays in product shipments resulting from product quality issues or defects, reliability issues, or a supplier's failure to consistently produce quality components;
- an outbreak of disease or similar public health threat, such as the existing threat of coronavirus, particularly as it may impact our supply chain;
- 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.

Any significant delay or interruption in the supply of components or sub-assemblies, or our inability to obtain substitute components, sub-assemblies or materials from alternate sources at acceptable prices and in a timely manner could impair our ability to meet the demand for our Zio service and harm our business.

Our revenue relies substantially on our Zio service, which is currently our only offering. If the Zio service or future product offerings fail to gain, or lose, market acceptance, our business will suffer.

Our current revenue is dependent on orders for the Zio service, and we expect that reimbursement for the Zio service will account for substantially all of 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 the Zio service; however, there can be no assurance that we will be able to successfully develop and commercialize any new products or services. Any new products may not be accepted by physicians or may merely replace revenue generated by our Zio service and not generate additional revenue. If we have difficulty launching new products, 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 selling effort. If we are unable to increase orders for the Zio service, expand reimbursement for the Zio service, or successfully develop and commercialize new products and services, our revenue and our ability to achieve and sustain profitability would be impaired.

Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business.

Our quarterly and annual results of operations, including our revenue, profitability and cash flow, may vary significantly in the future and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuation in quarterly and annual results may decrease the value of our common stock. Factors that may cause fluctuations in our quarterly and annual results include, without limitation:

- market awareness and acceptance of the Zio service;
- our ability to get payors under contract at acceptable reimbursement rates;
- the availability of reimbursement for the Zio service at acceptable rates through government programs;
- our ability to attract new customers and improve our business with existing customers;
- results and interpretations of clinical trials providing data relevant to the Zio service, whether conducted by us, competitors or third parties;
- the timing and success of new product introductions or product improvements by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations;
- changes in our pricing policies or those of our competitors;
- general economic, industry and market conditions;
- the impact of the COVID-19 pandemic on our operations and financial results;
- the regulatory environment;
- expenses or loss of sales associated with unforeseen product quality issues;
- timing of physician orders and demand for our Zio service;
- seasonality factors, such as patient and physician vacation schedules, severe weather conditions, and insurance deductibles, that hamper or otherwise restrict when a patient seeking diagnostic services such as the Zio service visits the ordering physician;
- the hiring, training, and retention of key employees, including our ability to expand our sales team and clinical operations team and to expand and coordinate our compliance training efforts in tandem;
- litigation or other claims against us for intellectual property infringement or otherwise;
- our ability to obtain additional financing as necessary; and
- advances and trends in new technologies and industry standards.

Because our quarterly results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

We have noticed seasonality in the use of our Zio service which, along with other factors such as severe weather, may cause quarterly fluctuations in our revenue.

During the summer months and the holiday seasons, we have observed that the use of our Zio service decreases, which reduces our revenue during those periods. We believe that the decrease in orders may result from physicians or their patients taking vacations. Certain weather conditions, including natural disasters, may also hamper or otherwise impact visits to ordering physicians or prevent patients from seeking diagnostic services, such as the Zio service. Similarly, we generally experience some effects of seasonality due to the renewal of insurance deductibles at the beginning of the calendar year. These factors may cause our results of operations to vary from quarter to quarter.

Reimbursement by CMS is highly regulated and subject to change; our failure to comply with applicable regulations could result in decreased revenue and may subject us to penalties or have an adverse impact on our business.

For the six months ended June 30, 2022, we received approximately 23% of our revenue from reimbursement for our Zio service by CMS. Under CMS guidelines for participation in the Medicare program CMS designates us as an IDTF. CMS imposes extensive and detailed requirements on IDTFs, including but not limited to: rules that govern how we structure our relationships with physicians, how and when we submit reimbursement claims, how we operate our monitoring facilities, and how and where we provide our monitoring services. Our failure to comply with applicable CMS rules could result in a discontinuation of our reimbursement under the CMS payment programs, our being required to return funds already paid to us, civil monetary penalties, criminal penalties and/or exclusion from CMS programs.

Changes in federal health care program coverage and CMS reimbursement rates for the Zio service could affect the adoption and profitability of our Zio service.

Government payors may change their coverage and reimbursement policies, as well as payment amounts, in a way that would prevent or limit reimbursement for our Zio service, which would significantly harm our business. Government and other third-party payors require us to report the service for which we are seeking reimbursement by using a Current Procedural Terminology ("CPT") code-set maintained by the American Medical Association ("AMA"). For Zio XT, we had historically utilized temporary CPT codes (or Category III CPT codes), used for newly introduced technologies specific to our category of diagnostic monitoring. The process to convert temporary Category III CPT codes to permanent Category I CPT codes is governed by the AMA and CMS.

Determinations of which products or services will be eligible for reimbursement by Medicare can be developed at the national level through a national coverage determination ("NCD") issued by CMS or at the local level through a local coverage determination ("LCD"), issued by one or more of the regional Medicare Administrative Contractors ("MACs"), who are private contractors that process and pay claims on behalf of CMS for different geographic regions. In the absence of a specific NCD, as has historically been the case with the Zio XT service, the MAC with jurisdiction over a specific geographic region will have the discretion to issue an LCD. Our Zio service may be eligible for reimbursement at the rates set by the regional MACs until CMS establishes national payment rates for the CPT codes that we use to seek reimbursement for the Zio XT service.

On October 25, 2019, the AMA's CPT Editorial Panel established eight new Category I CPT codes that are applicable to the Zio XT service and took effect on January 1, 2021. Category I CPT codes 93241 through 93248 are split between two sets of four codes with rates tied to those codes for (i) wear-time of greater than 48 hours and up to 7 days, and (ii) greater than 7 days and up to 15 days. We primarily rely on 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) to seek reimbursement for our Zio XT service. In November 2021, CMS published the Calendar Year 2022 Medicare Physician Fee Schedule Final Rule (the "2022 Final Rule"). In the 2022 Final Rule, CMS did not establish national pricing for Calendar Year 2022 for Category I CPT codes 93241, 93243, 93245 and 93247, which include the two CPT codes upon which we primarily rely for our Zio XT service. Instead, CMS designated these for contractor pricing in Calendar Year 2022, which meant that prices would be set regionally by each MAC.

In January 2022, Novitas Solutions, the MAC which covers the region where our IDTF in Houston, Texas is located, updated reimbursement rates for CPT codes 93243 and 93247 for its jurisdiction to $223 and $233, respectively. These updated rates were retroactive to January 1, 2022. These rates were higher than the rates posted by Novitas in 2021, but continue to be significantly below historical Medicare rates for our Zio XT service. In April 2022, NGS, the MAC which covers the region where our IDTF in Deerfield, Illinois is located, updated reimbursement rates for CPT codes 93243 and 93247 for its jurisdiction to $335 and $347, respectively. These updated rates were retroactive to January 1, 2022. These rates are higher than the historical Medicare rates for our Zio XT service.

In July 2022, CMS published its Calendar Year 2023 Medicare Physician Fee Schedule Proposed Rule (the "2023 Proposed Rule"). In the 2023 Proposed Rule, CMS proposed national payment rates for the Category I CPT codes that we primarily use to seek reimbursement for our Zio XT service. In the 2023 Proposed Rule, CMS proposed relative value units for CPT codes 93247 and 93243 and a Calendar Year 2023 "Conversion Factor" which we interpret, collectively with the Medicare payment reduction (sequestration) and the sequestration under the Statutory Pay-As-You-Go Act of 2010, to imply national payment rates of $215 and $204 for CPT codes 93247 and 93243 codes, respectively. Based on the proposed Calendar Year 2023 Geographic Practice Cost Index ("GPCI") modifiers applicable to the locations of our Medicare-enrolled IDTFs in Deerfield, Illinois, Houston, Texas, and San Francisco, California, we estimate the applicable payment rates could range from $218 to $295 for CPT code 93247 and $207 to $280 for CPT code 93243.

The 2023 Final Rule is expected to be announced by November 2022 for implementation on January 1, 2023. It is possible that CMS will adopt a lower national rate, a higher national rate, or continue applying contractor pricing.

We remain engaged with CMS and all of the MACs, and are working with other industry participants to submit additional cost data on long-term ECG monitoring for consideration to establish appropriate national or local rates. We cannot provide certainty at this time on the potential outcome of the discussions with the CMS or MACs or on the timing of any action to be taken.

Given the evolving nature of the healthcare industry and ongoing healthcare cost reforms, we are and will continue to be subject to changes to the level of Medicare coverage and reimbursement for our Zio service, and unfavorable coverage determinations at the national or local level could adversely affect our business and results of operations.

Further, a reduction in coverage by Medicare could cause some commercial third-party payors to implement similar reductions in their coverage or level of reimbursement of the Zio service. Although a large majority of commercial customers have re-contracted the Zio XT service at pre-existing rates since the establishment of the Category I codes on January 1, 2021, if we are unsuccessful in improving the Medicare rates, we believe that commercial rates may begin to be more negatively impacted.

As a result of the CPT code changes that took effect January 1, 2021, the number of claims from the first half of 2021, which contained differences between the submitted price and reimbursement rate and overall denials, increased significantly compared to our historical experience as a result of CPT code transition issues with the payors. We continue to work with the payors to collect on these claims, however, the collection cycle for these claims is significantly longer than usual and may lead to higher write-offs of doubtful accounts for those periods and negatively impact our results of operations.

If we are unable to achieve a level of revenues adequate to support our cost structure, or are unable to reduce our overall cost structure, this would raise substantial doubts about our ability to continue as a going concern.

Controls imposed by CMS and commercial third-party payors designed to reduce costs, commonly referred to as "utilization review," may 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 sampling of CMS patients must be reviewed by quality improvement organizations, which review the appropriateness of orders for services, the quality of care provided, and the appropriateness of reimbursement costs. Quality improvement organizations may deny payment for services or assess fines, and also have the authority to recommend to the U.S. Department of Health and Human Services, that a provider in substantial noncompliance with the standards of the quality improvement organization be excluded from participation in the Medicare program. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (the "Affordable Care Act"), potentially expands the use of prepayment review by Medicare contractors by eliminating statutory restrictions on their use and, as a result, efforts to impose more stringent cost controls are expected to continue. Utilization review is also a requirement of most non-governmental managed care organizations and other third-party payors. To date these controls have not had a significant effect on our operations, but significant limits on the scope of services reimbursed and on reimbursement rates and fees could have a material, adverse effect on our business, financial position, and results of operations in the future.

Each state's Medicaid program has its own coverage determinations related to our services, and some state Medicaid programs do not provide their recipients with coverage for our Zio service. Even if our Zio service is covered by a state Medicaid program, we must be enrolled as a Medicaid provider by the state in which the Medicaid recipient resides in order for us to be reimbursed by a state's Medicaid program. Even if we are recognized as a provider in a state, Medicare's rate for our Zio service may be low, and the Medicaid reimbursement amounts are sometimes as low, or lower, than the Medicare reimbursement rate. As a result of all of these factors, our Zio service is not reimbursed or only reimbursed at a very low dollar

amount by many state Medicaid programs; in some cases, a state Medicaid program's reimbursement rate for our Zio service might be zero dollars. Additionally, certain states may require Medicaid recipients to pay for part of the Zio service, and since the recipients of Medicaid are low-income individuals, we are often unable to collect any amounts directly from individual recipients of the Zio service covered by Medicaid. Low or zero-dollar Medicaid reimbursement rates for our Zio service would have an adverse effect on our business, gross margins, and revenues. Most of the Zio services we provide are reimbursed through Medicare or private third-party payors, not Medicaid, but if that were to change in the future, or the percentage of Zio services provided to Medicaid recipients were to increase, our gross margins would be adversely affected as a result.

Also, healthcare reform legislation or regulation may be proposed or enacted in the future that may adversely affect such policies and amounts. Changes in the healthcare industry directed at controlling healthcare costs or perceived over-utilization of ambulatory cardiac monitoring products and services could reduce the volume of Zio services ordered by physicians. If more healthcare cost controls are broadly instituted throughout the healthcare industry, the volume of cardiac monitoring solutions ordered could decrease, resulting in pricing pressure and declining demand for our Zio service. We cannot predict whether and to what extent existing coverage and reimbursement will continue to be available. If physicians, hospitals, and clinics are unable to obtain adequate coverage and government reimbursement of the Zio service, they are significantly less likely to use the Zio service and our business and operating results would be harmed.

In addition, any changes to, or repeal of, the Affordable Care Act or its implementing regulations may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

If third-party commercial payors do not provide any or adequate reimbursement, including as a result of the CMS and MAC reimbursement rates for our Zio XT service, rescind or modify their reimbursement policies, or delay payments for our Zio service, or if we are unable to successfully negotiate reimbursement contracts, our commercial success could be compromised.

We receive a substantial portion of our revenue from third-party private commercial payors, such as medical insurance companies. These commercial payors may reimburse our Zio service at inadequate rates, suspend or discontinue reimbursement at any time, impose requirements that may result in a greater number of denied claims, or require or increase co-payments from patients. The recent actions taken by CMS and MACs, including Novitas Solutions, to reduce the reimbursement rates for use of the Zio XT service by Medicare patients could influence the price that commercial payors are willing to pay for our Zio service. Contracts with commercial payors, which set forth the Zio XT service reimbursement rates for us and ordering physicians, could be terminated, or payors could seek to renegotiate them at any time to try to obtain pricing at reduced amounts at or near the Novitas Solutions reimbursement rates. Some payors do not have contracts with us, and others that are already in the process of negotiating contracts may look to negotiate lower reimbursement rates for the Zio XT service in response to actions taken by Novitas Solutions. Any such actions could have a significant and adverse effect on our revenue and the revenue of physicians who prescribe our Zio service. Physicians may not order our Zio service unless payors reimburse a substantial portion of the submitted costs, including the physician, hospital, or clinic's charges related to the application of certain products, including the Zio monitor and the interpretation of results which may inform a diagnosis. Additionally, certain payors may require that physicians order another arrhythmia diagnostic monitoring option prior to ordering the Zio service. There is significant uncertainty concerning third-party reimbursement of any new product or service until a contracted rate is established. Reimbursement by a commercial payor may depend on a number of factors, including, but not limited to, a payor's determination that the ordered service is:

- not experimental or investigational;
- appropriate for the specific patient;
- cost effective;
- supported by peer-reviewed publications; and
- accepted and used by physicians within their provider network.

Since each payor makes its own decision as to whether to establish a policy concerning reimbursement, or enter into a 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 third-party commercial payors, or do not continue to validate the clinical value of the Zio service through studies and physician adoption, the amount that we are reimbursed for our products may decline, our revenue may become less predictable, and we will need to expend more efforts on a claim-by-claim basis to obtain reimbursement for our products.

A substantial portion of our revenue is derived from third-party commercial payors who have pricing contracts with us, which means that the payor has agreed to a defined reimbursement rate for our services. These contracts provide a high degree of certainty to us, physicians, clinics and hospitals with respect to the rate at which our services will be reimbursed. These contracts also impose a number of obligations regarding billing and other matters, and our noncompliance with a material term of such contracts may result in termination of the contract and loss of any associated revenue. We expect to continue to dedicate resources to maintaining compliance with these pricing contracts, to ensure payors acknowledge and are aware of the clinical and economic value of our services, and the interest on the part of physicians, clinics, and hospitals who use our services and participate in their provider networks. However, we can provide no assurance that we will retain any given contractual payor relationship. A loss of these pricing contracts can increase the uncertainty of reimbursement of claims from third-party payors.

A portion of our revenue is derived from third-party commercial payors without such contracts in place. Without a contracted rate, reimbursement claims for our products are often denied upon submission, and we or our outside billing partner, XIFIN, Inc. ("XIFIN"), must appeal the denial. The appeals process is time-consuming, expensive, and may not result in full payment or any payment at all. In cases where there is no contracted rate for reimbursement it may be more difficult for us to acquire new accounts with physicians, clinics, and hospitals. In addition, in the absence of a contracted rate, there is typically a greater out-of-network, co-insurance or co-payment requirement which may result in payment delays or decreased likelihood of full collection. In some cases involving non-contracted insurance companies, we may not be able to collect any amount or may only be able to collect a portion of the invoiced amount for our services.

We expect to continue to dedicate resources to establishing pricing contracts with non-contracted insurance companies; however, we can provide no assurance that we will be successful in obtaining such pricing contracts or that such pricing contracts will contain reimbursement for our services at appropriate rates. If we fail to establish these contracts, we will be able to recognize revenue only based on an estimated average collection rate per historical cash collections. In addition, XIFIN may need to expend significant resources obtaining reimbursement on a claim-by-claim basis and in adjudicating claims which are denied altogether or not reimbursed at acceptable rates. We currently pay XIFIN a percentage of the amounts it collects on our behalf and this percentage may increase in the future if it needs to expend more resources in adjudicating such claims. We sometimes informally engage physicians, hospitals, and clinics to help establish contracts with third-party payors who insure their patients. We cannot provide any assurance that such physicians, hospitals, and clinics will continue to help us establish contracts in the future. Failure to establish contracts with more third-party payors may adversely affect our ability to increase our revenue. In addition, a failure to enter into contracts could affect a physician's willingness to order our services because of the administrative work involved in interacting with patients to answer their questions and help them obtain reimbursement for our services. If physicians are unwilling to order our services due to the lack of certainty and administrative work involved with patients covered by non-contracted insurance companies, or patients covered by non-contracted insurance companies are unwilling to risk that their insurance may charge additional out-of-pocket fees, our revenue could decline or fail to increase.

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 monitors, market, sell and support our Zio service, and analyze the data to produce Zio reports, which could result in inefficiencies and unanticipated costs, impacts to Zio reports or manufactured devices, and disruptions to our service operations. Additionally, rapid expansion could require us to rely on overtime to increase capacity that could, in turn, result in greater employee attrition and/or a loss in productivity during the process of recruiting and training additional resources and add to our operating expenses.

As we seek to gain greater efficiency, we may expand the automated portion of our Zio service and require productivity improvements from our certified cardiographic technicians. 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.

If we are unable to support demand for the Zio service or any of our future products or services, our business could suffer.

As demand for the Zio service or any of our future products or services increases, we will need to continue to scale our manufacturing capacity and algorithm processing technology, expand customer service, billing, and systems processes, and enhance our internal quality assurance program. We will also need to expand clinical operations, including adding certified cardiographic technicians and other personnel to process higher volumes of data. We cannot assure you that, with any increases in scale, required improvements will be successfully implemented, quality assurance will be maintained, or that appropriate personnel will be available to facilitate growth of our business. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing data or inability to meet increased demand. There can be no assurance that we will be able to perform our data analysis at a level consistent with demand, quality standards, and physician expectations. If we encounter difficulty meeting market demand, quality standards, or physician expectations, our reputation could be harmed and our future prospects and business could suffer.

We plan to introduce new products and services, and our business will be harmed if we are not successful in selling these new products and services to our existing customers and new customers

We have received FDA clearance for our Zio AT ECG Monitoring System, ("Zio AT"), which is designed to provide timely transmission of data during the wear period. However, we do not yet know whether Zio AT or any other new products and services will be well received and broadly adopted by physicians and their patients or whether sales will be sufficient for us to offset the costs of development, implementation, support, operation, sales, and marketing. Although we have performed extensive testing of our new products and services, their broad-based implementation may require more support than we anticipate, which would further increase our expenses. Additionally, new products and services may subject us to additional risks of product performance, customer complaints, and litigation. If orders of our new products and services are lower than we expect, or if we expend additional resources to fix unforeseen problems and develop modifications, our operating margins are likely to decrease.

We rely on single suppliers for some of the materials used in our products, and if any of those suppliers are unable or unwilling to produce these materials or supply them in the quantities that we need at the quality we require, we may not be able to find replacements or transition to alternative suppliers before our business is materially impacted.

We rely on single suppliers for the supply of our adhesive sub-assembly, disposable plastic housings, instruments and other materials that we use to manufacture and label our Zio monitors. These components and materials are critical and, in some cases, there are relatively few alternative sources of supply. 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 monitors if our existing suppliers were unable to satisfy our supply requirements. To utilize other supply sources, we would need to identify and qualify new suppliers to our quality standards, which could result in manufacturing delays and increase our expenses. Any supply interruption, such as those that we have experienced during the COVID-19 pandemic, could limit our ability to manufacture our products and could therefore harm our business, financial condition and results of operations. If our current suppliers and any alternative suppliers do not provide us with the materials we need to manufacture our products or perform our services, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, an interruption in our Zio service could occur. Any such interruption may significantly affect our future revenue and harm our relations and reputation with physicians, hospitals, clinics and patients.

If our manufacturing facility becomes damaged or inoperable, or if we are required to vacate the facility, we may be unable to manufacture and ship our Zio monitors, or we may experience delays in production or an increase in costs which could adversely affect our results of operations.

We currently manufacture and assemble the Zio monitors in a single location. Our products are comprise of components sourced from a variety of contract manufacturers, with final assembly completed at our facility in Cypress, California. Our facility and equipment, or those of our suppliers, could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, terrorism, pandemic outbreaks, flooding and power outages. Any of these may render it difficult or impossible for us to manufacture new products, ship assembled products, and/or receive returned units for some period of time. If our Cypress facility is inoperable for even a short period of time, the inability to manufacture, ship and receive our Zio monitors, and the interruption in research and development of any future products, may result in harm to our reputation, increased costs, the loss of orders and lower revenue. Furthermore, it could be costly and time consuming to repair or replace our facilities and the equipment we use to perform our research and development work and manufacture our products.

If we fail to increase our sales and marketing capabilities and develop broad brand awareness in a cost-effective manner, our growth will be impeded, and our business may suffer. However, increasing our sales and marketing efforts may expose us to additional risk from regulators, enforcement authorities, and competitors.

We plan to continue to expand and optimize our sales and marketing infrastructure in order to increase our ordering physician base and our business. Identifying and recruiting qualified personnel and training them in the application of the Zio service, on compliance with applicable federal and state laws and regulations, and our related internal policies and procedures, requires significant time, expense, and attention. It often takes several months or more before a sales representative is fully trained and productive. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenue. In particular, if we are unable to hire, develop, and retain talented sales personnel, or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenue.

Our ability to increase our customer base and achieve broader market acceptance of our products will depend, to a significant extent, on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. Our business may be harmed if our marketing efforts and expenditures do not generate a corresponding increase in revenue.

In addition, we believe that developing and maintaining broad awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of the Zio service and penetrating new accounts. Brand promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain, and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of the Zio service.

Our sales and marketing efforts and initiatives may subject us to additional scrutiny of our practices of effective communication of risk information, benefits, or claims under the oversight of the FDA, the Federal Trade Commission ("FTC"), or both agencies. For example, the FDA applies a heightened level of scrutiny to comparative claims when applying its statutory standards for advertising and promotion, including with regard to its requirement that promotional labeling be truthful and not misleading. There is potential for differing interpretations of whether certain communications are consistent with a product's FDA-required labeling, and FDA will evaluate communications on a fact-specific basis. In addition, making comparative claims may draw scrutiny from our competitors. Where a company makes a claim in advertising or promotion that its product is superior to the product of a competitor (or that the competitor's product is inferior), this creates a risk of a lawsuit by the competitor under federal and state false advertising or unfair and deceptive trade practices law, and possibly also state libel law. Such a suit may seek injunctive relief against further advertising, a court order directing corrective advertising, and compensatory and punitive damages where permitted by law. If our compliance program and training and monitoring do not effectively keep pace with our sales and marketing growth, we may encounter increased risk in execution of activities by our personnel, potential enforcement and other exposure.

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

Billing for IDTF services is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill several types of payors, including CMS, third-party commercial payors, healthcare providers, healthcare institutions, and patients, which may have different billing requirements, procedures, or expectations. We also must bill patient co-payments, co-insurance, and deductible amounts. We 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 price for our Zio service and the reimbursement rates of payors;
- compliance with complex federal and state regulations related to billing CMS;
- differences in coverage among payors and the effect of patient co-payments, co-insurance, and deductible amounts;
- differences in information and billing requirements among payors; and
- incorrect or missing patient history, indications, or billing information.

As a result of the CPT code changes that took effect January 1, 2021, the number of claims from the first half of 2021 which contained differences between the submitted price and reimbursement and overall denials increased significantly compared to our historical experience as a result of CPT code transition issues with the payors. We continue to work with the payors to collect on these claims and the collection cycle for these claims is significantly longer than usual and may lead to higher write-offs of doubtful accounts for those periods and negatively impact our results of operations.

Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, and undertake internal review procedures to evaluate compliance with applicable laws, regulations, and internal policies. Payors also conduct audits to evaluate claims, which may add further cost and uncertainty to the billing process. These billing complexities, and the related uncertainty in obtaining payment for our Zio service, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

The operation of our call centers and monitoring facilities is subject to rules and regulations governing IDTFs; failure to comply with these rules could prevent us from receiving reimbursement from CMS and some commercial payors.

In order to be enrolled in the Medicare program and reimbursed by CMS under the program, we established an IDTF. An IDTF is a "provider-type" designation under Medicare, defined by CMS as an entity independent of a hospital or physician's office in which diagnostic tests are performed by licensed, certified, or otherwise qualified nonphysician personnel under appropriate physician supervision. Our IDTFs are staffed by certified cardiographic technicians, who are overseen by a medical director who provides general supervision, including overall direction and control, of the tests performed by our IDTF, but who is not required to be present for tests. The existence of an IDTF allows us to bill a government payor for the Zio service through one or more MACs, such as Novitas Solutions, Noridian Healthcare Solutions, and Palmetto GBA. MACs are companies that operate on behalf of the federal government to process Medicare claims for reimbursement and allow us to obtain reimbursement for our Zio service at CMS or local MAC defined rates. Enrollment as an IDTF requires that we follow strict regulations governing how the center operates, such as requirements regarding the experience and certifications of the cardiographic technicians and supervising physicians. In addition, many commercial payors require our IDTFs to maintain accreditation and certification with the Joint Commission of American Hospitals. To do so we must demonstrate a specified quality standard and are subject to routine inspection and audits. These rules and regulations vary from location to location and are subject to change and differing interpretations. If they change, we may have to change the operating procedures at our IDTFs, which could increase our costs significantly. If we fail to obtain and maintain IDTF enrollment or accreditation and certification, our Zio service may no longer be reimbursed by CMS and some commercial payors, which would have a material adverse impact on our business.

During the second quarter of 2022, we recognized approximately six percent of our revenue from non-contracted third-party payors, and as a result, our quarterly operating results are difficult to predict.

We have limited visibility as to when we will receive payment for our Zio service 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 rely on a third-party billing company, XIFIN, to transmit and pursue claims with payors. A delay in transmitting or pursuing claims could have an adverse effect on our revenue.

While we manage the overall processing of claims, we rely on XIFIN to transmit substantially all of our claims to payors and pursue most claim denials. If XIFIN fails to submit claims for our Zio service to payors on a timely basis, if claims are not properly adjudicated upon a denial, or if we are required to switch to a different claims processor, we may experience delays in our ability to process receipt of payments from payors, which would have an adverse effect on our revenue and our business.

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

The market for ambulatory cardiac monitoring products and services is evolving rapidly and becoming increasingly competitive. Our Zio service competes with a variety of products and services that provide alternatives for ambulatory 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 the Zio service. Our ability to compete effectively depends on our ability to distinguish our company and the Zio service 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 ambulatory 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.) offer ambulatory cardiac monitoring services and also function as service providers. 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. Large medical device companies may continue to acquire or form alliances with these smaller companies in order to diversify their product offering and participate in the digital health space.

We have 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. has added capabilities on its watch platform to measure non-continuous ECG and to alert users to the potential presence of irregular heartbeats suggestive of asymptomatic AF. These competitors and potential competitors may introduce new products and services that more directly compete with our Zio service. Recently, there has been increased acquisition activity and consolidation in our industry. Many of our competitors and potential competitors have significantly greater financial and other resources than we do and have well-established reputations, broader product offerings, and worldwide distribution channels that are significantly larger and more effective than ours. If our competitors and potential competitors are better able to develop new ambulatory cardiac monitoring solutions than us, or develop more effective or less expensive cardiac monitoring solutions, they may render our current Zio service obsolete or non-competitive. Competitors may also be able to deploy larger or more effective sales and marketing resources than we currently have. Competition with these companies could result in price cutting, reduced profit margins, and loss of market share, any of which would harm our business, financial condition and results of operations.

In a competitive environment, a company's communications may also be subject to heightened scrutiny from regulators and competitors. Our communications are subject to compliance with laws, regulations, and guidance regarding promotional communications, including advertising and promotional labeling, and non-promotional communications, including certain educational and scientific exchanges. We are also subject to potential actions under federal law, including the Lanham Act, and congruous state law, which are designed to protect businesses against the unfair competition of misleading advertising or labeling.

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

The market for medical devices, including the ambulatory 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 ours, these barriers can be overcome. Demand for the Zio service and future related products or services could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our products and services could become obsolete and our revenue would decline as our customers purchase our competitors' products and services.

In order to remain competitive, we must continue to develop new product offerings and enhancements to the Zio service. 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 service, developing new products, or commercializing them in ways that achieve market acceptance. In addition, if we develop new products, sales of those products may reduce revenue generated from our existing products. Maintaining adequate research and development personnel and resources to meet the demands of the market is essential. If we are unable to develop new products, applications, or features, or improve our algorithms due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills, or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors devote a considerably greater amount of funds to their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

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

We have entered into a development agreement with Verily Life Sciences LLC (an Alphabet Company, referred to as "Verily") to develop certain next-generation AF screening, detection, or monitoring products, which involve combining Verily and our technology platforms and capabilities (the "Development Agreement"). As part of the Development Agreement, we paid Verily an up-front fee of $5.0 million in cash, and through June 30, 2022, we have achieved milestones and additional related payment obligations totaling $11.0 million. We have agreed to make additional payments over the term of the Development Agreement up to an aggregate of $1.75 million, subject to the achievement of certain development and regulatory milestones. The success of our collaboration with Verily is highly dependent on the efforts provided to the collaboration by Verily and us and the skill sets of our respective employees. Support of these development efforts requires significant resources, including research and development, manufacturing, quality assurance, and clinical and regulatory personnel. Even if our development and clinical trial efforts succeed, the FDA may not clear the developed products or may require additional product testing and clinical trials before clearing the developed products, which would result in product launch delays and additional expense. If cleared by the FDA, the developed products may not be accepted in the marketplace, and there is no assurance that adequate reimbursement will 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 developed products 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 products that achieve commercial success and could be terminated prior to developing any products. In the event of any termination or expiration of the Development Agreement, we may be required to devote additional resources to product 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 products, 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 products or result in significant additional future revenues for our company.

The continuing clinical acceptance of the Zio service depends upon maintaining strong working relationships with physicians. These relationships are subject to a high degree of scrutiny by government regulators and enforcement bodies.

The development, marketing, and ordering of the Zio service depends upon our ability to maintain strong working relationships with physicians and other key opinion leaders. We rely on these professionals' knowledge and experience for the development and marketing of our Zio service. Among other things, physicians assist us in clinical trials and product development matters and provide public presentations at trade conferences regarding the Zio service. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of the Zio service could suffer, which could harm our business, financial condition, and results of operations.

At the same time, the medical device industry's relationship with physicians is under increasing scrutiny by the Health and Human Services Office of the Inspector General ("OIG"), the Department of Justice ("DOJ"), state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules, and regulations governing our relationships

with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general, or other government agencies, could significantly harm our business.

We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future.

As of June 30, 2022, we had $34.9 million outstanding under our term loan provided by of our loan agreement with Silicon Valley Bank ("SVB"). We must make significant annual debt payments under the loan agreement which will divert resources from other activities. Our debt with SVB is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to, among other things, dispose of assets, undergo a change in control, merge or consolidate, enter into certain transactions with affiliates, make acquisitions, incur debt, incur liens, pay dividends, repurchase stock and make investments, in each case subject to certain exceptions. The covenants in the loan agreement, as well as in any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. Our ability to comply with these covenants may be affected by events beyond our control and future breaches of any of these covenants could result in a default under the loan agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the loan agreement to become immediately due and payable and terminate commitments to extend further credit. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

We are also exposed to the risk that our earnings and cash flows could be adversely impacted by fluctuations in interest rates. Our policy is to manage interest costs using the mix of fixed- and floating-rate debt, which we cannot guarantee will mitigate the risk of interest rate fluctuation.

We have recently experienced, and may continue to experience, inflationary costs and pressures, which could increase our costs and operating expenses and have a material adverse impact on our results of operations if we are unable to sufficiently reduce our expenses or offset rising costs.

We have recently experienced and may continue to experience rising costs due to inflation. We continue to monitor the effects of inflationary factors, such as increases in our cost of goods sold and selling and operating expenses, which may adversely affect our results of operations. Specifically, we have experienced inflationary costs affecting the cost of goods, including materials and the components for our Zio service, and have experienced inflationary pressure to increase the wages that we pay our employees, due to challenging labor market conditions. Competitive and regulatory conditions may restrict our ability to fully recover these costs through price increases. As a result, it may be difficult to fully offset the impact of persistent inflation. Our inability or failure to do so could have a material adverse effect on our business, financial condition, cash flow and results of operations or cause us to need to obtain additional capital in future earlier than anticipated.

We have recently experienced management turnover, which creates uncertainties and could harm our business.

We have recently experienced significant changes in our executive leadership. Quentin S. Blackford has served as our President and Chief Executive Officer since October 2021. Prior to that, Douglas Devine served as Interim Chief Executive Officer, in addition to his other roles, from June 2021 to October 2021 and Michael Coyle served as Chief Executive Officer from January 2021 to June 2021. Additionally, in March 2022, Kevin King, who was our President and Chief Executive Officer from July 2012 to January 2021, announced his resignation from the Board and is no longer a consultant to the Company.

Additionally, in June 2022, Judith Lenane retired from her position as the Company's Executive Vice President, Chief Clinical Officer, and Mintu Turakhia, M.D. M.A.S. was appointed as the Company's Chief Medical Officer and Chief Scientific Officer. In July 2022, David Vort resigned from his position as Executive Vice President, Chief Commercial Officer and Chad Patterson was hired to fill that position. Also in July 2022, we announced the expected appointment of Brice Bobzien as the Company's Chief Financial Officer and Reyna Fernandez as the Company's Executive Vice President, Chief Human Resources Officer. In connection with Brice Bobzien's appointment, Douglas Devine agreed to resign from his position as Chief Financial Officer of the Company, but will remain the Company's Chief Operating Officer.

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. In addition, executive leadership transition periods are often difficult as the new executives gain detailed knowledge of our operations, and friction can result from changes in strategy and management style. Management turnover inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution. 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 the employees noted above or other members of our management team left, other employees may follow them for new positions and those departures could harm our company as a result. If we are unable to attract and retain qualified management personnel, our business could suffer.

We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business.

Our success depends largely on the continued services of key members of our executive management team and others in key management positions. For example, the services of Quentin S. Blackford, our President and Chief Executive Officer, and Douglas J. Devine, our Chief Financial Officer and Chief Operating Officer, are essential to formulating and executing on corporate strategy and to ensuring the continued operations and integrity of financial reporting within our company. The services of Patrick Murphy, our Chief Legal Counsel and EVP, Quality, Regulatory, Market Access & Government Affairs, are critical for managing our legal, regulatory, quality, market access and government affairs functions. The services of Mark Day, our Chief Technology Officer, are critical for managing our research and development functions. Our employees may terminate their employment with us at any time. If we lose one or more key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy. We do not currently maintain key person life insurance policies on these or any of our employees.

In addition, research and development, manufacturing operations, and clinical operations depend on our ability to attract and retain highly skilled personnel, including engineers and certified cardiographic technicians. We may not be able to attract or retain highly qualified personnel, including engineers and certified cardiographic technicians in the future due to the competition for qualified personnel. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than us. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Francisco Bay Area, often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

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 business strategy includes international expansion. Doing business internationally involves 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 products and services in various countries;
- requirements to maintain data and the processing of that data on servers located within such countries;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- logistics and regulations associated with shipping and returning our Zio monitors following use;
- limits on our ability to penetrate international markets if we are required to process the Zio service 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 products and services and exposure to foreign currency exchange rate fluctuations;
- 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 United States Foreign Corrupt Practices Act of 1977 (“FCPA”), U.K. Bribery Act of 2010 and comparable laws and regulations in other countries;

- compliance risks associated with the General Data Protection Regulation (“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 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 European Union under the Medical Device Regulations ("EU MDR") that outline the requirements for medical device CE marketing; and
- compliance risks associated with the United Kingdom's Medical Device Regulations, which replaced the CE Marking requirements for medical devices marketed and sold in the United Kingdom with a UK Conformity Assessment ("UKCA") mark following the United Kingdom's withdrawal from the European Union.

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

Our relationships with business partners in new international markets may subject us to an increased risk of litigation.

As we expand our business internationally, if we cannot successfully manage the unique challenges presented by international markets and our relationships with new business partners within those markets, our expansion activities may be adversely affected and we may become subject to an increased risk of litigation.

We may become involved in disputes relating to our products, contracts and business relationships. Such disputes include 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. Any of these disputes may result in substantial costs to us, judgments, settlements and diversion of our management’s attention, which could adversely affect our business, financial condition or operating results. There is also a risk of adverse judgments, as the outcome of litigation in foreign jurisdictions can be inherently uncertain.

We could be adversely affected by violations of the FCPA, and similar worldwide anti-bribery laws which could have a material adverse effect on our business.

The FCPA and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from corruptly providing any benefits to government officials for the purpose of obtaining or retaining business. We are in the process of designing and implementing policies and procedures intended to help ensure compliance with these laws. In the future, we may operate in parts of the world that have experienced governmental corruption to some degree. We cannot assure you that our internal control policies and procedures will protect us from improper acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our business and have a material adverse effect on our business and operations.

In addition, the DOJ or other governmental agencies could impose a broad range of civil and criminal sanctions under the FCPA and other laws and regulations including, but not limited to, injunctive relief, disgorgement, fines, penalties, modifications to business practices including the termination or modification of existing business relationships, the imposition of compliance programs and the retention of a monitor to oversee compliance with the FCPA. The imposition of any of these sanctions or remedial measures could have a material adverse effect on our business and results of operations.

Our proprietary data analytics engine may not operate properly, which could damage our reputation, give rise to claims against us, or divert application of our resources from other purposes, any of which could harm our business and operating results.

The ECG data that is gathered through our Zio monitors is curated by algorithms that are part of our Zio service, and a Zio report is delivered to the ordering physician for interpretation and diagnosis. The continuous development, maintenance, and operation of our deep-learned backend data analytics engine is expensive and complex, and may involve unforeseen difficulties including material performance problems, undetected defects, or errors. We may encounter technical obstacles, and it is possible that we may discover additional problems that prevent our proprietary algorithms from operating properly. We may also attempt to develop new capabilities and incorporate new technologies, including artificial intelligence, which could impact our data analytics platform’s performance. If our data analytics platform does not function reliably or fails to meet physician or payor expectations in terms of performance, physicians may stop prescribing the Zio service and payors could attempt to cancel their contracts with us.

Any unforeseen difficulties we encounter in our existing or new software, cloud-based applications, telecommunication service providers, and analytics services, and any failure by us to identify and address them, could result in loss of revenue or market share, diversion of development resources, injury to our reputation, and increased service and maintenance costs. Correction of defects or errors could prove to be impossible or impracticable. The costs incurred in correcting any defects or errors may be substantial and could adversely affect our operating results.

Provision of the Zio service is dependent upon third-party vendors who are subject to disruptions, which could directly or indirectly harm our business and operating results.

The analysis we perform to create the diagnostic report for the Zio service is dependent upon a recording made by each device, which requires the physical return of the Zio XT monitor to one of our clinical centers. We predominantly rely on the U.S. Postal Service ("USPS") to perform this delivery service. Delivery of the Zio XT monitor to one of our clinical centers may be subject to disruption by natural disasters such as earthquake or flooding, labor disagreements or errors on behalf of USPS staff, operational and funding reductions negatively impacting USPS service capabilities, structural issues timely processing in some geographies, or other disruption to the USPS delivery infrastructure. Further, for the Zio AT monitor, we rely on the provision of cellular communication services for the timely transmission of patient information and reportable events. Once received, all data from both Zio XT and AT monitors is processed, curated and reported on through cloud-computing resources. The reliability of these communication and cloud services is also 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 of the Zio service, adversely affecting our operating results, causing significant distraction for management, and negatively impacting our business reputation.

Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or patients, or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we and our third-party billing and collections provider, XIFIN, collect, process, and store sensitive data, including legally protected personally identifiable health information about patients in the United States and in the United Kingdom. This personally identifiable information may include, among other information, names, addresses, phone numbers, email addresses, insurance account information, age, gender, and heart rhythm data. We also process and store, and use additional third parties to process and store, sensitive intellectual property and other proprietary business information, including that of our customers, payors, and collaborative partners. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems, and cloud-based computing center systems. These applications and data encompass a wide variety of business-critical information, including research and development information, commercial information, and business and financial information.

We are highly dependent on information technology networks and systems, including the internet and services hosted by Amazon Web Services and other third-party service providers, to securely process, transmit and store this critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns, or unauthorized disclosure or modifications of confidential information involving patient health information to become publicly available. The secure processing, storage, maintenance, and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information, including executing Business Associates Agreements (in compliance with HIPAA) and Data Processing Agreements (in compliance with GDPR) with applicable vendors. Although we take measures to protect sensitive information from unauthorized access or disclosure, cyber-attacks are becoming more sophisticated and frequent, and our information technology and infrastructure, and that of XIFIN and other third parties we utilize to process or store data, may be vulnerable to viruses and worms, phishing attacks, denial-of-service attacks, physical or electronic break-ins, attacks by hackers, breaches due to employee error, malfeasance, or misuse, or similar disruptions from unauthorized tampering. 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. While we have implemented data privacy and security measures that we believe are compliant with applicable privacy laws and regulations, some confidential and protected health information, is transmitted to us by third parties, who may not implement adequate security and privacy measures. Further, if third party service providers that process or store data on our behalf experience security breaches or violate applicable laws, agreements, or our policies, such events may also put our information at risk and could in turn have an adverse effect on our business.

A security breach or privacy violation that leads to disclosure or modification of, or prevents access to, patient information, including protected health information, could harm our reputation, compel us to comply with disparate state and federal breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures in a timely manner, the market perception of the effectiveness of our security measures could be harmed, our operations could be disrupted, our brand could be adversely affected, demand for our products and services may decrease, we may be unable to provide the Zio service, we may lose sales and customers, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. We may be required to expend significant capital and financial resources to invest in security measures, protect against such threats or to alleviate problems caused by breaches in security. In addition, these breaches and other inappropriate or unauthorized access can be difficult to detect, and any delay in identifying them may lead to increased harm to individuals. Although we have invested in our systems and the protection of our data to reduce the risk of an intrusion or interruption, and we monitor our systems on an ongoing basis for any current or potential threats, we can give no assurances that these measures and efforts will prevent all intrusions, interruptions, or breakdowns.

Because techniques used to obtain unauthorized access or to sabotage systems change frequently and generally are not recognized until launched, we may be unable to anticipate these techniques or to implement adequate preventive measures.

In the event that patients or physicians enable third parties to access their data on our systems, we cannot ensure the complete integrity or security of such data in our systems as we would not control that access. Third parties may also attempt to fraudulently induce our employees, or patients or physicians who use our technology, into disclosing sensitive information such as user names, passwords or other information. Third parties may also otherwise compromise our security measures in order to gain unauthorized access to the information we store. This could result in significant legal and financial exposure, a loss in confidence in the security of our service, interruptions or malfunctions in our service, and, ultimately, harm to our future business prospects and revenue.

Any such breach or interruption of our systems, or those of XIFIN or any of our third-party information technology partners, could compromise our networks or data security processes and sensitive information could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of patient information, such as HIPAA, GDPR, and the U.K. Data Protection Act 2018. Regardless of the merits of any such claim or proceeding, defending it could be costly and divert management's attention from leading our business. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform our services, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our current and future solutions and engage in other patient and clinician education and outreach efforts. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our business and competitive position.

Depending on the nature of the information compromised, in the event of a data breach or other unauthorized access to or acquisition of our customer, employee and patient data, we may also have obligations to notify users about the incident and we may need to provide some form of remedy for the individuals affected by the incident. A growing number of legislative and regulatory bodies have adopted consumer notification requirements in the event of unauthorized access to or acquisition of certain types of personal data. Such breach notification laws continue to evolve and may be inconsistent from one jurisdiction to another. Complying with these obligations could cause us to incur substantial costs and could increase negative publicity surrounding any incident that compromises personal data within our control (such as that of customers, patients and employees). In addition, the interpretation and application of consumer, health-related and data protection laws, rules and regulations in the United States, the UK, European Union and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws, rules and regulations may be interpreted and applied in a manner that is inconsistent with our practices or those of our distributors and partners. If we or these third parties are found to have violated such laws, rules or regulations, it could result in government-imposed fines, orders requiring that we or these third parties change our or their practices, or criminal charges, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business. In addition, California has enacted the California Consumer Privacy Act ("CCPA"), which became effective on January 1, 2020, and requires, among other things, disclosures to California consumers and afford such consumers abilities to opt out of certain sales of their personal information by us. It remains unclear how various provisions of the CCPA will be interpreted and enforced. The effects of the CCPA and other similar state laws are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply with this legislation.

The use, misuse, or off-label use of the Zio service may result in injuries that lead to product liability suits, which could be costly to our business.

The use, misuse, or off-label use of the Zio service may in the future result in outcomes and complications potentially leading to product liability claims. For example, we are aware that physicians have prescribed the Zio service off-label for pediatric patients. We have also received and may in the future receive product liability or other claims with respect to the Zio service, including claims related to skin irritation and alleged burns. In addition, if the Zio monitor is defectively designed, manufactured or labeled, contains defective components or is misused, we may become subject to costly litigation initiated by physicians, or the hospitals and clinics where physicians prescribing our Zio service work, or their patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management's attention from our core business, be expensive to defend and may result in sizable damage awards against us.

Although we maintain product liability insurance, we may not have sufficient insurance coverage for future product liability claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation, significantly increase our expenses, and reduce product sales. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results.

Our forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not increase at similar rates, if at all.

Growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. Our forecasts relating to, among other things, the expected growth in the ambulatory cardiac monitoring solutions market may prove to be inaccurate.

Our growth is subject to many factors, including whether the market for first-line ambulatory cardiac monitoring solutions continues to improve, the rate of market acceptance of the Zio service as compared to the products of our competitors, and our success in implementing our business strategies, each of which is subject to many risks and uncertainties. If our Zio service works as anticipated to provide a correct first-line diagnosis, it may lead to a decrease in the amount of ambulatory cardiac monitoring orders each year in the United States. This outcome would result if our Zio service is proven to produce the right diagnosis the first time, thereby reducing the need for additional testing. Accordingly, our forecasts of market opportunity should not be taken as indicative of our future growth.

We may acquire other companies or technologies, or enter into joint ventures or other strategic alliances, which could divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results.

We may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our ambulatory cardiac monitoring solutions portfolio, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment. In addition, any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with existing strategic partners or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired businesses; and
- possible compliance, regulatory, or product issues.

To date, the growth of our operations has been largely organic, and we have limited experience in acquiring other businesses or technologies or entering into joint ventures or strategic alliances. Acquisitions, joint ventures or strategic alliances could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business, joint venture or strategic alliance fails to materialize or fails to meet our expectations, our operating results, business and financial condition may suffer.

Consolidation of commercial payors could result in payors eliminating coverage or reducing reimbursement rates for our Zio service.

When payors combine their operations, the combined company may elect to reimburse our Zio service at the lowest rate paid by any of the participants in the consolidation or use its increased size to negotiate reduced rates. If one of the payors participating in the consolidation does not reimburse for the Zio service at all, the combined company may elect not to reimburse for the Zio service, which would adversely impact our operating results. While attempts by Aetna Inc. to acquire Humana Inc. and Anthem Inc. to acquire Cigna Corp. have been largely abandoned due to antitrust challenges by the DOJ, it is possible that these or other payor consolidations may occur in the future.

Our ability to utilize our net operating loss carryovers may be limited.

As of December 31, 2021, we had federal and state net operating loss carryforwards ("NOLs") of $464.3 million and $279.1 million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and have begun expiring for state purposes. We may use these NOLs to offset against taxable income for U.S. federal and state income tax purposes. However, Section 382 of the Internal Revenue Code, as amended, may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points (by value) over their lowest ownership percentage within a rolling three year period. Similar rules may apply under state tax laws. Future issuances or sales of our stock, including certain transactions involving our stock that are outside of our control, could cause an "ownership change." If an "ownership change" has occurred in the past or occurs in the future, Section 382 would impose an annual limit on the amount of pre-ownership change NOLs and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could, depending on the extent of such limitation and the NOLs previously used, result in our retaining less cash after payment of U.S. federal and state income taxes during any year in which we have taxable income, rather than losses, than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal and state income tax reporting purposes, which could adversely impact our operating results.

We have identified a material weakness in our internal control over financial reporting which could, if not remediated, result in material misstatements in our financial statements.

We are responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act. As disclosed in Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 28, 2022, we identified a material weakness in our internal control over financial reporting. A material weakness is defined as a deficiency, or 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 financial statements will not be prevented or detected on a timely basis. As a result of this material weakness, we concluded that our internal control over financial reporting was not effective based on criteria set forth by the Committee of Sponsoring Organization of the Treadway Commission in Internal Control-An Integrated Framework (2013).

To implement remedial measures as disclosed in Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 28, 2022, we committed additional resources, hired additional staff, and provided additional management oversight. If our remedial measures are insufficient to address the material weaknesses, or if additional material weaknesses or significant deficiencies in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements, and we could be required to restate our financial results. In addition, if we are unable to successfully remediate the material weakness that continues to exist and if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected.

Risks Related to Our Intellectual Property

We may become a party to intellectual property litigation, litigation resulting from employment disputes, or administrative proceedings that could be costly and could interfere with our ability to provide the Zio service.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties, especially those held by our competitors, may be alleged to cover our products or services, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include hardware and software components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products and services or to use product names. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents or otherwise obtained rights to other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time-consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand, and cause us to incur significant expenses or make substantial payments to satisfy judgments or settle claims. Vendors from which we purchase hardware or software may not indemnify or defend us in the event that such hardware or software is accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secrets.

Further, if such patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney's fees and court costs. In addition, if we are found to have willfully infringed third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device and services area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our Zio monitors or our Zio service to avoid infringement and our product development efforts may be negatively affected as a result.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office ("USPTO") may be necessary to determine priority with respect to our patents, patent applications, trademarks or trademark applications. We may also become involved in other proceedings, such as reexamination, inter partes review, derivation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing the Zio monitors and selling the Zio service or using product names, which would have a significant adverse impact on our business.

Additionally, we may need to commence proceedings against others to enforce our patents or trademarks, to protect our trade secrets or know how, or to determine the enforceability, scope and validity of the proprietary rights of others. These proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel. We may not prevail in any lawsuits that we initiate, a scenario that could also result in the invalidation of our asserted patents, and the damages or other remedies awarded, if any, may not be commercially meaningful. We may not be able to stop a competitor from marketing and selling products that are the same or similar to our products and services or from using product or service names that are the same or similar to ours, and our business may be harmed as a result.

We use certain open source software in the infrastructure supporting the Zio service. Licensees of open source software may be required to make public and use certain source code, to license proprietary software for free or to make certain derivative works available to others. As a result, we may face claims from companies that incorporate open source software into their products or from open source licensors, claiming ownership of, or demanding release of, the source code, the open source software or derivative works that were developed using such software, or otherwise seeking to enforce the terms of the applicable open source license. These claims could result in litigation and could require us to cease offering the Zio service unless and until we can re-engineer it to avoid infringement. This re-engineering process could require significant additional research and development resources, and we may not be able to complete it successfully. While we monitor and control the use of open source software in the Zio service and in any third party software that is incorporated into the Zio service, and we try to ensure

that no open source software is used in such a way as to require us to disclose the source code underlying the Zio service, there can be no guarantee that such use could not inadvertently occur. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, intellectual property protection, financial condition and operating results.

Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. 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. As of December 31, 2021, we owned, or retained exclusive license to, twenty-three issued U.S. patents, the earliest of which will expire in 2028. As of December 31, 2021, we also owned, or retained an exclusive license to, eight issued patents from the Japanese Patent Office, two issued patents from the Australian Patent Office, four issued patents from the Canadian Patent Office, five issued patents from the European Patent Office, three issued patents from the Korean Patent Office, and one issued patent from the Chinese Patent Office. The earliest expiration date of these international patents is 2027. As of December 31, 2021, we had twenty-six pending patent applications globally, including twelve in the United States, three in the European Patent Office, four in Japan, three Patent Cooperation Treaty ("PCT") international applications, and one in each of Australia, Korea, China and India. Our patents and patent applications are directed to covering key aspects of the design, manufacture and use of the Zio monitor and the Zio service.

We rely, in part, on our ability to obtain and maintain patent protection for our proprietary products and processes. The process of applying for and obtaining a patent is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. In addition, the issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Issued international patents may carry a requirement to "work" a patent in the applicable geography; failure to do so could lead to loss of the patent or the requirement to accept licensing terms, both of which would be favorable to our competitors. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid or unenforceable; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Litigation is time-consuming and expensive and would divert our resources.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, our business and competitive position may be harmed.

We rely heavily on trade secrets as well as invention assignment and confidentiality provisions that we have in contracts with our employees, consultants, collaborators and others to protect our algorithms and other aspects of our Zio service. We 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 these confidentiality agreements and other contractual restrictions. 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. Despite the protections we do place on our intellectual property, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology.

We may also employ individuals who were previously or are concurrently employed at research institutions or other medical device companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former or concurrent employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our products, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our Zio service, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business.

Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets, and agreement terms that address non-competition are difficult to enforce in many jurisdictions, and might not be enforceable in certain cases.

If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected.

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. 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. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands. Further, we cannot assure you that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. 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.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act ("Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a "first-to-invent" system to a "first-to-file" system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO, administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. Under the new post grant provisions of the Leahy-Smith Act, the USPTO introduced procedures that provide additional administrative pathways for third parties to challenge issued patents. Inter partes review ("IPR") is one of these procedures. The number of IPR challenges filed is increasing, and in many cases, the USPTO is canceling or significantly narrowing issued patent claims. Accordingly, even if a patent is granted by the USPTO, there is risk that it may not withstand an IPR challenge. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Recent case law has increased uncertainty regarding the availability of patent protection for certain technologies and the costs associated with obtaining patent protection for those technologies. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In particular, the 2014 decision by the U.S. Supreme Court in *Alice Corp. v. CLS Bank International* has increased the difficulty of obtaining new software patents and enforcing existing software patents. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

Risks Related to Government Regulation

Changes in the regulatory environment may constrain or require us to restructure our operations, 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, and new regulations may adversely affect our business. We cannot assure you 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, or that the healthcare regulatory environment will not change in a way that restricts our operations. In addition, there is risk that the U.S. Congress may implement changes in laws and regulations governing healthcare service providers, including measures to control costs, or reductions in reimbursement levels, which may adversely affect our business and results of operations.

Government payors, such as CMS, as well as insurers, have increased their efforts to control the cost, utilization, and delivery of healthcare services. From time to time, the U.S. Congress has considered and implemented changes in the CMS fee schedules in conjunction with budgetary legislation. Further reductions of reimbursement by CMS for services, or changes in policy regarding coverage of tests or other requirements for payment, such as prior authorization or a physician or qualified practitioner's signature on orders, may be implemented from time to time. Reductions in the reimbursement rates and changes in payment policies of other third-party payors may occur as well. Similar changes in the past have resulted in reduced payments as well as added costs and have added more complex regulatory and administrative requirements. For example, on January 29, 2021, Novitas Solutions, a MAC that we, physicians, and hospitals rely on to process Medicare reimbursement claims related to our Zio service, published reimbursement rates that were considerably lower than expected. On January 10, 2022, Novitas Solutions published rates for 2022 that were retroactive to January 1, 2022 and replaced the rates that it had published in 2021. These revised rates were higher than the rates posted in 2021, but continue to be significantly below the historical Medicare rates for our Zio XT service. Further changes in federal, state, local, and third-party payor regulations or policies may have a material adverse impact on our business. Actions by agencies regulating insurance or changes in other laws, regulations, or policies may also have a material adverse effect on our business.

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

The products and services we offer are highly regulated, and there can be no assurance that the regulatory environment in which we operate will not 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 fraud and abuse and other laws and regulations that may restrict the financial arrangements and relationships through which we market, sell, and distribute our products and services. 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 applicable to our Zio service and regulatory agencies enforcing those laws and regulations;
- 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 CMS programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the FCPA, the U.K. 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, created under the Affordable Care Act, and its implementing regulations, which requires manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services, information related to payments or other transfers of value made to licensed physicians and certain mid-level health

practitioners and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; HIPAA also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- The E.U. GDPR and the U.K. 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 European Union's Medical Device Directives and Medical Device Regulations ("EU MDR") that outline requirements for medical device CE marking;
- the United Kingdom's Medical Device Regulations 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 UK Conformity Assessment (UKCA) mark; and
- state law equivalents of each of the above U.S. federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The Affordable Care Act was enacted in 2010. The Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, 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 False Claims Act including mandatory treble damages and significant per-claim penalties, which were increased to $12,537 to $25,076 per false claim in May 2022.

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 Medicaid, 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.

If we fail to obtain and maintain necessary regulatory clearances or approvals for, or fail to meet ongoing compliance conditions related to, the Zio monitors and Zio service, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations would be harmed.

The Zio monitors, including the associated software and algorithm, and the Zio service are subject to extensive regulation by the FDA and CMS in the United States, and by the Competent Authorities in the European Union and the United Kingdom. Such regulations are wide ranging and govern, among other things:

- product design, development, manufacture, and release;
- laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution;
- premarketing clearance or approval;
- service operations, including IDTF locations;
- record keeping;
- product marketing, promotion and advertising, sales and distribution; and
- post-market surveillance, including complaint handling and reporting of deaths or serious injuries and certain categories of field correction and removals.

Before a new medical device or service, or a new intended use for an existing product or service, can be marketed in the United States, a company must first submit and receive either 510(k) clearance, De Novo marketing rights or premarket approval from the FDA, unless an exemption applies. Either process can be expensive, lengthy and unpredictable. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, 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) clearance to market the Zio monitors and the Zio service (Software as a Medical Device elements of the overall service), our clearance can be revoked if safety, efficacy, or significant regulatory compliance problems develop. Even planned changes and improvements to devices and their uses can trigger the need for a new 510(k). FDA requirements dictate that we must evaluate potential changes and document our decision-making regarding the need for additional submissions and clearances.

In addition, we are required to file various reports with the FDA, and E.U. or U.K. regulators, including reports required by each jurisdiction's adverse event and field action reporting regulations. These reports are often required for if our Zio monitors or service 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. If these reports are not filed in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. These reports are typically publicly available information in most jurisdictions, including the United States.

If we initiate a recall (whether a correction made relative to a device that remains in the field, which could be through a labeling or software update, or removal and return of that device to us) for our Zio service to reduce a risk to health posed by the Zio service, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. Depending on the reason for the correction and 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 services is used. Furthermore, even if we adhere to regulatory standards and expectations in our corrective actions, the public nature of recalls can result in broader negative publicity and perceptions, which could harm our reputation.

We have several monitoring centers throughout the United States that analyze the data obtained from cardiac monitors and report related preliminary observation to physicians. In order for us to receive reimbursement from Medicare and some commercial payors, our monitoring centers must be enrolled as IDTFs in the Medicare program. Enrollment as an IDTF requires that we follow strict regulations governing how our monitoring centers operate, such as requirements regarding qualifications of the technicians who review data transmitted from our monitors. These rules can vary from location to location and are subject to change. If they change, we may have to change the operating procedures at our monitoring centers, which could increase our costs significantly. If we fail to obtain and maintain our IDTF enrollment, our services may no longer be reimbursed by Medicare and some commercial payors, which could have a material adverse impact on our business.

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.

The FDA and FTC also regulate the advertising and promotion of our products and services, requiring not only that our claims be truthful and not misleading, but also that claims about our devices and services are consistent with 510(k) clearances and that data and studies we use to support such claims are scientifically appropriate and statistically sound. More generally, we must have a reasonable basis and adequate substantiation for claims made in our advertising. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. Similar to the FDA and FTC, the European Union under the EU Medical Device Regulations and the United Kingdom under the UK Medical Device Regulations have similar requirements and enforcement action regarding promotional material.

The FDA, CMS, FTC, and state and international authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by any such agency, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil money penalties;
- suspension or termination of participation in federal health care programs;
- repair, replacement, or refund requirements, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of either production, distribution or service operation;
- restrictions to our ability to export or import any medical devices or components thereof;
- denial of our requests for regulatory clearance or premarket approval of new products or services, new intended uses or modifications to existing products or services;
- withdrawal or restriction of regulatory clearance or premarket approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition could be harmed.

Changes or modifications to the Zio monitors, labeling of the Zio monitors, or Zio service may require new 510(k) clearances, CE Mark, UKCA Mark or other premarket approvals or may require us to recall or cease marketing our products and services until clearances are obtained.

Significant changes or modifications in design, components, method of manufacturer or the intended use or technological characteristics of the Zio monitors or Zio service may require new 510(k) clearances, De Novo applications, premarket approvals or CE Mark certification (E.U.) or UKCA Mark certification (U.K.). Unless effectively planned for in advance of our desired marketing timeline, in some circumstances we may be required to cease marketing certain products until clearances or approvals are obtained, for example, if a change was made to reduce risk to health or remedy an FDA violation. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new clearance or approval; however, the FDA can review a manufacturer's decision. We may not be able to obtain additional 510(k) clearances, or De Novo or premarket approvals for new products or for modifications to, or additional indications for, the Zio monitors or Zio service in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to the Zio monitors and Zio service in the past that we believe do not require additional clearances or approvals, and we may make additional modifications in the future. If the FDA or a E.U./U.K. Notified Body disagrees and requires new clearances or approvals for any of these modifications, we may be required to recall and to stop selling or marketing the Zio monitors and Zio service as modified, which could harm our operating results and require us to redesign our products or services. In these circumstances, we may be subject to significant enforcement actions.

If we or our suppliers fail to comply with the FDA's QSR or the European Union's Medical Device Directive and Medical Device Regulations, or United Kingdom's Medical Device Regulations, our manufacturing or distribution operations could be delayed or shut down and our revenue could suffer.

Our manufacturing and design processes and those of our third-party suppliers are required to comply with the FDA's Quality System Regulation ("QSR") and the EU's Medical Device Directive ("MDD"), through May 2021, after which time compliance with the MDR transitional provisions will be required until full transition to MDR compliance is achieved. Additionally, the UK will require the UKCA marking per new policies released by MHRA. All of these regulations cover procedures and documentation requirements for the design, testing, production, control, quality assurance, labeling, packaging, storage, shipping, and post-market surveillance of Zio monitors and associated software. We are also subject to similar state requirements and licenses, and to ongoing ISO 13485 and ISO 14971 compliance in all operations to maintain our CE Mark. In addition, we must engage in extensive recordkeeping and reporting and must make available our facilities and records for periodic announced or unannounced inspections by governmental agencies, including the FDA, state authorities, Notified Bodies and comparable agencies in other countries. Inspections may be initiated on a routine or for-cause basis. If regulatory inspections result in allegations of significant noncompliance that we are unable to address to the satisfaction of applicable regulatory authorities, it is possible that our operations could be disrupted and our manufacturing interrupted. Depending on the matters involved, failure to take adequate corrective action in response to an adverse regulatory inspection could result in, among other things, a shutdown of our manufacturing or product distribution operations, significant fines, suspension of marketing clearances and approvals, seizures, or large-scale recalls of our device, operating restrictions, warning letters, and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our product and cause our revenue to decline.
We are registered with the FDA as a medical device specifications developer and manufacturer. This is in addition to our CMS-regulated status as an IDTF. The FDA has broad post-market and regulatory enforcement powers. We are subject to announced or unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Public Health ("CDPH") to determine our compliance with the QSR and other regulations at both our design and manufacturing facilities, and these inspections may include the manufacturing facilities of our suppliers. During the course of the COVID-19 pandemic, FDA in some cases utilized Remote Regulatory Assessments ("RRAs") and in July 2022 draft guidance it has indicated plans to continue using RRAs to supplement on-site inspection in the near term, while still budgeting and planning for increased in-person inspections now that most significant pandemic limitations on travel and in-person interactions have been lifted in many areas.

We are also registered with a Notified Body for the EU as a medical device design developer, manufacturer, and distributor. Our current E.U. Notified Body is the National Standard Authority of Ireland ("NSAI"). We seek to maintain ISO 13485 certifications in the normal course of business. We are in the process of transitioning to a new Notified Body, the British Standards Institution ("BSI") for the purposes of UKCA marking and CE marking under the new E.U. MDR regulation. Such transitions carry a certain degree of uncertainty and risk of audit observations as each Notified Body may interpret and enforce the U.K. and E.U. regulations differently. Additionally, such transitions from E.U. MDD to E.U. MDR regulation require both Quality Management System and technical product assessments and are often complex, time consuming, and costly.

We can provide no assurance that we will continue to remain in compliance with the QSR or E.U. MDD, E.U. MDR, or UK MDR. If the FDA, CDPH, NSAI, BSI or other U.S. or international regulatory agencies inspect any of our facilities and discover compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a delay at our manufacturing facility we may be unable to produce Zio monitors, which would harm our business.

Zio monitors may in the future be subject to product recalls that could harm our reputation.

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or device defects. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, design issues, labeling issues, or various regulatory compliance topics. Recalls of Zio monitors and associated software would divert managerial attention, be expensive, harm our reputation with customers and harm our financial condition and results of operations. A recall announcement would also negatively affect our stock price.

Healthcare reform measures could hinder or prevent the Zio service's commercial success.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could harm our future revenues and profitability and the demand for the Zio service. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. We face uncertainties that might result from modifications or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. Any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our Zio service;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject us to significant liability.

Our research and development and manufacturing operations may involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

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.

We have based a significant portion of our non-U.S. operations in the United Kingdom. In June 2016, a referendum was held in the U.K. which resulted in a majority voting in favor of the U.K. withdrawing from the E.U. (commonly referred to as "Brexit"). Pursuant to legislation approved by the U.K. Parliament and the E.U. Parliament in January 2020, the U.K. withdrew from the E.U. with effect from 11 p.m. (GMT) on January 31, 2020 on the terms of a withdrawal agreement agreed between the U.K. and the E.U. in October 2019. On December 24, 2020, the U.K. and E.U. agreed to a trade deal (the "Trade and Cooperation Agreement") which was ratified by the U.K. on December 30, 2020. The Trade and Cooperation Agreement is subject to formal approval by the European Parliament and the Council of the European Union before it comes into effect and has been applied provisionally since January 1, 2021. There are still a number of areas of uncertainty in connection with the future of the U.K. and its relationship with the E.U. and the application and interpretation of the Trade and Cooperation Agreement, and Brexit related matters may take several years to be clarified and resolved. For example, because a significant proportion of the regulatory framework in the U.K. is currently derived from E.U. directives and regulations, Brexit could result in material changes to the regulatory regime applicable to many of our current operations. Although the Trade and Cooperation Agreement offers U.K. and E.U. companies preferential access to each other's markets, ensuring imported goods will be free of tariffs and quotas, economic relations between the U.K. and the E.U. will now be 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 service in the U.K. and E.U. Accordingly, it is possible that new terms of the Trade and Cooperation Agreement may adversely affect our operations and financial results. We are currently in the process of evaluating our own risks and uncertainties to ascertain what financial, trade, regulatory and legal implications the Trade and Cooperation Agreement could have on our operations in the U.K. and otherwise. Finally, uncertainty surrounding Brexit has contributed to recent fluctuations in the U.K. economy as a whole which could experience future disruptions. As a result, Brexit could cause financial and capital markets within and outside the U.K. or the E.U. to constrict, thereby negatively impacting our ability to finance our U. K. operations which could also have an adverse effect on our results of operations and financial condition.

Risks Related to Our Common Stock

Future sales and issuances of securities could negatively affect our stock price and dilute the ownership interest of our existing investors.

Our expected future capital requirements may depend on many factors, including expanding our customer base, the expansion of our sales force, and the timing and extent of spending on the development of our technology to increase our product offerings. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Additionally, new investors could gain rights, preferences and privileges senior to those of existing holders of our common stock. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

Sales or issuances of a substantial amount of securities, or the perception that such sales could occur, may cause a decline in the price of our common stock. Future resales of our common stock by our existing stockholders could cause the market price of our common stock to decline. In addition, the shares of common stock subject to outstanding options and restricted stock units under our 2016 Equity Incentive Plan and our 2016 Employee Stock Purchase Plan and the shares reserved for future issuance under both such plans may become eligible for sale in the public markets in the future, subject to certain legal and control limitations.

We may sell shares or other securities in any offering at a price per share that is less than the price per share paid by existing investors, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by existing investors.

The market price of our common stock may fluctuate substantially, and you could lose all or part of your investment.

The market price of our common stock may continue to fluctuate substantially in response to, among other things, the risk factors described in this Quarterly Report on Form 10-Q and other factors, many of which are beyond our control, including:

- changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' estimates;

- quarterly variations in our or our competitors' results of operations;
- the impact or anticipated impact of the COVID-19 pandemic on us;
- periodic fluctuations in our revenue, due in part to the way in which we recognize revenue;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors, including deteriorating market conditions due to investor concerns regarding inflation and continuing hostilities between Russia and Ukraine, which could lead to volatility in foreign currency and capital markets;
- changes in reimbursement coverage and rates by current or potential payors;
- changes in CPT codes or the establishment of new CPT codes applicable to the Zio service;
- changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- actual or anticipated changes in regulatory oversight of our products;
- the results of our clinical trials;
- the loss of key personnel, including changes in our board of directors and management;
- legislation or regulation affecting our market;
- lawsuits threatened or filed against us;
- the announcement of new products or product enhancements by us or our competitors;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- announcements related to patents issued to us or our competitors and to litigation; and
- developments in our industry.

Fluctuations in our stock price, volume of shares traded, and changes in our market valuations may make our stock less attractive to certain investors. Stockholders may file securities class action litigation following periods of market volatility. Securities litigation, like the current action we are subject to in the District Court for the Northern District of California, could subject us to substantial costs, divert resources and the attention of management from our business, and adversely affect our business, results of operations, financial condition, reputation and cash flows. These factors may materially and adversely affect the market price of our common stock.

If securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions 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. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our target studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these 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 our stock price or trading volume to decline.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain executive management and qualified board members.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd Frank Act, the listing requirements of The NASDAQ Stock Market and other applicable securities laws, rules and regulations. Compliance with these laws, rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, our management and other personnel divert attention from operational and other business matters to devote

substantial time to these public company requirements. In particular, we incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404. We continue to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. We cannot predict or estimate the amount of additional costs we will incur in order to remain compliant with our public company reporting requirements or the timing of such costs. Additional compensation costs and any future equity awards will increase our compensation expense, which will increase our general and administrative expense and could adversely affect our profitability.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. 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 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 harmed.

As a public company, it is more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our board of directors, particularly to serve on our audit committee and compensation committee. In addition, compliance with applicable rules and regulations for public companies is generally more expensive than it is for private companies.

As a result of disclosure of information in this filing and in other filings required of a public company, our business and financial condition is more visible, which could be advantageous to our competitors and other third parties and could result in threatened or actual litigation. If such claims are successful, our business and operating results could be harmed, and even if the claims are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and operating results.

Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws, and Delaware law, could discourage a change in control of our company or a change in our management.

Our amended and restated certificate of incorporation and bylaws contain provisions that might enable our management to resist a takeover. These provisions include:

- advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholders' notice;
- a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws;
- the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;
- allowing stockholders to remove directors only for cause;
- a requirement that the authorized number of directors may be changed only by resolution of the board of directors;
- allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law;
- a requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent;
- limiting the forum to Delaware for certain litigation against us; and
- limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president (in the absence of a chief executive officer).

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder.

Our amended and restated certificate of incorporation and bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' abilities to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and bylaws provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or to our stockholders, (iii) any action asserting a claim against the company or any director or officer of the company arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or bylaws, or (v) any action asserting a claim against us governed by the internal affairs doctrine, in each such case subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. Our investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Our bylaws further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation or 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, financial condition and operating results.

We have not paid dividends in the past and do not expect to pay dividends in the future, and, as a result, any return on investment may be limited to the value of our stock.

We have never paid dividends and do not anticipate paying dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. In addition, our loan agreement with Silicon Valley Bank limits our ability to, among other things, pay dividends or make other distributions or payments on account of our common stock, subject to certain exceptions. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates and you sell our common stock thereafter.

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.

ITEM 6. EXHIBITS

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

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	10/25/16	3.1	
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	8-K	6/23/20	3.1	
3.3	Amended and Restated Bylaws.	8-K	10/25/16	3.2	
3.4	Certificate of Amendment to the Amended and Restated Bylaws.	8-K	8/14/20	3.1	
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	XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	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 and are not to be incorporated by reference into any filing of the Company under the Securities Exchange Act of 1933 or the Securities Exchange Act of 1934, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

iRhythm Technologies, Inc.

Date: August 5, 2022

By: /s/ Quentin S. Blackford

Quentin S. Blackford
President and Chief Executive Officer

(Principal Executive Officer)

Date: August 5, 2022

By: /s/ Douglas J. Devine

Douglas J. Devine
Chief Financial Officer and Chief Operating Officer

(Principal Financial and Accounting 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.

/s/ Quentin S. Blackford

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

Date: August 5, 2022

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, Douglas J. Devine, 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.

/s/ Douglas J. Devine

Douglas J. Devine
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: August 5, 2022

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, 2022, as filed with the Securities and Exchange Commission (the "Report"), Quentin S. Blackford, as Chief Executive Officer of the Company, Douglas J. Devine, as Chief Financial Officer of the Company, each hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350), to his knowledge:

1. The Report, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act of 1934, as amended; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Quentin S. Blackford

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

Date: August 5, 2022

/s/ Douglas J. Devine

Douglas J. Devine
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: August 5, 2022

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.